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HUDSON RIVER PCBs REASSESSMENT RI/FS
RESPONSIVENESS SUMMARY FOR
PHASE 2 - ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

APRIL 1999

For

U.S. Environmental Protection Agency
Region 2
and
U.S. Army Corps of Engineers
Kansas City District

Book 1 of 1

TAMS Consultants, Inc.
and
Menzie-Cura & Associates, Inc.

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

April 27, 1999

To All Interested Parties:

The U.S. Environmental Protection Agency (USEPA) is pleased to release the Responsiveness Summary for the Phase 2 Ecological Risk Assessment Scope of Work (ERASOW) for the Hudson River PCBs Reassessment Remedial Investigation/Feasibility Study (Reassessment RI/FS).

This Responsiveness Summary contains USEPA's responses to the public comments received on the September 1998 ERASOW. The ERASOW presented USEPA's general approach for conducting the Ecological Risk Assessments for the Upper Hudson River and for the Lower Hudson River. The Upper Hudson River Ecological Risk Assessment will be completed in Summer 1999. The Lower Hudson River Ecological Risk Assessment will be completed following USEPA's review of the revised Thomann-Farley model developed for the Hudson River Foundation.

If you have any questions regarding this Responsiveness Summary or the Reassessment RI/FS in general, please contact Ann Rychlenski, the Community Relations Coordinator for the site, at (212) 637-3672.

Sincerely yours,

William McCabe

for Richard L. Caspe, Director
Emergency and Remedial Response Division

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TABLE OF CONTENTS

HUDSON RIVER PCBs REASSESSMENT RI/FS
RESPONSIVENESS SUMMARY FOR
PHASE 2 - ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

APRIL 1999

TABLE OF CONTENTS

BOOK 1 OF 1 Page

HUDSON RIVER PCBs REASSESSMENT RI/FS
RESPONSIVENESS SUMMARY FOR
PHASE 2 - ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

APRIL 1999

TABLE OF CONTENTS

BOOK 1 OF 1 Page

HUDSON RIVER PCBs REASSESSMENT RI/FS
RESPONSIVENESS SUMMARY FOR
PHASE 2 - ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

APRIL 1999

TABLE OF CONTENTS

ACRONYMS

Ah	Aryl Hydrocarbon
ARAR	Applicable or Relevant and Appropriate Requirement
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BSAF	Biota:Sediment Accumulation Factors
CBR	Critical Body Residue
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
COE	Corps of Engineers
DEIR	Data Evaluation and Interpretation Report
DNAPL	Dense Non-Aqueous Phase Liquid
DQO	Data Quality Objectives
ERA	Ecological Risk Assessment
ERL	Effects Range-Low
ERM	Effects Range-Median
FDA	Food and Drug Administration
FFBAF	Foraging Fish Bioaccumulation Factor
FS	Feasibility Study
GE	General Electric
GM	Geometric Mean
GSD	Geometric Standard Deviation
HROC	Hudson River PCBs Oversight Committee
JLG	Joint Liaison Group
LOAEL	Lowest-Observed-Adverse-Effect-Level
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NPL	National Priorities List
NOAA	National Oceanic and Atmospheric Administration
NOAEL	No-Observed-Adverse-Effect-Level
NYSDEC	New York State Department of Environmental Conservation
NYSDOH	New York State Department of Health
NYSDOS	New York State Department of Sanitation
ORNL	Oak Ridge National Laboratories
PBAF	Pelagic Invertebrate Bioaccumulation Factor
PCB	Polychlorinated Biphenyl
PEL	Probable Effect Level
PFBAF	Piscivorous Fish Bioaccumulation Factor

ACRONYMS

RI	Remedial Investigation
RI/FS	Remedial Investigation/Feasibility Study
ROD	Record of Decision
RM	River Mile
RPI	Rensselaer Polytechnic Institute
RRI/FS	Reassessment Remedial Investigation/Feasibility Study
SARA	Superfund Amendments and Reauthorization Act of 1986
SMDP	Scientific/Management Decision Point
SOW	Scope of Work
STC	Science and Technical Committee
TAGM	Technical and Administrative Guidance Memorandum
TCDD	2,3,7,8-Tetrachlorodibenzo-p-dioxin
TEF	Toxicity Equivalency Factor
TIP	Thompson Island Pool
TRV	Toxicity Reference Value
TSCA	Toxic Substances Control Act
USEPA	United States Environmental Protection Agency
USFWS	US Fish and Wildlife Service
WHO	World Health Organization
WQC	Water Quality Criteria

Introduction

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HUDSON RIVER PCBs REASSESSMENT RI/FS
RESPONSIVENESS SUMMARY
PHASE 2 - ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

APRIL 1999

I. INTRODUCTION AND COMMENT DIRECTORY

1. Introduction

The U.S. Environmental Protection Agency (USEPA) has prepared this Responsiveness Summary to address comments received during the public comment period on the Phase 2 Ecological Risk Assessment Scope of Work (ERASOW) for the Hudson River PCBs Reassessment Remedial Investigation/Feasibility Study (Reassessment RI/FS), dated September 1998.

For the Hudson River PCBs Reassessment RI/FS, USEPA has established a Community Interaction Program (CIP) to elicit on-going feedback through regular meetings and discussion and to facilitate review of and comment upon work plans and reports prepared during all phases of the Reassessment RI/FS.

Because of the large number of CIP participants and associated costs of reproduction, the ERASOW is incorporated by reference and is not reproduced herein. No revised ERASOW will be published. The comment responses and revisions noted herein are considered to amend the ERASOW. For complete coverage, the ERASOW and this Responsiveness Summary must be used together.

The first part of this three-part Responsiveness Summary is entitled, "Introduction and Comment Directory." It describes the ERASOW review and commenting process, explains the organization and format of comments and responses, and contains a comment directory.

The second part, entitled, "Responses to Comments on the Ecological Risk Assessment Scope of Work," contains USEPA's responses to all significant comments. Responses are grouped according to the section number of the ERASOW to which they refer. For example, responses to comments on Section 2.2 of the ERASOW are found in Section 2.2 of the Responsiveness Summary. Additional information about how to locate responses to comments is contained in the Comment Directory.

The third part, entitled, "Comments on Ecological Risk Assessment Scope of Work," contains copies of the comments submitted to USEPA. The comments are identified by commenter and comment number, as further explained in the Comment Directory.

1.1 Recent Developments

USEPA received the revised Thomann-Farley model, which was developed for the Hudson River Foundation, on April 27, 1999. USEPA will review the model to determine its appropriateness for use in performing the Mid-Hudson ERA. In the ERASOW (p. 1), USEPA noted that the Upper Hudson and Mid-Hudson ERAs may be developed at different times.

2. Commenting Process

This section documents and explains the commenting process and the organization of comments and responses in this document. Readers interested in finding responses to their comments may skip this section and go directly to the tab labeled "Comment Directory."

2.1 Distribution of ERASOW

The ERASOW, issued in September 1998, was distributed to federal and state agencies and officials, participants in the CIP and General Electric Company (GE), as shown in Table 1. Distribution was made to approximately 100 agencies, groups, and individuals. Copies of the ERASOW were also made available for public review in 17 Information Repositories, as shown in Table 2 and on the USEPA Region 2 internet webpage, entitled "Hudson River PCBs Superfund Site Reassessment," at www.epa.gov/hudson.

2.2 Review Period and Public Availability Meetings

Review of and comment on the ERASOW occurred from September 23, 1998 to November 2, 1998. On September 23, USEPA held a Joint Liaison Group meeting open to the public at the Holiday Inn at Latham, New York. Subsequently, on October 20, USEPA sponsored an availability session at the Marriott Hotel in Albany, New York to answer questions from the public regarding the ERASOW. These meetings were conducted in accordance with USEPA's *Community Relations in Superfund: Handbook, Interim Version (1988)*. Minutes of the Joint Liaison Group meeting are available for public review at the Information Repositories listed in Table 2.

TABLE 1
DISTRIBUTION OF REPORTS

HUDSON RIVER PCBs OVERSIGHT COMMITTEE MEMBERS

- USEPA ERRD Deputy Division Director (Chair)
- USEPA Project Managers
- USEPA Community Relations Coordinator, Chair of the Steering Committee
- NYSDEC Division of Hazardous Waste Management representative
- NYSDEC Division of Construction Management representative
- National Oceanic and Atmospheric Administration (NOAA) representative
- Agency for Toxic Substances and Disease Registry (ATSDR) representative
- US Army Corps of Engineers representative
- New York State Thruway Authority (Department of Canals) representative
- USDOI (US Fish and Wildlife Service) representative
- New York State Department of Health representative
- GE representative
- Liaison Group Chairpeople
- Scientific and Technical Committee representative

SCIENTIFIC AND TECHNICAL COMMITTEE MEMBERS

The members of the Science and Technical Committee (STC) are scientists and technical researchers who provide technical input by evaluating the scientific data collected on the Reassessment RI/FS, identifying additional sources of information and on-going research relevant to the Reassessment RI/FS, and commenting on USEPA documents. Members of the STC are familiar with the site, PCBs, modeling, toxicology, and other relevant disciplines.

- Dr. Daniel Abramowicz
- Dr. Donald Aulenbach
- Dr. James Bonner, Texas A&M University
- Dr. Richard Bopp, Rensselaer Polytechnic Institute
- Dr. Brian Bush, New York State Dept. of Health
- Dr. Lenore Clesceri, Rensselaer Polytechnic Institute
- Mr. Kenneth Darmer
- Mr. John Davis, New York State Dept. of Law
- Dr. Robert Dexter, EVS Consultants, Inc.
- Dr. Kevin Farley, Manhattan College

TABLE 1
DISTRIBUTION OF REPORTS(Cont.)

- Dr. Jay Field, National Oceanic and Atmospheric Administration
- Dr. Ken Pearsall, U.S. Geological Survey
- Dr. John Herbich, Texas A&M University
- Dr. Behrus Jahan-Parwar, SUNY - Albany
- Dr. Nancy Kim, New York State Dept. of Health
- Dr. William Nicholson, Mt. Sinai Medical Center
- Dr. George Putman, SUNY - Albany
- Dr. G-Yull Rhee, New York State Dept. of Health
- Dr. Francis Reilly, Jr., The Reilly Group
- Dr. John Sanders
- Ms. Anne Secord, U.S. Fish and Wildlife Service
- Dr. Ronald Sloan, New York State Dept. of Environmental Conservation

STEERING COMMITTEE MEMBERS

- USEPA Community Relations Coordinator (Chair)
- Governmental Liaison Group Chair and two Co-chairs
- Citizen Liaison Group Chair and two Co-chairs
- Agricultural Liaison Group Chair and two Co-chairs
- Environmental Liaison Group Chair and two Co-chairs
- USEPA Project Managers
- NYSDEC Technical representative
- NYSDEC Community Affairs representative

FEDERAL AND STATE REPRESENTATIVES

Copies of the Reports were sent to relevant federal and state representatives who have been involved with this project. These include, in part, the following:

- The Hon. Daniel P. Moynihan
- The Hon. Charles E. Schumer
- The Hon. John E. Sweeny
- The Hon. Nita Lowey
- The Hon. Maurice Hinchey
- The Hon. Ronald B. Stafford
- The Hon. Michael McNulty
- The Hon. Sue Kelly
- The Hon. Benjamin Gilman
- The Hon. Richard Brodsky
- The Hon. Bobby D'Andrea

17 INFORMATION REPOSITORIES (*see* Table 2).

TABLE 2
INFORMATION REPOSITORIES

Adriance Memorial Library
93 Market Street
Poughkeepsie, NY 12601

Catskill Public Library
1 Franklin Street
Catskill, NY 12414

^ Cornell Cooperative Extension
Sea Grant Office
74 John Street
Kingston, NY 12401

Crandall Library
City Park
Glens Falls, NY 12801

County Clerk's Office
Washington County Office Building
Upper Broadway
Fort Edward, NY 12828

* ^ Marist College Library
Marist College
290 North Road
Poughkeepsie, NY 12601

* New York State Library
CEC Empire State Plaza
Albany, NY 12230

New York State Department
of Environmental Conservation
Division of Hazardous Waste Remediation
50 Wolf Road, Room 212
Albany, NY 12233

* ^ R. G. Folsom Library
Rensselaer Polytechnic Institute
Troy, NY 12180-3590

Saratoga County EMC
50 West High Street
Ballston Spa, NY 12020

* Saratoga Springs Public Library
49 Henry Street
Saratoga Springs, NY 12866

* ^ SUNY at Albany Library
1400 Washington Avenue
Albany, NY 12222

* ^ Sojourner Truth Library
SUNY at New Paltz
New Paltz, NY 12561

Troy Public Library
100 Second Street
Troy, NY 12180

U.S. Environmental Protection
Agency
290 Broadway
New York, NY 10007

* ^ U.S. Military Academy Library
Building 757
West Point, NY 10996

White Plains Public Library
100 Martine Avenue
White Plains, NY 12601

* ***Repositories with Database Report CD-ROM (as of 10/98)***

^ ***Repositories without Project Documents Binder (as of 10/98)***

As stated in USEPA's letter transmitting the ERASOW, all citizens were urged to participate in the Reassessment process and to join one of the Liaison Groups formed as part of the CIP.

2.3 Receipt of Comments

Comments on the ERASOW were received in two ways: letters and oral statements made at the September 23, 1998 Joint Liaison Group meeting. USEPA's responses to comments raised at the Joint Liaison Group meeting are provided in the meeting minutes.

All significant comments received on the ERASOW are addressed in this Responsiveness Summary. Comments were received from 6 commenters. Total comments numbered approximately 80.

2.4 Distribution of Responsiveness Summary

This Responsiveness Summary will be distributed to the Liaison Group Chairs and Co-Chairs and interested public officials. This Responsiveness Summary will be placed in the 17 Information Repositories and is part of the Administrative Record.

3. Organization of ERASOW Comments and Responsiveness Summary

3.1 Identification of Comments

Each submission commenting on the ERASOW was assigned the letter "E" for ERASOW and one of the following letter codes:

N - Federal agencies and officials;
D - State agencies and officials;
A - Local agencies and officials;
P - Community Interaction Program;
S - Public Interest Groups and Individuals; and
G - GE.

The letter codes were assigned for the convenience of readers and to assist in the organization of this document. Priority or special treatment was neither intended nor given in the responses to comments.

Once a letter code was assigned, each submission was then assigned a number, in the order that it was received and processed, such as EN1, EN2 and so on. Each different comment within a submission was assigned a separate subnumber. Thus, if a federal agency submission contained three different comments, they would be designated as EN1-1, EN1-2, and EN1-3. Written comment letters are reprinted following the fourth tab of this document.

The alphanumeric code associated with each reprinted written submission is marked at the top right corner of the first page of the comment letter. The subnumbers designating individual comments are marked in the margin. Comment submissions are reprinted in numerical order by letter code in the following order: EN, ED, EA, EP, ES and EG.

3.2 Location of Responses to Comments

The Comment Directory, following this text, contains a complete listing of all commenters and comments. This directory allows readers to find responses to comments and provides several items of information.

- The first column lists the names of commenters. Comments are grouped first by: EN (Federal), ED (State), EA (Local), EP (Community Interaction Program), ES (Public Interest Group or Individual), or EG (GE).
- The second column identifies the alphanumeric comment code (e.g., EF1-1) assigned to each comment.
- The third column identifies the location of the response by the ERASOW Section number. For example, comments raised in Section 2.1 of the ERASOW can be found in the corresponding Section 2.1 of the Responses, following the third tab of this document.
- The fourth, fifth, and sixth columns list key words that describe the subject matter of each comment. Readers will find these key works helpful as a means to identify subjects of interest and related comments.

Responses are grouped and consolidated by section number in order that all responses to related comments appear together for the convenience of the reader interested in responses to related or similar comments.

4. COMMENT DIRECTORY

4.1 Guide to Comment Directory

This section contains a diagram illustrating how to find responses to comments. The Comment Directory follows. As stated in the Introduction, this document does not reproduce the ERASOW. Readers are urged to use this Responsiveness Summary in conjunction with the ERASOW.

Step 1	Step 2	Step 3
Find the commenter or the key words of interest in the Comment Directory.	Obtain the alphanumeric comment codes and the corresponding ERASOW section.	Find the responses following the Responses tab. Use the Table of Contents to locate the page of the Responsiveness Summary for the ERASOW section.
Key to Comment Codes:		
Comment codes are in the format EX-a E=ERASOW X=Commenter Group (N=Federal, D=State, A=Local, P=Community Interaction Program, S=Public Interest Group, G=GE) a=Numbered comment		

Example:

COMMENT RESPONSE ASSIGNMENT FOR THE ERASOW

AGENCY/ Name	Comment CODE	REPORT SECTION	KEY WORDS 1	KEY WORDS 2	KEY WORDS 3
NOAA /Rosman	EN-1	1.2	Tissue Samples		

300972

Comment Directory

300973

4.2 Comment Directory

AGENCY/ NAME	COMMENT CODE	REPORT SECTION	KEYWORDS 1	KEYWORDS 2	KEYWORDS 3
NOAA/Rosman	EN-1	1.2	Tissue Samples	PCB Tissue Analysis	Dataset
NOAA/Rosman	EN-2	2.1.3	Endangered Species	Threatened Species	Lower Hudson River
NOAA/Rosman	EN-3	2.5	Soil Clean up Levels	TAGMS	Sediments
NOAA/Rosman	EN-4	4.2.1	Benthic Communities	Metrics	Taxa
NOAA/Rosman	EN-5	2.6.1	PCB Concentrations	Surface Water	AWQC
NOAA/Rosman	EN-6	3.1.6	Mammalian Receptors	Floodplain	Exposure Assessment
NOAA/Rosman	EN-7	3.3	Exposure Assessment	Body Burdens	Exposure Point Concentrations
NOAA/Rosman	EN-8	3.4	Ingestion Pathways	Dose Calculation	Surface Water
NOAA/Rosman	EN-9	4.2.1	Benthic Communities	Metrics	-
NOAA/Rosman	EN-10	4.1	TEQ	TEF	Tissue Concentrations
NOAA/Rosman	EN-11	4.2.2	Measurement Effects	Reproductive Effects	Fish
NOAA/Rosman	EN-12	5.3	Benthic Communities	Uncertainty	Effects association
NOAA/Rosman	EN-13	5.4	Population Level Effects	Risk Characterization	Uncertainty
NOAA/Rosman	EN-14	References	Add References	-	-
NOAA/Rosman	EN-15	Table 1	Sediment Guidelines	Assessment Endpoints	Significant Habitats
NOAA/Rosman	EN-16	Table 2	Shortnose Sturgeon	Invertebrates	-
NOAA/Rosman	EN-17	Appendix A	Models	Exposure Assessmnet	-
NOAA/Rosman	EN-18	Appendix A	Congeners	-	-
NOAA/Rosman	EN-19	Appendix A	River Segments	EPC Derivation	Sediments
NYSDEC/Ports	ED-1	1.1	Fort Edward Dam	Dam Removal	-
NYSDEC/Ports	ED-2	1.3	PCB Concentrations	Dietary Concentrations	-
NYSDEC/Ports	ED-3	2.1.1	Whorled Pogonia	-	-
NYSDEC/Ports	ED-4	2.2	Contaminants of Concern	PCBs	Ecological Assessment
NYSDEC/Ports	ED-5	2.5	Measurement Endpoints	PCB Body Burdens	Tree Swallow
NYSDEC/Ports	ED-6	2.3	Shortnose Sturgeon	Piscivorous Species	Omnivorous Species
NYSDEC/Ports	ED-7	2.6.4	Mink	New York State	Literature Cited

NYSDEC/Ports	ED-8	3.3.5	Bald Eagles	NYSDEC Research	-
NYSDEC/Ports	ED-9	3	Linear Approach	Receptors	Peripheral habitats
NYSDEC/Ports	ED-10	6.1	Uncertainty	Clarity	-
SCEMC	EA-1	1.5	ORNL	Synopsis	Relevant Points
SCEMC	EA-2	1.6	NRDA Plan	Quantitative	Receptors
SCEMC	EA-3	2.1.3	PCB Sources	Upper Hudson	Lower Hudson
SCEMC	EA-4	2.5	Disease	Deformaties	Benthic Communities
SCEMC	EA-5	2.6.5	Bald Eagle	Threatened	Endangered
SCEMC	EA-6	3.2	Striped Bass	Sturgeon	Lower Hudson
SCEMC	EA-7	3.2	Time varying model	-	-
SCEMC	EA-8	3.3.3	GE data	-	-
SCEMC	EA-9	3.4	Dose formula	PCB intake	Factor
SCEMC	EA-10	4.1	Level of Effort	Hudson River	Impacts
SCEMC	EA-11	4.1	Congener	BZ#77	-
SCEMC	EA-12	5.3	Qualitative	-	-
SCEMC	EA-13	5.4	Effects assessment	Extrapolation	-
SCEMC	EA-14	6.1	Exposure	Upper Bound	Lower Bound
SCEMC	EA-15	Appendix A	Food Chain Model	Bioenergetic Model	Seasonal Time Scales
SUNY/Putman	EP-1	4.2.1	Exposure Levels	TRV	Uncertainty
SUNY/Putman	EP-2	4.1.1	Chronic Exposure	Measurement Effects	Receptors
SUNY/Putman	EP-3	General Comments	Exposure Concentrations	Great Lakes	St. Lawrence River
Scenic Hudson	ES-1	4.1	PCB Toxicity	Receptor Species	-
Scenic Hudson	ES-2	General Comments	Mink	Population Decline	Diversity
Scenic Hudson	ES-3	2.6	Avian Receptors	Knowledge	References
Scenic Hudson	ES-4	2.7	Impacts	Risk	NRDA
Scenic Hudson	ES-5	4.1	Endpoints	Reproduction	Development
Scenic Hudson	ES-6	4.1.1	PCB Toxicity	NOAEL	Threshold
Scenic Hudson	ES-7	4.1	Toxic Equivalency Factors	BZ#126	Congener
Scenic Hudson	ES-8	4.2	Measurement Effects	Toxicological Data	Sources
Scenic Hudson	ES-9	Table 1	Assessment Endpoint	Measurement Endpoint	Benthic Communities
GE	EG-1	1	Baseline ERA	Toxicity quotient	Uncertainty
GE	EG-2	6.1	Site conceptual model	TRVs	Relevant endpoints
GE	EG-3	2.3 and 6.1	Endpoints	Translating	Population-level risk
GE	EG-4	2.2	Other stressors	PCBs	-
GE	EG-5	2	Objectives	Endpoints	-
GE	EG-6	2.3	Endpoints	Criteria	-
GE	EG-7	2.5	Measurement endpoints	Assessment endpoints	-

GE	EG-8	3.3	Site characterization	Receptors	-
GE	EG-9	2.1	Definition of the "site"	Lower Hudson River	-
GE	EG-10	2.2	Contaminants of Concern	Metals exposure	Herbicides, Pesticides
GE	EG-11	2.4	Site Conceptual Model	Exposure pathways	Aquatic vegetation
GE	EG-12	2.6	Receptors	-	-
GE	EG-13	3.1	Exposure Pathways	-	-
GE	EG-14	3.2	Fate & Transport	Models	-
GE	EG-15	3.3	Exposure concentration	-	-
GE	EG-16	3.4	Models	-	-
GE	EG-17	4.1	Toxicity	TEF	TEQ
GE	EG-18	5.4	Risk characterization	Models	TRV
GE	EG-19	6	Uncertainty	Sensitivity analysis	-
GE	EG-20	6.1	Uncertainty	Sensitivity analysis	-

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Responses

300978

II. RESPONSE TO COMMENTS ON THE ERASOW

General Comments

Response to EP-3

Consistent with USEPA's risk assessment guidance and the NCP (§300.430(d)(4)), the objective of the ERA is to assess risk on a site-specific basis. The ERA will not compare the Hudson River PCBs site to other sites contaminated with PCBs.

Response to EG-1

Consistent with USEPA's risk guidance, the ERASOW begins with the contaminant of concern and works up to assess risk to individuals, populations, and communities (a "bottom-up" approach), rather than starting with field population and community information and working down to identify the contaminant of concern ("top-down" approach), as proposed by the commenter. The bottom-up approach is then combined with the independent results of a probabilistic analysis in a weight-of-evidence approach to determine whether concentrations of PCBs present in the Hudson River may cause adverse effects in individuals and populations of representative receptors. A weight-of-evidence approach is preferred for the Hudson River PCBs site because examination of several lines of evidence increases confidence in the results of the study of this complex Superfund site.

Additional information regarding the contaminants of concern is provided in the responses in Section II. 2.2, Contaminants of Concern. Additional information regarding risks to biological communities and populations is provided in the responses in Section II. 2.3, Assessment Endpoints. Additional information regarding uncertainty in the ERA is provided in the responses in Section II 6.1, Approaches to Assessing Uncertainty.

Response to ES-2

Qualitative information on the "health" of the Upper Hudson River ecosystem, limited to any observations made during the ecological field sampling, will be presented in the problem formulation (Step 3) discussion in the ERA.

1. INTRODUCTION

1.1 Site History

Response to ED-1

The comment on the relative importance of the removal of the Fort Edward Dam is acknowledged and will be incorporated into future reports, where applicable.

1.2 Ecological Risk Assessment in the Superfund Process

Response to EN-1

All relevant data received by USEPA during preparation of the ERA will be considered for incorporation into the ERA, as time permits. Data received after release of the ERA will be reviewed to determine whether they are directly applicable to the ERA, and if so, they will be considered in any additional analyses or responses to comments.

1.3 Results of Phase 1 Ecological Risk Assessment

Response to ED-2

The comment on editing for clarity is acknowledged and will be incorporated into future reports, where applicable.

1.4 Changes in EPA Risk Assessment Guidance Since the Phase 1 Assessment

No significant comments were received on Section 1.4.

1.5 Additional Toxicological Benchmarks Developed by ORNL Since the Phase 1 Assessment

Response to EA-1

USEPA will identify and explain the use of any Oak Ridge National Laboratories (ORNL) report used in the ERA. The ORNL reports summarize scientific literature and may be used as a starting point for a literature search on toxicological benchmarks.

1.6 Organization of the Phase 2 ERA Based on USEPA 1997 Guidance

Response to EA-2

The draft scope for the Hudson River Natural Resource Damage Assessment (NRDA) Plan issued in 1998 correctly stated that much of the information to quantify injury to various receptors is likely not available; however, it also states that the necessary information will be developed. Similarly, the information necessary to assess risk in the ERA will be developed by USEPA based on available water, sediment, aquatic invertebrate, and fish data.

Limited mink and otter data from the New York State Toxic Substances Monitoring Program (1982) and Foley et al. (1988) will be provided in the ERA. The mink's exposure to PCBs will be estimated using a food chain model that calculates PCB uptake from its food source (including forage fish), from direct contact with PCB-contaminated sediments, and from ingestion of PCB-contaminated surface water. Heavy metals data from the Upper Hudson River (Phase 2 1993 Ecological Sampling Database) will be discussed in the benthic macroinvertebrate community analysis section.

Available data are sufficient to perform a quantitative and qualitative assessment of ecological risk posed by the Hudson River PCBs site.

2. PROBLEM FORMULATION

Response to EG-5

The commenter recommends focusing the ERA on three questions related to the adverse effects of PCBs on biological community structure and population dynamics. The first question is whether PCBs from the site currently are adversely affecting biological community structure or the population dynamics of the key receptors. As explained in the response to EG-3, biological community structure and population dynamics of vertebrate receptors are not emphasized in the "bottom-up" approach of the Superfund baseline risk assessment. Instead, consistent with USEPA guidance, assessment endpoints were selected to identify risk to receptors of concern that could be adversely affected by contaminants from the site (ERASOW, p. 13).

The second question asks when will PCBs from the site no longer adversely affect biological community structure or population dynamics under a "no action" remedy. Again, the bottom-up approach of the Superfund risk assessment emphasizes risk to individual receptors of concern, rather than on community structure or population dynamics. The ERA will model future fish body burdens to determine if predicted concentrations of PCBs will adversely affect biological receptors over a 25-year time frame, beginning at the time of data collection (i.e., 1993 to 2018). Both mean and 95% upper confidence limit (UCL) PCB concentrations will be calculated, absent any remediation. Because many receptors at various trophic levels are being evaluated, an estimate of when the PCBs would no longer adversely affect the biological community is not an appropriate assessment endpoint.

The third question is to what degree will remediation reduce the time to reach the point at which PCBs are no longer adversely affecting biological community structure or population dynamics. As stated above, the ERA focuses on key biological receptors rather than an entire biological community or population. Moreover, evaluation of remedial alternatives that address risk is part of risk management, which is the step after completion of the baseline risk assessment (ERASOW, p. 9). Accordingly, this question is outside of the scope of the ERA.

2.1 Site Characterization

Response to EG-9

USEPA has consistently defined the site to include the Lower Hudson River since at least April 1984, when the Agency issued its FS for the site and before the site was listed on the National Priorities List (codified at 40 CFR Part 300, App. B). In its September 25, 1984 Record of Decision, USEPA defines the site by reference to three figures which, together, depict the site as the entire 200-mile stretch of the River from Hudson Falls to the Battery in New York City, plus the remnant deposits. In addition, during the Reassessment RI/FS, USEPA has consistently defined the site as including the Upper and Lower River (*e.g.*, the Scope of Work for Hudson River Reassessment RI/FS (December 1990) and the Phase 1 Report for the Reassessment RI/FS (August 1991)). The comment regarding USEPA's use of the results of the ERA (including the Lower Hudson ERA) in evaluating remedial alternatives is a risk management issue, and therefore beyond the scope of the ERA. USEPA decision-makers will consider risk management following completion of the ERA.

2.1.1 Upper Hudson River

Response to ED-3

The small whorled pogonia (*Isotria medeloides*), a member of the orchid family, is listed as a federal threatened species. It is listed in New York State as a historic species, last seen in 1976. However, because it is generally found in dry soils in mid-aged woodlands, it will not be discussed in the ERA.

2.1.2 Thompson Island Pool

No significant comments were received on Section 2.1.2.

2.1.3 Lower Hudson River

Response to EN-2

As appropriate, endangered or threatened species in the Lower Hudson River will be discussed in the ERA.

Response to EA-3

The ERA for the Lower Hudson River is appropriate because, as noted in the ERASOW (p. 12), the Lower Hudson River has several ecologically sensitive areas that give it ecological importance. Sufficient information exists to perform the ERA for the Lower Hudson River.

2.2 Contaminants of Concern

Response to EG-4, EG-10, and ED-4

The ERA is part of USEPA's reassessment of its 1984 no-action decision with respect to PCB contaminated sediments in the Upper Hudson River (ERASOW, p. 12). As such, the ERASOW focuses on PCBs in the Upper Hudson River sediments. Step 1, which includes screening for preliminary contaminants of concern (COCs), was performed in the *Phase 1 Report Review Copy Interim Characterization and Evaluation Hudson River PCB Reassessment RI/FS* (August 1991) and will be summarized in the ERA (see ERASOW, p. 7). PCBs were identified as the primary COCs, given the quantity released, their persistence in the environment, their toxicity, and their known bioaccumulative effects.

2.3 Assessment Endpoints

Response to EG-3 and EG-6

USEPA agrees that one of the assessment endpoints of the ERA is sustainability (i.e., survival and reproduction) of local Hudson River populations (ERASOW, p. 14). The ERA will estimate the potential for risk under future conditions based on modeling results (Baseline Modeling Report, due May 1999). Potential risk will be based on the probability that future concentrations will result in body burdens or doses that exceed the selected toxicity reference values (TRVs) for each receptor population.

Consistent with USEPA risk guidance (USEPA, 1997), the assessment endpoints identified in the ERASOW are primarily individual-level risks, such as survival or growth, rather than the sustainability of communities or populations. Direct measurement of population-level endpoints is problematic because it is difficult to identify a discrete population and to determine the proportion of individuals in a population that constitutes a population-level change, which could lead to an underestimation of ecological risk. While there is uncertainty associated with extrapolating from an individual-level risk to a community or population, such an approach is protective of the environment.

USEPA agrees that it must select appropriate TRVs as measures of effect and that the appropriate criteria are those provided in USEPA guidance. The TRVs that will be used are based on peer-reviewed scientific studies. The uncertainty associated with them does not compromise the integrity of the ERA. It is unrealistic to expect the scientific literature to provide species- and habitat-specific TRVs for all endpoints examined. Surrogate species are routinely used in ecological risk assessments to calculate risks to the biological community. It should be noted that even TRVs derived for specific areas and species have uncertainty and variability associated with them.

Response to ED-6

The shortnose sturgeon and brown bullhead are omnivorous, as indicated in the text (ERASOW, p. 18-19). Table 1 of the ERASOW should have included a separate assessment endpoint for omnivorous fish, as follows.

Assessment Endpoint	Specific Ecological Receptor "Endpoint Species"	Measures Exposure	Effect
Survival, growth, and reproduction of local omnivorous fish populations	brown bullhead shortnose sturgeon	Food Chain Modeling PCB Conc. in Prey Body Burdens PCB in Water/Sed.	Exceed. of TRV Exceed. of Pop. Effects Exceeds WQC

2.4 Site Conceptual Model

Response to EG-11

Consistent with USEPA guidance (USEPA, 1997), the site conceptual model in the ERASOW (p. 14) identified the sources, media, pathways, and routes of exposure that will be evaluated in the ERA. Environmental fate processes, such as burial and dechlorination, are not included in the conceptual model, but will be presented in the Baseline Modeling Report (due May 1999), which will be used to estimate future concentrations of PCBs. The presence of other contaminants and stressors will be considered during risk management, as appropriate (see response to comments EG-4, EG-10, and ED-4). The diagram of the conceptual model (Figure 5 of the ERASOW) could have shown aquatic vegetation as the food source of some lower trophic level receptors (e.g., herbivores). However, aquatic vegetation was not included because it generally does not bioaccumulate PCBs and therefore does not contribute a significant amount of PCBs to benthic invertebrates.

2.5 Measurement Endpoints

Response to EG-7

Consistent with USEPA guidance (USEPA, 1997), the ERASOW identified individual-level measurement endpoints, rather than population or community-level endpoints, for individual-level assessment endpoints. As with the assessment endpoints, direct measurement of population-level measurement endpoints is problematic because it is difficult to identify a discrete population and to determine the proportion of individuals in a population that constitutes a population-level change, which could lead to an underestimation of ecological risk The measurement endpoints will be used to determine the potential for community or population-level effects based on individual risk. While there is uncertainty associated with extrapolating from an individual-level risk to a community or population, such an approach is protective of the environment.

The measurement endpoints identified in the ERASOW include ambient water quality criteria AWQC), sediment quality values, and TRVs. A comparison of site data to these values is being conducted as part of the ERA to update the comparison done earlier in the Phase 1 Report (USEPA, 1991). This is consistent with USEPA guidance, which states, "measurement endpoints can include measures of exposure as well as measures of effect" (USEPA, 1997).

The TRVs, as well as other measurement endpoints, will be selected based on the criteria set forth in the ERASOW (p. 15), which are strength of the association between the measurement endpoint and the assessment endpoint, data quality, and study design and execution. These three broad criteria encompass the eight criteria identified by the commenter.

USEPA acknowledges the commenter's agreement with USEPA's use of a weight-of-evidence approach. The quality of each measurement endpoint will be evaluated according to the attributes identified by Menzie et al. (1996) and will be discussed in ERA. USEPA notes that Dr. Menzie will be directly involved for the Hudson River PCBs Reassessment ERA.

Response to ED-5

Measured PCB body burdens are available for benthic invertebrates, forage fish, piscivorous fish, and insectivorous birds, as listed in Table 1 of the ERASOW. PCB concentrations in receptors that have no measured body burdens will be modeled based on food chain exposure models and concentrations of PCBs measured in the Hudson River, and/or biomagnification factors from the scientific literature (for example, for concentrations in eggs of piscivorous birds). USEPA will contact agencies and organizations with information on fish and wildlife populations along the Hudson to ensure that all receptor species feed in, at, or near the river. The potential receptor species listed in the ERASOW were selected to be representative of different behaviors and feeding strategies.

Response to EN-3

USEPA agrees that the correct citation for the New York State Department of Environmental Conservation (NYSDEC) TAGM for screening contaminated sediments is NYSDEC (1998).

Response to EA-4

Disease and deformities observed during sampling would not necessarily be attributed to PCBs. Rather, the observations would be included in a weight-of-evidence approach, which would consider the location of observations, the number of observations, the measured PCB concentrations in the area, and other measurements.

2.6 Receptors of Concern

Response to EG-12

USEPA selected the largemouth bass, but not the smallmouth bass, as a potential fish receptor (ERASOW, p. 19). The smallmouth bass was erroneously included in Table 1. As discussed in the response to ED-3, the whorled pogonia will not be included in the ERA because its habitat is not found along the Hudson River. The northern harrier is a State species of special concern that is a potential receptor to be considered in the ERA because it feeds and nests in marshes or wetlands that could receive PCBs during flood events. The striped bass and shortnose sturgeon occur predominantly in the Lower Hudson River; however, shortnose sturgeon have been sighted in the Upper Hudson River (Bain, personal communication). The striped bass was selected to evaluate the ecological risk posed by contaminated sediment, water and fish in the Lower Hudson (see also response to EA-6) and the shortnose sturgeon was selected because it is a federally-listed endangered species.

Response to ES-3

Please provide the references so they can be evaluated for use in the ERA.

2.6.1 Macroinvertebrate Communities

Response to EN-5

USEPA agrees with the comment. As stated in the ERASOW (p. 44), the PCB concentrations in Hudson River surface water will be compared to freshwater or marine AWQC, depending on the salinity of the water. The Upper Hudson River is exclusively freshwater and only the last three Lower Hudson River locations sampled in the Phase 2 ecological sampling program (RM 58.7 and lower) are saline and can be compared to saltwater criteria.

2.6.2 Fish Receptors

2.6.3 Avian Receptors

No significant comments were received on Sections 2.6.2 and 2.6.3.

2.6.4 Mammalian Receptors

Response to ED-7

USEPA agrees with the comment. The citation for Foley et al. (1988) will be evaluated for use in the ERA. The Palmer and Fowler (1975) reference will be included in the references section of the ERA.

2.6.5 Threatened and Endangered Species

Response to EA-5

The bald eagle is a federally-listed threatened and a New York State-listed endangered species, and therefore is appropriately mentioned in Section 2.6.5, Threatened and Endangered Species.

2.6.6 Significant Habitats

No significant comments were received on Section 2.6.6..

2.7 Risk Questions

Response to ES-4

USEPA will use the term "adversely affecting"in the ERA rather than "impacting" to distinguish it from a natural resources damage assessment

3. EXPOSURE ASSESSMENT

Response to ED-9

Consistent with USEPA guidance (USEPA, 1997), the ecological risk posed by the site will be assessed both quantitatively and qualitatively. For the quantitative portion of the ERA, USEPA first identified species that are most directly in contact with the PCBs in the Hudson River and were therefore assumed to have the greatest potential for ecological risk. From this list of species, USEPA identified receptors that occupy different positions within the food web and that have a variety of behavioral and feeding strategies, such as the mink, the brown bat, and the great blue heron. The overall risk to the ecosystem will be assessed by considering the quantitative risks to the various individual receptor species and by measuring the benthic community structure, combined with a discussion of the risk along exposure pathways that were not quantitatively assessed. Exposure via pathways outside of the Hudson River, such as direct contact with PCBs in river bank and floodplain sediments, will be mentioned as additional pathways of exposure.

3.1 Exposure Pathways

Response to EG-13

Consistent with USEPA guidance (USEPA, 1997), the diets of receptor species will be determined using the USEPA Wildlife Exposure Factors Handbook (USEPA, 1993) and, as appropriate, site-specific information from the scientific literature. USEPA has copies of the references cited by the commenter (Robinson, 1992; McCarty, 1995; Secord and McCarty, 1997; Exponent, 1998; and Secord, 1998).

3.1.1 PCBs in Sediments

3.1.2 PCBs in Water

3.1.3 Benthic Invertebrates

3.1.4 Fish Receptors

3.1.5 Avian Receptor

No significant comments were received on Sections 3.1.1 to 3.1.5.

3.1.6 Mammalian Receptors

Response to EN-6

USEPA selected the mink, rather than the shrew or meadow vole, as one of the mammalian receptors of concern. Although shrews, voles, and mink may all be exposed to PCBs from direct contact with sediments on the river banks and floodplains, the mink was selected as a receptor of concern because of its documented sensitivity to PCBs and its reliance on fish as a food source (ERASOW, p. 20). USEPA selected the raccoon because it is a mammal with a different feeding strategy (i.e., omnivore) than the mink. (With respect to avian receptors, the bald eagle was selected as an avian receptor of concern, rather than other accipiters (hawks), because it is on both the federal and New York State lists of threatened and endangered species and there have been recent sightings of it along the Hudson River (ERASOW, p. 21)). The receptors of concern are representative of different species that may be adversely affected by the site and is not intended to be all-inclusive.

3.2 Quantification of PCB Fate and Transport

Response to EG-14

USEPA will use fate and transport models to describe the distribution of PCBs in the sediments and water of the Hudson River. These modeled concentrations of PCBs in sediments and water will be used in the ERA as initial concentrations in several bioaccumulation models. One of the bioaccumulation models is a Gobas-type time-variable mechanistic model. The ERA will be peer reviewed and USEPA will respond to the peer reviewers' comments in a responsiveness summary.

Response to EA-6

The risks to striped bass and shortnose sturgeon will be assessed, though not explicitly modeled, using sediment, water and fish data that are representative of their respective habitats, including spawning locations and winter holdover locations (ERASOW, p. 28). USEPA intends to assess the risk to the striped bass using the revised Thomann/Farley model.

Response to EA-7

Consistent with USEPA guidance (USEPA, 1997), the ERA will assess future risk (1993 to 2018), assuming no remediation, by using modeled exposure concentrations. In modeling the future concentrations at various time intervals for mammalian and avian receptors, the initial concentration may be held constant for the first five or ten years, even if the model suggests a time-varying decrease in concentration (ERASOW, p. 29), or may be recalculated annually, as suggested by the commenter. Holding the concentrations constant is a conservative approach that may lead to an overestimation of risk, but it is protective of the environment given the expected variations in concentrations throughout the site. A sensitivity analysis performed for the Monte Carlo method will provide some indication of the degree to which the risk may be overestimated, and the uncertainty associated with using this approach would be discussed in the ERA.

3.3 Observed Exposure Concentration

Response to EN-7 and EG-15

USEPA will use appropriate statistics from the observed data to characterize exposures and body burdens, including arithmetic averages and 95 percent upper confidence limits (UCLs) on these averages (ERASOW, p. 30). Because the observed concentrations are best described by lognormal distributions (Baseline Modeling Report, due May 1999), the formula to estimate 95% UCL for lognormal distributions, also known as Land's method, will be used (Gilbert, 1987). These statistics are appropriate for use in the ERA because the receptors of concern are expected to contact the sediments and water column over a large area rather than remain in one localized spot. Appropriate statistics may include a mean exposure level with appropriate quantification of uncertainty, where the data are sufficient to be characterized as a distribution described by a mean and a standard deviation (ERASOW, p. 30).

The field measurements of benthic invertebrate BSAFs will be compared to laboratory and other field measurements, such as sediment data, in assessing the risk to benthic invertebrates. For modeled exposure concentrations of PCBs in benthic invertebrates, the concentrations will be estimated from a distribution of the site-specific BSAFs derived in the Baseline Modeling Report (due May 1999) (ERASOW, p. 34). The site-specific fish body burdens will be used to calibrate and validate the models (Baseline Modeling Report, due May 1999). Insectivorous birds and mammals living along the Hudson River are assumed to feed mainly on flying insects with partial aquatic life histories based upon Hudson River and New York State studies (e.g., Buchler, 1976; Robertson et al., 1992; Secord and McCarty, 1997). PCB concentrations in flying aquatic insect prey will be based on the results of the field sampling program (i.e., macroinvertebrate and sediment data) with a factor to account for metamorphic partitioning between shed exuviae and the emerging flying insect.

Response to EG-8

The ERA will evaluate all relevant data sets that have been published or otherwise made available to USEPA, where appropriate. Studies cited by the commenter will be reviewed, including NYSDEC (1977), NMFS and USFWS (1985), ASMFC (1990), NYSDEC (1993), Kynard (1997), NMFS (1997), Secord and McCarty (1997), Exponent (1998), and USFWS (1998). Mr. Nye of NYSDEC will be contacted.

While USEPA will evaluate the data in the studies cited by the commenter, it does not agree with all of the commenter's interpretations of those data with respect to benthic and phytophilous macroinvertebrates, fish, and birds at the site. For example, studies on fish abundance do not necessarily reflect the response of fish to PCBs as factors, because the fishing advisories may have a greater overall effect on abundance. In addition, the commenter stated that USEPA should eliminate the tree swallow as a receptor species due to the Secord and McCarty (1997) study, claiming that the study "show(s) that even high body burdens of PCBs have not affected the reproductive success of tree swallows." In fact, Secord and McCarty (1997) stated, "...tree swallows breeding along the Hudson River had lower reproductive success than tree swallows from an uncontaminated site" and "PCB concentrations and toxic equivalency quotients detected in tree swallows have significant implications for migratory birds that breed or migrate along the Hudson River." Therefore, it is appropriate that the tree swallow be retained as a receptor species.

3.3.1 Sediment Concentrations

3.3.2 Water Column Concentrations

No significant comments were received on Sections 3.3.1 and 3.3.2.

3.3.3 Benthic Invertebrate Concentrations

Response to EA-8

GE has collected data on PCB concentrations in various media in the Hudson River, and GE's data will be used to supplement USEPA's dataset, as appropriate (ERASOW, p. 30). GE's sediment data will be evaluated for appropriateness to supplement USEPA's high-resolution and low-resolution sediment sampling programs (ERASOW, p. 30). Data were collected in the 1993 Phase 2 field sampling program specifically for the ERA, and therefore these data will receive priority in the ERA.

3.3.4 Fish Concentrations

No significant comments were received on Section 3.3.4.

3.3.5 Avian Concentrations

Response to ED-8

USEPA acknowledges the commenter's offer to provide additional data on bald eagles as it becomes available and may incorporate the data into the ERA if time permits.

3.3.6 Mammalian Concentrations

No significant comments were received on Section 3.3.6.

3.4 Modeled Exposure Concentrations

Response to EG-16 and EA-9

In the ERA, USEPA will use modeled exposure concentrations in addition to observed exposure concentrations to assess ecological risk. USEPA will use all appropriate data to calibrate and validate both the probabilistic bioaccumulation food chain model and modified Gobas time-varying mechanistic models (FISHPATH and FISHRAND) for PCB concentrations in fish in the Baseline Modeling Report (due May 1999). Even with such validation, there will be uncertainty which, consistent with USEPA's risk guidance (USEPA, 1997), will be quantified to the extent possible. There are insufficient avian and mammalian Hudson River PCB data to field-validate vertebrate exposure models, and field collection of some vertebrate species could adversely affect Hudson River populations (e.g., bald eagle, river otter).

The ERASOW (p. 32-33) presents general forms of the equations to be used for direct ingestion of water and for dietary doses from ingestion of prey (i.e., food). For the dietary dose equation, USEPA does not agree that the ingestion rate term is per day. As stated in the ERASOW (p. 33), the dose may be expressed as either a critical body residue or as an average daily exposed dose. USEPA does agree that the concentration of PCBs in food items is on a wet weight basis.

The ERASOW does not detail how the ingested dose will be translated into body burdens. The specific equations to describe the conversions require additional terms, such as assimilation and metabolic efficiencies, and depend on the physiology of the given species and, to some extent, on the structure of the PCB congener being ingested (ERASOW, p, 33). This level of detail is beyond the scope of the ERASOW. However, where appropriate, USEPA will describe in the ERA the method used to convert ingested dose to absorbed doses (i.e., body burdens) for each species and each congener-based toxicity equivalency factors (TEFs). These methods may range from assuming that 100% of ingested dose is available to the species, to using exposure models such as the bioaccumulation model for fish. A literature-based biomagnification factor (USEPA, 1994) will be used to predict concentration of PCBs in eggs of pisciverous birds.

As stated in the ERASOW (p. 33), the input values for these equations will be obtained from the scientific literature. For the Hudson River ERA, the relevant literature includes site-specific studies, USEPA's Wildlife Exposure Factors Handbook (USEPA, 1993), and other references. The studies cited (Salyer and Langler, 1949; Davis, 1980, Landum et al., 1993; and Kaufman, 1996) will be evaluated for use in the ERA.

USEPA disagrees with the comment that it would be more appropriate to obtain exposure point concentrations for fish by multiplying an average BSAF by an average surface sediment PCB concentration. Rather, USEPA will obtain exposure point concentrations for fish by compiling PCB concentrations by location (ERASOW, p. 31). The Upper Hudson River will be divided into three reaches (RM 189, 168, and 154). The pooling of data from Upper Hudson River sampling locations is done to account for forage fish obtaining benthic invertebrates from a large area rather than from one isolated location. The locations in the Lower Hudson River are considered to be separate habitats and therefore fish PCB concentrations are not combined.

Response to EN-8

Because limited data are available for nearshore water concentrations, whole water average and 95% UCL concentrations will be used for all receptors. For species whose predominant habitat is the shoreline, the 95% UCL may provide a more appropriate concentration than the average, as concentrations may be higher along the shoreline.

3.4.1 Benthic Invertebrate Receptors

3.4.2 Fish Receptors

3.4.3 Avian Receptors

3.4.4 Mammalian Receptors

No significant comments were received on Sections 3.4.1 to 3.4.4.

4. EFFECTS ASSESSMENT

4.1 Estimating the Toxicity of PCBs

Response to ES-1 and ES-5

For each receptor species, a toxicity reference value (TRV) will be selected based on studies that examine the effects of PCBs on survival (lethality), growth, or reproduction (ERASOW, p. 37). Reproductive effects are broadly defined to include larval/fetal development. Studies that examine the effects of PCBs on other sublethal endpoints will be presented, but not used to select TRVs. TRVs for fish will be expressed as critical body residues in adult fish and fry (e.g., mg/kg whole body weight) and as lipid-normalized concentrations in eggs (e.g., mg/kg lipid in eggs). TRVs for avian and mammalian receptors will be expressed as daily doses (e.g., mg/kg whole body weight). TRVs for birds will also be expressed as concentrations in eggs (e.g., mg/kg wet wt egg). No additional toxicity studies are planned. A summary of published studies in the scientific literature will be provided in the ERA.

Response to EA-10

USEPA did not conduct site-specific toxicological studies at different locations along the entire length of Hudson River because it would have required numerous toxicological studies conducted over a period of several years. This would have delayed the Superfund process and added significantly to the cost of the ERA. Rather, USEPA focused its efforts on obtaining site-specific sediment, water, benthic invertebrate, and fish data, which will be used along with the toxicological studies from the scientific literature to estimate PCB toxicity to Hudson River ecological receptors. Toxicological studies used to establish TRVs will be chronic studies, because exposure of ecological receptors to PCBs is expected to be long-term. In addition, reproductive effects of PCBs are typically studied in long-term exposure scenarios. The uncertainty associated with using TRVs derived from toxicological studies in scientific literature rather than site-specific toxicological studies will be addressed in the ERA.

Response to EG-17, EN-10, ES-7, and EA-11

The ERASOW (p. 37-38) outlined two approaches for assessing PCB toxicity: the Total PCBs and Aroclor mixture toxicities approach, and the most recent PCB congener-specific toxicities and Toxicity Equivalency Factors (TEFs) approach. USEPA agrees that use of the TEF approach has significantly improved the understanding of the relative toxicities of different PCB congeners and of the aggregated toxicity of PCB mixtures. However, USEPA disagrees with the suggestion that the TEF approach should be eliminated from the ERA because TEF studies may yield conservative benchmarks that indicate lower adverse effect levels than those derived using the Total PCBs and Aroclor mixture toxicities approach. Rather, consistent with the recommendations published following a USEPA-sponsored workshop (ERG, 1998), USEPA believes that both approaches are appropriate for use in the ERA. USEPA will use the TEF approach for all congeners covered by World Health Organization (WHO) TEFs (i.e., BZ# 77, 81, 126, 169, 105, 114, 118, 123, 156, 157, 167, and 189; Van der Berg et al., 1998), if the site data are adequate to support its use (ERASOW, p. 39). In the ERA, USEPA will present an evaluation of the data sets for each of the 12 congeners with a WHO TEF value.

4.1.1 Total PCBs and Aroclor Toxicities

Response to ES-6

To clarify the ERASOW (p. 38), one of the toxicity reference values (i.e., dose) for chronic effects of PCBs will be based on the No-Observed-Adverse-Effect-Level (NOAEL), and will be adjusted to reflect differences from test species to receptor species, and from sub-chronic to chronic values.

Response to EP-2

The potential for adverse effects will be based on comparisons of measured and modeled exposure concentrations to both appropriate regulatory standards and TRVs obtained from the scientific literature, even if no adverse effects are observed in the receptors of concern. The 1993 Phase 2 benthic invertebrate data compares communities from similar habitats along different reaches (i.e., varying PCB concentrations) of the Thompson Island Pool in the Upper Hudson River to determine community-level differences. As noted in the ERASOW (p. 39), areas with low PCB concentrations will be considered more representative of reference areas than areas with elevated PCB concentrations. TRVs for benthic invertebrates have been deleted as a measurement endpoint, as discussed in the response to ES-9.

4.1.2 Congener-specific Toxicity and the Toxicity Equivalency Factors (TEF) Approach

No significant comments were received on Section 4.1.2.

4.2 Measures of Effect

Response to ES-8

The full citations for all sources of toxicological data used in the ERA will be provided in the references section of the ERA.

4.2.1 Benthic Invertebrate Communities

Response to EN-4 and EN-9

A quantitative index of EPT species (Ephemeroptera, Plecoptera, and Tricoptera, such as mayflies, stoneflies, and caddisflies) and an EPT to Chironomidae ratio are not appropriate for the Hudson River, because large rivers generally do not have the shallow, fast-moving water and the rocky bottom that is the preferred habitat of many EPT species. In addition, the EPT to Chironomidae ratio may be skewed; the number of Chironomid species may be high for reasons other than water quality. The diversity indices will be used as a measure of benthic macroinvertebrate community structure to compare similar habitats along different reaches of the river (ERASOW, p. 39). The USEPA (1989) reference cited by the commenter was revised in 1997 (Revision to Rapid Bioassessment Protocols For Use in Streams and Rivers: Periphyton, Benthic, Macroinvertebrates, and Fish, USEPA 841-D-97-002).

Response to EP-1

The ERA will use predicted (1993 to 2018) sediment, water, and fish PCB concentrations calculated for the Baseline Modeling Report (due May 1999), as well as measured concentrations from the 1993 Phase 2 field sampling program. The predicted concentrations of PCBs in all media modeled are lower than the initial (i.e., 1993) levels, in accordance with data collected since the 1993 Phase 2 field investigation.

4.2.2 Fish Receptors

Response to EN-11

As stated in the ERASOW (p. 40), the effects to fish will be calculated using measured (for current) and modeled (for future) PCB body burdens, using a critical body residue approach. Toxicity Reference Values (TRVs), which represent the lowest PCB concentrations that have been shown to cause adverse effects in test species, will be obtained from the scientific literature. The approach used to select TRVs will evaluate the sensitivity of the endpoint and quality of the study, as recommended by the commenter. When selecting total PCB body burden TRVs for fish, preference will be given to studies that measure actual tissue concentration. Studies examining the effects of PCBs on fish eggs will be used to develop TRVs for fish eggs and will be provided on a lipid-normalized basis.

4.2.3 Avian Receptors

4.2.4 Mammalian Receptors

4.2.5 Threatened and Endangered Species

4.2.6 Significant Habitats

No significant comments were received on Sections 4.2.3 to 4.2.6.

5. RISK CHARACTERIZATION

5.1 Surface Water Concentrations

5.2 Sediment Concentrations

No significant comments were received on Sections 5.1 and 5.2.

5.3 Benthic Invertebrates

Response to EN-12 and EA-12

Benthic community data will be analyzed qualitatively using a weight-of-evidence approach due to the difficulty in attributing specific results or differences between stations to PCBs alone (ERA SOW, p. 45). The presence of contaminants in sediments other than PCBs, natural variability in ecosystems, and human disturbances of habitats and their potential effects on benthic community structure will be discussed in the ERA.

5.4 Fish Receptors

Response to EG-18

USEPA agrees that the ERA should provide an estimate of population-level risks to fish posed by PCBs at the site (ERASOW, p. 46) and that Suter (1993) presented a number of approaches to characterize population-level risk (ERASOW, p. 45). However, USEPA disagrees with the comments that the ERASOW misrepresents Suter's work and that the ERA will not address the magnitude of population-level risk for fish. The equations presented in the ERASOW (p. 46-47) are a general form of the model that may be used to relate individual-level to population-level risks; however, the exact form would depend primarily on the availability of toxicological data and the form in which the exposure data are expressed (ERASOW, p. 47). Other approaches that may be used include logit or probit functions to describe dose-effect and a logistic model to express the probability that a receptor of concern will exceed a particular effect level (ERASOW, p. 47). The results of the logit or probit approach would be combined with mortality and reproductive rates in a population growth model to estimate population-level effects. The approach ultimately selected for use in the ERA will address the magnitude of population-level risk, if it is found to exist.

Response to EN-13

USEPA acknowledges the statement that the commenter disagrees with the concept of evaluating population-level effects as a component of an ecological risk assessment for remedial decision-making. However, the evaluation of population-level effects is consistent with USEPA's Ecological Risk Assessment Guidance for Superfund (USEPA, 1997). The term "population" and the approximate percent of affected individuals ascribed to population-level changes at an expected exposure concentration will be discussed in the ERA. Consistent with USEPA guidance (USEPA, 1997), the ERA will be appropriately protective of the environment in estimating risk at the population level.

Response to EA-13

As noted in the ERASOW (p. 46), the first step in characterizing population-level risk is to "[d]efine the effects assessment as an extrapolation of series or statistical extrapolations." To clarify, this means statistically combining the individual dose effect curves, which are extrapolations of measured observations and modeled data, into a single dose effect curve that describes the expected response for the entire population, which is a further extrapolation.

5.5 Avian Receptors

5.6 Mammalian Receptors

5.7 Threatened and Endangered Species

5.8 Significant Habitats

No significant comments were received on Sections 5.5 to 5.8.

6. UNCERTAINTY ANALYSIS

Response to EG-19

USEPA disagrees with the comment that the absence of site-specific ecological data creates such uncertainty regarding population and community-level risk that the ERA will be of little use in the remedial analysis. First, the ERA will be based on site-specific water, sediment, and biota (i.e., benthic invertebrate and fish) data. Second, the assessment of effects to benthic macroinvertebrate communities will be performed using the methods set forth in USEPA guidance (USEPA, 1997). Third, consistent with USEPA guidance (USEPA, 1997), uncertainty will be discussed qualitatively, and quantitatively when possible, in the ERA. Once completed, the results of the ERA will be used in Step 8 - Risk Management, to evaluate remedial alternatives (ERASOW, p. 9).

6.1 Approaches to Assessing Uncertainty

Response to EG-2 and EG-3

The commenter expresses concern regarding the uncertainty in modeling ingested doses and body burdens and uncertainty in TRVs. A variety of fish, avian, and mammalian receptors at various trophic levels will be evaluated in ERA. Information on ingestion rates in wild populations will be used when available. When these rates are not available, ingestion rates based on captive populations or allometric equations (e.g., Nagy, 1987) will be used. The dosage of PCBs will be calculated based on PCBs in sediment, water, invertebrates, and fish from both the measured concentrations from the 1993 Phase 2 dataset and predicted concentrations from the bioaccumulation modeling (Baseline Modeling Report, due May 1999). The calculation of two exposure estimates provides a basis for comparison and a method of validating modeling results. The TRVs are based on the results of scientific studies showing observable, repeatable effects, directly related to PCBs. TRVs will be selected for each receptor based on long-term studies on taxonomically similar species. TRVs are intended for individual-level effects. The extrapolation to population or community effects is based on site-specific conditions.

Another part of the weight-of-evidence approach is comparing sediment and water column studies to accepted standards, criteria, or guidelines. Although these comparisons do not provide a quantitative estimate of risk, the magnitude of the risk can be approximated by examining the ratio of observed and predicted PCB concentrations to guidelines. It should be noted that regulatory criteria and guidelines are based on individual-level observations.

Conducting various river specific studies beyond what NYSDEC, the US Fish and Wildlife Service, and others are already conducting would provide more elements to the weight-of-evidence, but will introduce such broad uncertainties of their own that they are unlikely to reduce general uncertainty in the assessment. Population numbers, age-class and annual reproductive success vary so widely in nature that only large long-term studies can ever begin to address such uncertainty.

Further, the ERA will provide adequate information for decision makers when considered in conjunction with other parts of the Reassessment RI/FS, such as the Human Health Risk Assessment, the Data Evaluation and Interpretation Report, and the results of the modeling. The Hudson River PCBs Superfund site, stretching for nearly 200 river miles, has been contaminated by PCBs for over 50 years. Consequently, the site is complex on both a spatial and temporal scale and decision-makers will benefit from multiple lines of evidence regarding risk management.

Response to EA-14 and EG-20

To clarify, using a sensitivity analysis to assess uncertainty, one model parameter will be varied by a fixed percentage while all other parameters are held constant (ERASOW, p. 53). Use of the upper bound on the ingestion rate of a prey item for the avian and mammalian models was presented as an example. The sensitivity analysis will use the lower bound as well.

Response to ED-10

The ERASOW (p. 53) described an approach to assessing uncertainty, which is lack of knowledge, and variability, which is the natural heterogeneity present in the environment. Consistent with USEPA guidance (USEPA, 1996b), a Monte Carlo-type analysis can be used to assess variability and uncertainty simultaneously by selecting one value to represent variability (i.e., the 75th percentile) and then systematically changing the value to consider the uncertainty around it (i.e., a triangular distribution).

REFERENCES

Response to EN-14

USEPA will ensure that the missing references are included in the ERA, as appropriate.

Table Number 1: Assessment and Measurement Endpoints

Response to EN-15

Exceedance of sediment guidelines will be included as effects endpoints to the benthic community structure; survival, growth, and reproduction of benthic invertebrates; and protection of significant habitats endpoints in the ERA. The shortnose sturgeon and brown bullhead will be identified as omnivores in relevant tables of the ERA (ERASOW, p. 19).

Response to ES-9

The ecological community indices (diversity, evenness, dominance) are considered to be exposure measures because they provide an estimate of the overall health of the benthic invertebrate community. In contrast, comparison of benthic community indices at a different time or location (e.g., different PCB concentrations) is an effects measure. Estimated exceedance of toxicity reference values (TRVs) for benthic community structure is deleted from the ERASOW. The TRVs are not an appropriate measurement endpoint for benthic invertebrate community structure as a source of food for local fish and wildlife because TRVs are species-specific and do not apply to risk at the community level.

Table Number 2: Trophic Levels, Exposure Pathways, and Food Sources

Response to EN-16

USEPA agrees that the shortnose sturgeon feeds primarily on invertebrates. The feeding habits of the shortnose sturgeon will be revised in the tables and text of the ERA, consistent with the ERASOW (p. 27).

APPENDIX A MODELING APPROACHES

Response to EN-17

USEPA agrees with the comment that the modeling approaches in Appendix A are general. The ERASOW provides an outline of the work to be performed in the ERA. The models that are used to assess risk will be fully described in the ERA.

Response to EN-18

The congeners that may be modeled include the congeners proposed for evaluation in the TEQ approach (see response to EG-17, EN-10, ES-7, and EA-11). Most of the TEF congeners analyzed were not detected in the samples collected.

Response to EN-19

River segments will be determined based on the spatial scale of the fate and transport (HUDTOX) modeling. Sediment concentrations in these reaches will be based on the results of the HUDTOX modeling. For most fish species, the model segments are expected to encompass the exposure zones for fish that may be caught in a particular segment of the river.

Response to EA-15

Bioaccumulation will be predicted using several models (each of which incorporates a different methodology) (Baseline Modeling Report, due May 1999). Fish PCB body burdens will be predicted over a 25-year time frame (1993-2018). The time-varying mechanistic model developed by GE will not be used, but USEPA will use a modified Gobas time-varying mechanistic model (see response to EG-14).

ADDITIONAL REFERENCES

Bain, M.B. March 1999. Cornell University. Personal communication by telephone.

Van den Berg, M., L. Birnbaum, A.T.C. Bosveld, B. Brunstrom, P. Cook, M. Feeley, J.P. Giesy, A. Hanberg, R. Hasegawa, S.W. Kennedy, T. Kubiak, J. C. Larsen, F.X. Rolaf van Leeuwen, A.K. Jjien Liem, C. Nolt, R.E. Peterson, L. Poellinger, S. Safe, D. Schrenk, d. Tillitt, M. Tyslind, M. Younges, F. Waern, and T. Zacharewski. 1998. Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. *Environmental Health Perspectives*. Vol. 106 (12):775-792.

III. COMMENTS ON ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

Copies of the comments received during the public comment period follow.

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Federal

U.S. DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
National Ocean Service
Office of Ocean Resources Conservation and Assessment
Hazardous Materials Response and Assessment Division
Coastal Resources Coordination Branch
290 Broadway, Rm 1831
New York, New York 10007

November 4, 1998

Doug Tomchuk
U.S. EPA
Program Support Branch
290 Broadway
New York, NY 10007

Dear Doug:

Thank you for the opportunity to review the September, 1998 *Hudson River PCBs Reassessment RI/FS, Phase 2 Ecological Risk Assessment Scope of Work.* The following comments are submitted by the National Oceanic and Atmospheric Administration (NOAA).

Background

The primary objectives of the baseline ecological risk assessment (ERA) are to quantify risks to selected biological receptors and communities exposed to releases of PCBs in the Hudson River. Current risk evaluations will be derived primarily from the EPA 1993 Phase 2 ecological sampling program and NYSDEC/NOAA 1993 and 1995 PCB congener-specific fish data. It will also include other Phase 2 investigations. Future risk will be determined from the pending Baseline Modeling Report. Other data may include 1970's-1980's RI/FS data, NYSDEC annual fish tissue data since 1971, GE fish data, NYSDOH 1972 benthic invertebrate data and USFWS/NYSDEC avian PCB data.

The interim ERA of the Phase 1 report concluded that PCBs in surface water, sediment and fish exceed state and federal guidelines. Specifically, surface water PCB concentrations exceeded ambient water quality criteria for protection of aquatic life. Fish tissue in the Upper Hudson exceed USFWS guidelines for trout. Piscivorous wildlife are consuming fish with PCBs potentially at higher concentrations than recommended by NYSDEC or USFWS. Sediment PCBs also exceed sediment guidelines.

Summary

EPA issued new policies related to ecological risk assessment. The Hudson River ERA will incorporate new guidelines and criteria, utilize point and probabilistic estimates of effects, qualitatively address endocrine effects, consider the applicability of toxic equivalency factors (TEFs) and prioritize ecological entities for protection.

The Screening Level Problem Formulation and Ecological Effects Evaluation were completed as part of the Phase 1 activities. Study Design, Data Quality Objectives and Field Verification of the Sampling Design were performed as part of the 1993 Ecological Sampling Plan.

This Scope of Work (SOW) covers three of the eight steps of an EPA ERA. Baseline Risk Assessment Problem Formulation will use new guidance and studies to select assessment endpoints and to develop a conceptual model. Site Investigation and an Analysis of Exposure and Effects will be based on site investigation results and model output. Risk Characterization will utilize a weight of evidence approach.

The SOW deals with three distinct sections of the Hudson River: the Upper Hudson, the Thompson Island Pool (TIP) and the Lower Hudson. It covers the 200 miles of the Hudson from the Battery to Hudson Falls, encompassing freshwater, brackish and estuarine habitats. PCBs will be examined as congeners, total PCBs and aroclors.

Macroinvertebrates were sampled for PCB-congener body burdens and for benthic community ecological metrics. Structure will be measured by evenness, dominance and diversity. PCB water-column concentrations will be compared to ambient water quality criteria (AWQC) and sediments will be assessed using freshwater and estuarine screening level guidelines.

Eight species of fish representing various trophic levels will be evaluated. Measured PCB tissue contaminant levels will be utilized for all species except the federally endangered shortnose sturgeon for which body burdens will be modeled. Contaminant profiles will be developed for each species.

Avian receptors include the tree swallow, mallard, belted kingfisher, great blue heron, and federally threatened bald eagle. Mammalian species include the little brown bat, mink, and raccoon.

Significant habitats to NOAA, NYSDEC, and USFWS will be evaluated.

Assessment endpoints include:

- Benthic community structure as food source to fish and wildlife,
- Survival, growth and reproduction of localized benthic macroinvertebrate community and local forage and piscivorous fish populations,
- Protection (i.e., survival and reproduction) of wildlife (piscivorous and insectivorous birds; piscivorous, insectivorous and omnivorous mammals), and
- Protection of significant habitats.

Measurement endpoints include

- Benthic community indices relative to trophic transfer of PCBs,
- Fish tissue residues to evaluate trophic transfer of PCBs,
- Fish and wildlife tissue residues to determine exceedances of PCB effect-level thresholds,
- Water PCB concentrations comparison to NYS AWQC for protection of piscivorous wildlife, and
- Sediment PCB concentrations comparison to applicable sediment benchmarks.

Risk estimates will be developed from measurement endpoints. Exposure concentrations will be modeled for species for which data are unavailable.

Comments

The authors of the ERA SOW present a concise and clear description of the planned approach to assess exposure and risk to receptors from Hudson River PCB-contaminated media. The approach is well-thought out and is consistent with current ERA guidance. The ERA will rely entirely on existing data and modeling in the exposure assessment and information in the published literature to assess toxicity; while considerable information is available for the exposure assessment, the lack of field measurements of toxicity endpoints may result in a high degree of uncertainty in the risk characterization. Most of the comments that follow primarily identify points for clarification.

Page 4 Section 1.2: NYSDEC and USFWS are in the process of collecting tissue samples for PCB tissue analysis (waterfowl, macroinvertebrates, mink, turtles, bald eagles). This pending dataset should be considered during the ERA. We recognize that results are not currently available EN-1 but they should be considered upon availability to support the modeled concentrations and to enhance the available data incorporated into the risk assessment.

Page 12 Para 2: State and federally endangered and threatened species should have been listed in the Lower Hudson River Section 2.1.3 to be consistent with the description of the Upper Hudson River. **EN-2**

Page 16 Last Bullet, Page 18 Para 1, Page 44 Para 2, Page 45 Para 3: The NYSDEC sediment benchmark is incorrectly attributed to the NYSDEC soil cleanup levels (TAGMs) developed for protection of human health. The cited document (NYSDEC 1993) correctly identifies the technical guidance for screening contaminated sediments, but it should be noted that there is a March 1998 edition. **EN-3**

Page 16 First Bullet, Page 18 Para 1: Richness, abundance and biomass were assessed in the benthic macroinvertebrate community study. Proposed ecological metrics include diversity, evenness and dominance. Metrics selected should aid in the assessment of whether the biological community is impaired and to what degree. Community similarity indices are appropriate but reference sites are required for comparison and none were sampled. EPT index and the ratio of EPT to Chironomidae are other metrics suggested by EPA (1989). Diversity indices should not be used because they can provide misleading information. For example, it is well known that diversity is low in unperturbed desert environments. Since diversity is based on total number of taxa and abundance of each taxa, stations with low abundance of many taxa could have a higher diversity index then stations with high abundance but fewer taxa. It is important to consider whether species intolerant to the COC are absent or reduced and whether the contribution of pollution tolerant species has increased. **EN-4**

Page 18 Section 2.6.1 PCB concentrations in the water column should be compared to freshwater or marine AWQC depending on the salinity of the water. **EN-5**

Page 28 Para 1 and Page 31 Para 4: Mammalian receptors in the Upper Hudson should include small mammals such as shrews and meadow voles, which utilize the river banks and floodplains that are potentially contaminated with PCBs and represent an important feeding area for upper trophic avian and mammalian carnivores. By not considering floodplains in the ERA, risk to mink, raccoons and accipiters will most likely be underestimated. Excluding floodplains from the risk assessment also ignores a potential source of PCBs that can recontaminate riverine habitats during flood and scour events. The ERA should address all significant exposure pathways. **EN-6**

Page 30 Para 1: According to Section 3.3, appropriate statistics for characterizing exposures and body burdens will include arithmetic averages and the upper 95% confidence interval (95% UCI). Other references throughout the SOW refer to the use of averages but not the 95% UCI. Will the 95% UCI be employed for all receptors? In the case of benthic invertebrates (Section 3.4.1), PCB concentrations will be estimated from a distribution of site-specific BSAFs. Can we assume that the variable estimator will be the arithmetic mean and 95% UCI? **EN-7**

Page 32: Direct ingestion of water is considered an exposure pathway and the dose from water is calculated from the average concentration. PCB concentrations may be higher along shorelines than in mid-channel transect sample concentrations, resulting in an higher exposure to receptors predominantly utilizing the shoreline habitat. It is not clear whether averaged nearshore water column concentrations or averages over a broader spatial area will be used. **EN-8**

Page 39 Para 1: Benthic macroinvertebrate effects measures should include the ecological metrics specified above in the comment for page 18. See EPA (1989). **EN-9**

Pages 37-39: The ERA mentions the use of a toxicity equivalence (TEQ) approach with calculated TEFs compared to modeled congener-specific PCB tissue concentrations. Appendix A does not explain whether this will be done for each of the models. **EN-10**

Page 40 Para 2: "Measurement effects will be based on test species most similar to the receptor..." Limited data are available for PCB residue-based effects in fish, so it may be advisable to use an approach that evaluates the sensitivity of the endpoint and the quality of the study. Measured body burden concentrations will need to be adjusted for concentration in the target tissue. For example, evaluation of reproductive effects, where the initial exposure occurs via maternal transfer to the egg, may require estimation of PCB concentrations in the mature egg from measured whole-body or muscle tissue concentrations. Exposure concentrations for developing larvae should also include exposure to PCBs in water and food. EN-11

Page 43 Para 1 and Page 45 Para 2: Benthic community structure data will be analyzed qualitatively because there are concerns that it will be difficult to attribute specific results or differences between stations to PCBs alone. In that most sediments contain mixtures of contaminants and that benthic community structure data are generally viewed quantitatively, we recommend the latter analysis following a weight of evidence approach. Consideration can be given to the presence of other contaminants in the assessment of uncertainty. EN-12

Pages 45-47 and Table 1: In general, NOAA does not agree with the concept of evaluating population-level effects as a component of an ecological risk assessment for remedial decision-making. The vague termonology used to describe population-level risk characterization can lead to nonconservative determinations. Neither "population" nor the percent of affected individuals ascribed to population-level changes at an effective concencentration has been defined. EN-13

References: Add Bain (1997), Gilbert (1979) and Novak (198x). These are referenced in the text but missing from the reference section. NYSDEC (1998) should be substituted for NYSDEC (1993). EN-14

Table 1: See Page 18 comments above regarding the use of diversity indices. Add exceedance of sediment guidelines in the "Effects" column for the following assessment endpoints: benthic community structure; survival, growth and reproduction of benthic invertebrates; and protection of significant habitats. Shortnose sturgeon and brown bullhead are incorrectly identified in Table 1 as forage fish and piscivorous fish, respectively. The text correctly describes them as omnivores. EN-1

Tables 1 and 2: Shortnose sturgeon feed primarily on invertebrates (Bain 1997). Their feeding habits should be revised in these tables, consistent with Section 3.1.4 on page 27. EN-16

Appendix A: Modeling Approaches. The descriptions of the models are very general. EN-17

Page A-1: It is stated that "individual congeners" will be modeled and estimates will be provided in a form that can be used for ERA - which congeners will be modeled and how will data for those congeners be used in the ERA? EN-18

Page A-2: How will river "segments" be determined? How will sediment concentrations for the segmentation used in the modeling be derived? EN-19

Thank you for your continual efforts in keeping NOAA apprised of the progress at this site. Please contact me at (212) 637-3259 or Jay Field at 206-526-6404 should you have any questions or would like further assistance.

Sincerely,

Lisa Rosman

Lisa Rosman
NOAA Coastal Resource Coordinator

References

Bain, MB 1997. Atlantic and shortnose sturgeons of the Hudson River: common and divergent life history attributes. Environ Biol Fish 48:347-358.

EPA 1989. Rapid Bioassessment Protocols for Use in Streams and Rivers, Benthic Macroinvertebrates and Fish, EPA/444/4-89-001, Office of Water, May 1989.

NYSDEC 1998. Technical Guidance for Screening Contaminated Sediments, New York State Department of Environmental Protection, Division of Fish and Wildlife, Division of Marine Resources, March 1998.

cc: Mindy Pensak, DESA/HWSB
Robert Hargrove, DEPP/SPMM
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William Ports, NYSDEC
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State

New York State Department of Environmental Conservation
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November 9, 1998

Mr. Douglas Tomchuk
United States Environmental Protection Agency
Region II
290 Broadway - 20th Floor
New York, NY 10007-1866

Re: Hudson River PCBs Site Reassessment RI/FS
Site No.: 5-46-031

Dear Mr. Tomchuk:

The following comments are on the Hudson River PCBs Reassessment RI/FS, Phase 3 Feasibility Study Scope of Work and Phase 2 Ecological Risk Assessment Scope of Work, dated September 1998.

Feasibility Study Scope of Work

Section 1, Page 3. The text states, "computer models will be employed to assist in the selection of remedial objectives as well as to assess the likely success of any remedial action in attaining these goals." Generally, the remedial action objectives are based on applicable or relevant and appropriate requirements (ARARs) and/or risk assessment findings. Models are generally used to assist in predicting whether specific remedial measures will enable the goals to be achieved. The scope of work should explain how the computer models will be used to select remedial objectives.

Section 1.2, Page 5. The Scope of Work should clearly state that all of the exposure routes found to be of concern in the Human Health Risk Assessment (HHRA) are addressed in the Feasibility Study.

Section 2.2 Page 12 and 13 and Section 4. We suspect that the depositional areas just south of Remnant Site 3 and adjacent to Remnant Site 4 contain PCB contaminated sediments. Remedial alternatives should include consideration of such areas above Rogers Island.

Section 2.2 Page 15 and 16. The DEC piscivorus wildlife criteria (0.1 ppm in whole fish) must be included in the Final Selection of Remedial Action Objectives, particularly where the reference to the 'desired level in fish' occurs.

Section 2.2 Page 15. The second bullet on the page cites cancer risk as the basis for determination of acceptable PCB levels in near-shore sediments. This bullet should be clarified to indicate that the basis for determination of acceptable PCB levels in near-shore sediments will be based on any appropriate risks, cancer or non-cancer, as determined in the HHRA.

Section 2.3. The report between Section 2.3 (Development of Remedial Action Objectives and General Response Actions, page 17) and Section 4 (Development, Screening and Detailed Analysis Remedial Alternatives, page 26) is not consistent as to whether institutional controls are part of a no action alternative. This apparent discrepancy needs to be clarified.

Section 2.3 Page 17. The term "on-site" as used in conjunction with identifying general response actions should be more clearly defined. As it is currently defined in the text, one might conclude that the superfund site includes a 2-mile corridor along either bank of the river.

Table 1 Potential Chemical -Specific ARARS and Criteria, Advisories and Guidance state that the inclusion of the U.S. Food and Drug Administration tolerance limit for PCBs in fish (2 ppm) as an ARAR is relevant and appropriate but that its consideration in the RI/FS is to be determined. This is confusing and should be clarified. Regardless of what is done with the Table, the FDA tolerance limit should be used as an ARAR.

Ecological Risk Assessment Scope of Work

Page 1, at bottom and top of Page 2 - The removal of the Fort Edward Dam is overstated as a defining event for the impact on contaminating the Hudson River. The write-up on page 3 of the Feasibility Study Scope of Work provides a better perspective on the dam removal and this should be reiterated in place of the referenced passage in the Ecological Risk Assessment Scope of Work. **ED-1**

Page 5, fourth bullet - It is recommended that this passage be revised for clarity to read as follows: Estimated PCB concentrations in the diets of fish eating birds and mammals at the site are similar to or higher than dietary concentrations recommended by USFWS or NYSDEC (TAMS/Gradient, 1991). **ED-2**

Page 11, last line - Explain a little further about the 'whorled pogonia.' Is this a plant or animal? **ED-3**

Page 12 & 13, Section 2.2 Contaminants of Concern - There needs to be some rationale provided for limiting the discussion to PCBs. If this is to be an 'ecological assessment,' recognition at least of the existence of other contaminants in the system is in order. **ED-4**

Page 16, 'Measurement endpoints', third bullet - 'PCB body burdens' are not included in the measurement endpoints as listed in Table 1. For example, on the second page of the table the only species mentioned that would have body burdens measured is the tree swallow. Where actual Hudson River samples which provide body burden data are not available, literature values may be used. Also, please note that other species of animals mentioned may not be feeding in the river and hence, may not be accumulating high levels or may not be impacted. **ED-5**

Table 1 - Why is the short nose sturgeon listed as a forage species? If it is truly endangered, is it expected to comprise a large part of the food base for piscivorus species? Under piscivorus fish at the bottom of the first page, it would be more accurate to recognize many of these as omnivorous. Any piscivorus habits of the species may be functions of life stage and size. **ED-6**

Page 20, paragraph 4 - There are data available on PCBs in mink for New York State in Foley et al. The full citation is available if desired. In the next paragraph, Palmer and Fowler are not in the literature cited section, whereas Hornshaw et al. from the paragraph above is in the literature cited On page 21, the Gilbert 1989 citation is not in the literature cited section either. **ED-7**

Page 31, section 3.3.5 - More data on bald eagles may soon be available based on ongoing NYSDEC research. If this will be of use, please let us know. **ED-8**

Throughout Sections 3, 4 and 5, the assessment approach described is 'linear.' The focus is almost exclusively on the river, not as an ecosystem, but as a north-south geographic feature. The species outlined for the Ecological Risk Assessment are considered to derive their energy from the river itself and there is little weight given to some of the most productive habitats or ecological zones. Except for some forage species and benthic invertebrates the shallow, near shore littoral areas are not evaluated. There is no mention of the transition zone from aquatic to terrestrial habitats and likewise the riparian, wetted perimeter, and flood plain habitats are absent from discussion. Reptiles, amphibians, soil invertebrates (e.g., earthworms, burrowing insect larvae), mammals (e.g., shrews and moles), birds such as woodcock form a diverse complex array of organisms inhabiting these peripheral habitats which may be larger in spatial extent than those directly associated with the river. In addition then to the direct exposure to animals in these habitats, there is the re-exposure to the aquatic system of PCB running off the surface of the flood-plain. Although the concentrations are relatively low, it represents a widespread surficial phenomenon which should be taken into account in the risk assessment. **ED-9**

On page 53, paragraph 2 - This paragraph should be rewritten and expanded for clarity. Otherwise, eliminate it since it does not impart useful information. **ED-10**

If you have any questions on the above, please call me at (518) 457-5637.

Sincerely,

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

Enclosure

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bc: E. Crotty
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Local

HUDSON RIVER PCBs REASSESSMENT RI/FS
COMMENTS ON PHASE 2 ECOLOGICAL RISK ASSESSMENT
SCOPE OF WORK, DATED SEPTEMBER, 1998

Prepared by David D. Adams, Member-at-Large
Saratoga County Environmental Management Council

1. Section 1.5, P.6: It is recommended that a synopsis of the ORNL reports be included in the Ecological Risk Assessment giving the relevant points used in the Risk Assessment. **EA-1**

2. Section 1.6, P. 8 and Table 1: The draft scope for the Hudson River Natural Resource Damages Assessment Plan, September 1988 states that information to quantify injury to aquatic insects, birds, reptiles and amphibians, and mammels is "likely not available". In view of this statement, why does EPA believe sufficient information to realistically evaluate ecological risk in these areas is available? Wouldn't it make for a better evaluation to focus the ecological risk assessment on those areas (water, sediment) and species (fish, invertibrates) for which data are available? The ecological risk assessment seems in many areas to be qualitative enough without resorting to further speculative treatment of species for which data specific to the Hudson River are lacking. It is noted that the Peer Review Committee reviewing the Preliminary Model Cabitration Report commented on the desirability of getting data on mink and on concentration of heavy metals. **EA-2**

3. Section 2.1,3, P. 12: Is there enough information on the sources of PCB's in the Lower Hudson River to make a risk assessment of this area meaningful in terms of the effects of remedial action in the Upper Hudson on species in the Lower Hudson? If not, it is not evident what benefit a risk assessment of the Lower Hudson River has to this study. **EA-3**

4. Section 2.5, P. 17: How can observations on "disease & deformities during sampling" be of use when toxic materials other than PCBs present in the Hudson River that could cause any observed disease or deformity are not being evaluated? Again, this entire risk assessment is so fraught with qualitative aspects that it should not be further clouded by further unsubstantiated considerations. (For example, it is noted that in reply to a question at the October 20th Availability Session regarding beuthic community indices, it was stated that specific information relating these indices to PCB concentrations is not available and a qualitative approach would be used. Similar responses occurred several other times in response to question at the Availability Session. (See also the discussion on P. 22 on measurement endpoints). **EA-4**

5. Section 2.6.5, P. 21: The bald eagle should be deleted from consideration as a threatened or endangered species. **EA-5**

6. Section 3.2, P. 28: How can striped bass be properly evaluated using Upper Hudson River data when they are most heavily exposed to PCB sources in the Lower Hudson **EA-6**

independent of the Upper Hudson? This species, and the sturgeon, should be eliminated from the risk assessment.

6. Section 3.2, P. 29: It makes no sense to run a model which shows a time-varying decrease over time and then ignore the model results in the risk assessment. The risk assessment procedure should be modified to allow proper consideration of the model results. **EA-7**

7. Section 3.3, P. 29: Available GE data should also be considered here and elsewhere. **EA-8**

8. Section 3.4, P. 32: The dose formula should include a factor to account for the fraction of PCB intake absorbed **EA-9**

9. Section 4.1, P. 37: The size of the Hudson River and level of effort required to obtain site-specific data are not acceptable excuses when weighted against the potential impacts resulting from the risk assessment. EPA owes the communities in the Hudson River area a better evaluation than what is evident from this SOW. **EA-10**

10. Section 4.2.3, P. 39: The decision to use only congener BZ#77 should be reviewed to see if the other congener data can also be used. **EA-11**

11. Section 5.3, P. 45: The second paragraph highlights another example of the highly qualitative nature of this assessment. **EA-12**

12. Section 5.4, P. 46: The statement at the top of the page says the "effects assessment" is an extrapolation of an extrapolation which seems highly questionable. This statement should be clarified. **EA-13**

13. Section 6.1, P. 53: Lower bounds as well as upper bounds should be considered. **EA-14**

14. P.A.-2: The food chain model should be a bioenergetic model as recommended by the Peer Review Committee for the Preliminary Model Calibration Report. Also, consideration should be given to the model developed by GE and to seasonal time scales. **EA-15**

Community Interaction Program

301017

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EP-1

UNIVERSITY AT ALBANY
STATE UNIVERSITY OF NEW YORK

October 29, 1998

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

ATTN: ERA SOW Comments, Phase 2 Ecological Risk Assessment

Dear Mr. Tomchuck:

I have reviewed the above referenced document and submit the following comments:

1. The use of 1993 field sampling data for estimating body burdens will overestimate exposure levels relative to toxicity reference values (p. 40). There will also be a bias in comparisons to water quality criteria, because PCB concentrations in both the water column and fish have since declined, and were also lower prior to 1990. The relation of existing concentrations to body burdens is dynamic, not static, and body burdens have a variable lag effect depending upon the receptor. To attempt to model future body burden levels or response on the basis of one direct observation/organism or group at a fixed point in time will produce unacceptable uncertainty in the results. **EP-1**

2. What will determine a chronic exposure level, or whether (p. 38) a toxicological adverse reaction has occurred in organisms? Is this by comparison to a toxicity threshold level from the literature or a regulatory standard (e.g. fish), even if no adverse effect is observed, i.e. an assumed toxicity effect in the absence of any direct observation? The relevance of threshold or reaction levels from the literature, or as determined in other settings with different receptors or test species must be established. It is not clear how a fixed time point (1993) benthic invertebrate community assessment (p. 39) will accomplish this, given the dynamic variation occurring in the other two "effect measures" (p. 39). **EP-2**

3. Comparison data (exposure concentrations; observed ecosystem reactions; type of PCB and system recovery status, etc.) for other PCB contaminated sites, such as the Great Lakes and St. Lawrence River, should be included; and the risk characterization of same provided for perspective. What are the similarities and difference to the Hudson, and how might these affect the risk assessment? **EP-3**

In retrospect, this type of comparison should be applied to the SOW previously prepared for the assessment of human exposure risk. An estimate of population exposure risk derived via extrapolation from laboratory exposure studies at high PCB doses or other indirect means is profoundly uncertain when the actual health statistics for a human population of documented exposure history, and observable body burden, can be obtained and/or directly measured, as at Ft. Edward, Hudson Falls, and the Mohawk Indian tract on the St. Lawrence River. This is no less a matter of ecosystem effects evaluation, with the advantage of a much longer receptor history. Data of this type is critical to a resolution of the current debate about risk assessment in human.

Very truly yours,

George W. Putman, dlp

George W. Putman,
Emeritus, Dept. of Earth and
and Atmospheric Sciences Faculty

Public Interest Groups

301020

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Scenic Hudson's Comments on
USEPA's Hudson River PCBs Reassessment RI/FS
Phase 2 Ecological Risk Assessment
Scope of Work

As with the human health risk assessment, a full characterization of ecological effects associated with exposure to Hudson River PCBs is a critical part of EPA's Reassessment of the Hudson River. While we believe the overall approach to assessing ecological risks seems reasonable, as does the discussion of PCBs, we have the following concerns:

General Comments:

Toxicity of PCBs - It appears that PCB toxicity is not sufficiently documented. We do not have great confidence that the measurement of PCB toxicity in receptor species will be properly conducted. We suggest that EPA review the approach used and the contractor's experience with ecological risk assessment to ensure a useful ecological risk assessment is completed. **ES-1**

The discussion of the toxicity of PCBs is lacking in reference material. A considerable amount of literature exists, regarding this subject, and should be included in the assessment.

Overall Ecological Health

From examining the range of PCB concentrations that exist in the Hudson River ecosystem and the effects of those concentrations on various receptor species it would seem reasonable to include a qualitative discussion of the health of the entire ecosystem and disappearance of certain species such as the mink. Certain factors such as the population decline of the mink, is an indicator as to the health and diversity of the ecosystem. Unquantified, but important, effects of PCB contamination will fall by the wayside in a EPA number driven decision-making process. From our experience, studying environmental impacts and assessments, issues relegated to qualitative discussions are often dismissed and have little bearing on the outcome. However, a qualitative discussion as to the overall health of the Upper Hudson River ecosystem is better than no discussion at all. **ES-2**

Other concerns:

Section 2.6. **Receptors of Concern**, pg.17 - Once again we are concerned that the risk assessment is based on the proper knowledge of receptor species, particularly of avian receptors (Section 2.6.3, pg. 19). Several critical references are not sited for this section. **ES-3**

more...

email: scenichu@mhv.net

Section 2.7, **Risk Questions,** pg. 22 - In the last sentence, the use of the word "impacting" is not appropriate for a risk assessment. The risk assessment should show whether there is a risk or not, it does not have to show impact. The word impact would more appropriately be used in the *Natural Resources Damage Assessment.* **ES-4**

Section 4.1, **Estimating the Toxicity of PCBs,** pg. 37 - Toxicological endpoints that will be evaluated in the ERA should include *Reproduction* and *'Development'.* **ES-5**

Section 4.1.1 **Total PCBs and Aroclor Toxicities,** pg. 38 - The last sentence in the first paragraph incorrectly uses the word "threshold". A threshold is where effects start. This sentence is confusing as, "No-Observed-Adverse-Effect-Level (NOAEL) toxicity values" will be used as "thresholds" for estimating adverse ecological impacts. Please clarify. **ES-6**

Section 4.1.2 **Congener-specific Toxicity and the Toxic Equivalency Factors (TEF) Approach** -pg. 39 - In discussion of congener specific toxicity assessment it is indicated that "of the most toxic (coplanars) congeners, the Phase 2 database includes usable data for BZ#77 only. If the data are adequate..." First, it is not clear as to how this data will be used. Secondly, we question whether or not an assessment can be based on BZ#77 data only. BZ#126 is usually the most important congener used in ecological risk assessment. The most meaningful data set should be used to properly assess ecological risks **ES-7**

Section 4.2, **Measures of Effect**, pg. 39 - Sources of toxicological data, which "will include refereed scientific literature, the USEPA AQUIRE database, and government publications", are too vague. Please identify sources of toxicological data more specifically. **ES-8**

Table 1 **Assessment and Measurement Endpoints**, (page 1 of 3). Regarding the first **Assessment Endpoint** identified, *Benthic community structure as food source for local fish and wildlife, Ecological community indices (diversity, evenness, dominance)* placed under *Measures/Exposure* is a measure of effect, not exposure, and should be moved to the *Effect* column. Under *the Effect* column - *Estimated Exceedance of Toxicity Reference Value (TRVs)* is species-specific and is not generally used for a community and should be deleted. **ES-9**

11/10/98

General Electric

EG-1

GE Corporate
Environmental Programs

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New York State EHS Affairs

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November 2, 1998

Mr. Douglas Tomchuk
USEPA – Region 2
290 Broadway – 20th Floor
New York, N.Y. 10007-1866

RE: ERA SOW Comments

Dear Mr. Tomchuk:

The process of preparing an ecological risk assessment to assess, with reasonable certainty, the ecological effects of PCBs in the Upper Hudson River is truly a daunting one. Extreme care must be given to several issues, including adequately assessing communities or populations of benthic invertebrates, fish, birds and mammals in the river and adjacent land, and differentiating between effects of PCBs on these populations and effects of other contaminants, such as mercury and lead, and other human disturbances.

Unfortunately, we are concerned that the process EPA has developed for this assessment will not prove at all useful to its intended goal. The course which EPA sets out in the Scope of Work is little more than a screening level analysis. Apart from a limited study of benthic invertebrates, the Agency has not, and is not planning to, collect data on the biota of the Hudson and its shoreline. No information gathered during this process, other than the concentration of PCBs in the water column, sediments or limited selection of biota, will be specific to the Upper Hudson River. Such an analysis, while potentially useful for developing future investigation and analysis, cannot illuminate whether PCBs are affecting the sustainability of biological communities or populations present at this particular site.

This failure to attain site-specific information on the wildlife populations of the Upper Hudson River will result in significant uncertainty in the risk assessment – we urge that the uncertainty be quantified and stated candidly so that the public may understand the likelihood of obtaining any particular ecological change as a result of a recommended clean-up plan.

We look forward to the Agency's response to the enclosed detailed comments regarding the Ecological Risk Assessment Scope of Work. If the Agency would like to discuss these comments in greater detail, please do not hesitate to contact me.

Sincerely,

Melvin B. Schweiger / MSE

Melvin B. Schweiger

cc: Richard Caspe
William McCabe
Melvin Hauptman
John Cahill
Douglas Fischer
Albert DiBernardo
Charles Menzie

COMMENTS OF GENERAL ELECTRIC COMPANY ON HUDSON RIVER PCBS REASSESSMENT RI/FS PHASE 2 ECOLOGICAL RISK ASSESSMENT SCOPE OF WORK

November 2, 1998

TABLE OF CONTENTS

I. Introduction and Executive Summary

The General Electric Company ("GE") is pleased to submit these comments on the "Hudson River PCBs Reassessment RI/FS Phase 2 Ecological Risk Assessment Scope of Work" ("SOW").

The purpose of conducting an ecological risk assessment ("ERA") under Superfund is to aid in making a decision on the appropriate remedial course of action. To be useful in remedial decision-making, an ERA needs to be focused on the conditions at the Superfund site in question and to have substantial certainty associated with its predictions. These benchmarks must be met if the risk manager is to be able to use the risk assessment to project with reasonable specificity the ecological changes that will be accomplished by various remedial actions.

In the case of the Hudson River PCBs Superfund site ("Site"), the chemical of concern to EPA entered the river beginning approximately 50 years ago. Direct discharges from the manufacturing processes ceased approximately 20 years ago. For some period since, there have been seeps of PCBs entering the river. These have now been reduced to quite low levels. Given the persistence of PCBs, often in dechlorinated form, these simple facts provide the opportunity for an analysis of the ecological effects of PCBs on a large scale: Over 50 years and 40 miles of river, what impacts, if any, have PCBs had on the populations of benthic invertebrates, fish, birds, and mammals in the River and the adjacent land?

Unfortunately, EPA has failed to take advantage of this opportunity. Apart from a limited study of benthic invertebrates, the Agency elected not to collect data on the biota of the Hudson and its shoreline in order to examine effects, if any, of PCBs on wild populations.

Consequently, it will now be very difficult, if at all possible, for EPA to conduct an ERA that will be useful in selecting a remedial action.

The course that EPA sets out in the SOW is largely a screening-level analysis. Possible concentrations of PCBs in various receptor species will be deduced by "modeling" the dose or body burden that the animals receive, and those values will be compared to PCB levels reported in the literature as associated with some effect in individuals of the receptor species. With the exception of benthic invertebrate community analysis, EPA has not proposed any analysis of effects on populations or communities. The only site-specific information to be used is the concentration of PCBs in the water column, the river sediments and a limited selection of biota. This type of analysis can tell one whether there is a basis for further investigation and analysis; it cannot be used to determine whether unacceptable impacts are occurring or are likely to occur. In other words, while the proposed analysis may be useful for generating risk hypotheses, it does not adequately test the hypotheses. Real data on ecological health are needed for that.

The fundamental limitation of the proposed analyses is their inherent uncertainty. First, there is little or no measurement of the actual exposure of biota at the Site. Second, there is no method to extrapolate from predicted effects in individuals to determine whether the sustainability of the population is affected. Third, there is no critical analysis of the literature to determine whether and how particular studies should be employed at the Site.

It is unfortunate that these obstacles were not overcome by data collection and analysis at the Site over the more than 15 years that EPA has been assessing the Upper Hudson River. These unfortunate circumstances lead to two important results in the present ERA:

- Substantial effort must be made to limit and narrow the uncertainty in the risk assessment, including the obvious task of testing the postulated risk; and

- The degree of uncertainty at the end of the assessment will probably be large; consequently, the final uncertainty of the results must be quantified where possible and otherwise stated candidly so that the risk manager and the public understand the likelihood of obtaining any particular ecological change as a result of a particular remedial action.

At a Superfund site the size of the Hudson Site, EPA will presumably be examining to what extent, if any, a remedial course of action can or will affect the sustainability of the wild populations which are examined. At least five actions will be necessary to narrow and limit the uncertainty of the risk assessment:

- First, the exposure of animals to PCBs from the Hudson must be rigorously analyzed, using site-specific information where possible, and the uncertainty of estimated exposure must be quantified.

- Second, the literature studies relied on in the assessment must be critically examined. What is the uncertainty in extrapolating from one species to another? What is known of the dose/response relationship? Was the study conducted correctly? Where use of a study introduces uncertainty to the analysis, it must be quantified.

- Third, the relationship of effects on individuals to effects on the dynamics of the population must be explicated, taking into account the density-dependent response of the population. Once again, uncertainty must be recognized explicitly.

- Fourth, the existing data on the biota of the Hudson and its shorelines must be examined to assure that any projections of the risk assessment are consistent with the facts. A similar comparison must be made to the peer-reviewed literature.

- Fifth, in order to determine whether the reduction of PCBs in the water column or sediments will have an effect on the exposed biota, effects of other organic chemicals and metals must be examined. Obviously, chemicals other than PCBs as well as other stressors, affect the biota of the Hudson. If those effects are not understood, it is not possible to tell whether remediation of PCBs will have the desired beneficial effects.

These five steps need to be applied to the assessment of the effects of PCBs not only at the present levels found in the water column and the sediments but also at those future levels which will occur under "no action" or other remedial courses. The element of time is important; a central issue for the Agency is to determine how much a particular remedial action will accelerate the time at which a particular population-level effect will cease.

At the conclusion of this exercise, the Agency must set out the uncertainty associated with its estimates of how the sustainability of populations of the Hudson will be changed by specific remedial actions, so that the risk manager and the public can determine the level of confidence to place in the predictions of the ERA in deciding on a remedial course of action.

II. <u>The Proposed Ecological Risk Assessment Will Not Provide Sufficient Information for Remedial Decision-making</u> EG-1

To be useful to a decision-maker, the baseline ERA at a Superfund site must provide reliable information that is not subject to unreasonable uncertainty. EPA (1998a) states that risks must be "characterized in terms of magnitude, severity, and spatial and temporal distribution of effects." The SOW's proposal for the ERA at this Site fails this basic test. The approach set out in the SOW is to use a very limited set of site-specific data in conjunction with models to estimate both the ingested dose of PCBs by receptors in the Hudson River and the PCB body burdens of these biota. These exposure estimates will then be compared to literature-derived "toxicity reference values" ("TRVs") to develop a "toxicity quotient" ("TQ"). Alternatively PCB concentrations in water and sediment will be compared directly to generic ambient water criteria or sediment values. Under this method, either concentrations in environmental media that exceed regulatory criteria or values or a computed TQ which is greater than one will be deemed to identify unacceptable risk to individual organisms. The substantial uncertainty that this method incorporates, combined with its inability to provide quantitative information about risks to biological communities or populations, makes it inadequate for a baseline ERA for a site the size and complexity of the Hudson River PCBs Superfund site. Consequently, the information generated by the planned ERA will be of little assistance to the Agency's decision about appropriate remedies for the site. With no reasonably certain estimate of the true risks that PCBs in the Hudson River pose to biological communities or populations, the Agency will not be able to discern whether risk reduction measures are necessary and, if so, to what extent any remedial alternative would reduce those risks to acceptable levels faster than would occur under the no-action scenario.

EPA could have planned to conduct a better and more useful ERA for the Site. The Agency, other federal and state government agencies, and numerous independent scientists have been studying the presence and effects of PCBs in the Hudson River for more than two decades. In 1990, EPA announced that it would reassess its 1984 Record of Decision for the Site. The initial step in this reassessment was to collect and summarize existing information about the Site and determine what additional data were needed to complete the reassessment. The 1991 Phase 1 Report for the Site contained this initial summary, including the results of a screening-level ERA for the Site, which concluded that a "comprehensive ecological risk assessment, including population, community and ecosystem interactions in response to PCB exposure, is not possible with available data" (EPA 1991). Despite this acknowledgment, the only new information EPA proposed to collect to support the baseline ERA was some limited data on macroinvertebrate communities in the upper Hudson (EPA 1992). EPA chose not to collect additional data about the health and abundance of fish, birds, mammals or other species of interest, and the SOW makes clear that the Agency does not intend to consider the substantial real world data that can provide additional insight into these issues.

Instead, the Agency is proposing to perform a perfunctory ERA that is more appropriate for a 5-acre landfill than for a 40-mile reach of river. This is wholly inadequate for several reasons.

Several of the methods set out in the SOW are not intended for use in a baseline risk assessment. Comparison of PCB concentrations in water and sediments to regulatory or guidance criteria, such as ambient water criteria or generic sediment guidelines, is a screening technique intended to provide a quick indication of the potential ecological risk (EPA 1997). The screening informs the risk assessor whether additional investigation is warranted but does not provide a conclusion that ecological risk actually exists. Indeed, this was the method primarily employed in the Phase 1 Report, and repeating it now will not provide additional knowledge of actual ecological risk. The SOW, nevertheless, proposes to rely on such screening-level analyses.

Even where the Agency intends to go beyond this screening-level examination, the information and analyses to be generated will be of little use in remedial decision-making because they will be subject to substantial uncertainty. This uncertainty results from several aspects of the Agency's approach. First, having collected little data on PCB concentrations in biota, the SOW proposes to rely primarily on modeling both ingested doses and body burdens. There are little or no data against which to validate and calibrate the results of such models, leaving the risk assessment with an unknown level of uncertainty. The SOW, moreover, indicates that the Agency does not intend to consider the majority of the available data on the health and abundance of biota, including selected receptors, which provide a critical line of evidence and to which the model results must be compared.

EG-2

Second, the SOW proposes to compare the uncertain results of modeling to uncertain TRVs derived from the lab or other ecological settings which may bear little resemblance to the Hudson. In many instances, TRVs may not exist for the endpoints or species being examined, or the TRVs may be insufficient for conclusive risk analyses. This leads to further uncertainty when these results must be extrapolated to relevant endpoints or species of concern.

EG-3

Third, the assessment endpoints set out in the SOW identify only individual-level risks, such as survival or reproduction. As a result, the uncertainty of the models and TRVs is compounded by the uncertainty of translating the analysis of individual-level risks to community or population-level risks. What makes this problem worse, is that the full extent of this uncertainty cannot be quantified. One can have little confidence in an analysis that is subject to unquantifiable and unknown uncertainty.

EG-4

An additional shortcoming of the proposed ERA is that it will to consider the risks associated with other stressors, such as contaminants other than PCBs and human disturbances to the ecosystem. An analysis that focuses solely on PCBs will not place those risks in the context of the overall stresses on the ecosystem. Without an assessment of the <u>relative</u> risks associated with PCBs, EPA will not be able to determine whether remedial actions focused on PCBs will actually be beneficial to the ecosystem. In other words, the ERA will provide no information to allow the decision-maker to assess whether the reduction of PCBs in the Hudson River will produce any tangible benefits to the ecosystem.

Accordingly, the proposed ERA will be of little assistance to the remedial decision-makers. The substantial uncertainty associated with the proposed approach, the failure to assess population or community risks from PCBs, and the inability to place such risks in the context of other stressors limit the utility of the information to be derived from the ERA. In fact, the ERA will primarily be useful in demonstrating that-there is no risk to certain receptors from the present concentrations and mass of PCBs. As a result, EPA has two choices if it decides to proceed with an ERA of the type set out in the SOW. The Agency can examine the screening-level results, and where the potential for risk is indicated, can set out to collect site-specific effects data.

Alternatively, without sufficient data to test the risk hypotheses, the Agency must candidly recognize the substantial uncertainty and very limited usefulness of the ERA in its remedial decision-making.

III. The SOW Lacks a Clear Statement of the Objectives and Description of Assessment and Measurement Endpoints

A. The ERA Needs a Clear Statement of Objectives

EG-5

Perhaps the most important element of the risk assessment is defining its objectives -- a related set of questions which it is intended to answer. The structure, scope and details of the ERA depend on and flow from clearly defined objectives. Without such goals, one is unable to determine what endpoints should be assessed and what measurements should be made. In other words, one needs first to develop a set of hypotheses in the context of what is known about the Site before determining the analyses and data required to test those hypotheses.

As the SOW explains, the overall objective of the ecological risk assessment is to aid in the reassessment of the 1984 Record of Decision (SOW at 12). This, in turn, depends on an understanding of whether PCBs in the upper Hudson constrain "the ability of populations and/or communities to sustain themselves at or near" the Site (EPA 1998a). The SOW, however, does not present any questions whose answers will provide information relevant to this issue. We recommend focusing the ERA to answer the following questions:

- Are PCBs currently adversely affecting biological community structure or the population dynamics of the key receptors?
- If so, when will PCBs no longer adversely affect biological community structure or population dynamics under No Action?
- If so, to what degree will remediation reduce the time to reach the point at which PCBs are no longer adversely affecting biological community structure or population dynamics in comparison to No Action?

These questions provide a basis for deriving assessment endpoints that can be used to determine whether biological communities or populations are at risk and, if so, whether PCBs are causing those risks. These objectives, moreover, permit the selection of measurement endpoints with relevance to those assessment endpoints.

B. <u>The Assessment Endpoints Should Focus on the Sustainability of Biological Communities or Populations</u> **EG-6**

An assessment endpoint is a valued characteristic of an ecological receptor that may be affected by exposure to a stressor (Suter 1990). Assessment endpoints are explicit expressions of the actual environmental value to be protected (EPA 1997; 1998b). That is, assessment endpoints are the specific ecological values or characteristics of the selected receptors, the risks to which are quantified by the risk assessment. They usually consist of an entity (population, community, or habitat) and a property (population number, rate of growth, community structure). They are designed to provide answers to the defined objectives for the ERA.

Suter (1990) has suggested criteria for evaluating potential assessment endpoints: unambiguous operational definition; accessibility to prediction and measurement; susceptibility; biological relevance; and societal relevance. As EPA (1998a) states, the "goal of the Superfund program is to maintain and ensure self-sustaining populations/communities." Therefore, in the context of the Hudson River, the appropriate assessment endpoint is the sustainability of communities or populations native to the Upper Hudson River.

EG-7

C. <u>The Measurement Endpoints Should Provide Information Relevant to the Assessment Endpoints and Should Go Beyond the Approaches Described in the SOW</u>

Measurement endpoints are measurable responses to a stressor that are related to the assessment endpoints (Suter 1990; 1993). Relationships between the measurement endpoints and assessment endpoints enable the risk assessor to use the results of field observations, bioassays, and literature reviews to decide whether a risk of harm has resulted or is likely to result from the stressors. While using a measurement endpoint to approximate or estimate the effects on an assessment endpoint introduces uncertainty into the assessment, that uncertainty will be minimized by selecting measurement endpoints that are closely related to the selected assessment endpoints and by developing multiple lines of evidence.

There are several different types of measurement endpoints, including benchmarks, literature-based TRVs, direct measures obtained through field surveys or toxicity tests, and biomarkers. To match a measurement approach with a given receptor and assessment endpoint, one must consider several aspects of the measurement endpoints, including: technical feasibility; strength of association with the assessment endpoint; specificity of the measured effect to the chemical, receptor and site of interest; and representativeness of the various measurement approaches.

Unfortunately, the measurement endpoints proposed in the SOW are focused on individual-level effects, such as survival, growth, and reproduction, and no method is suggested to translate these results to community or population-level responses. Indeed, the SOW acknowledges that, although the methods it intends to use characterize risk at the individual level, "if risks are present at the individual level, they may or may not be important at the population level." For example, the SOW identifies survival, growth and reproduction as assessment endpoints for fish and invertebrates. While these may appear to relate to macroinvertebrate communities and fish populations, they only reflect effects on individuals. Abundance, persistence, diversity, and trophic structure are population or community level endpoints. The

SOW does not include any method for linking changes in survival, growth or reproduction in individuals to changes in population or community status. The ERA must establish measurement endpoints aimed at ensuring the maintenance of sustainable populations and communities.

1. The Measurement Endpoints Described in the SOW Have Significant Limitations

The measurement endpoints proposed in the SOW are primarily screening-level endpoints in which PCB concentrations in water or sediments are compared to ambient water quality criteria ("AWQC"), sediment quality values ("SQVs"), or TRVs. These approaches can not constitute the primary measures of ecological risk in the baseline ERA for this Site.

Reliance on screening-level benchmark values, such as AWQCs and SQVs, in a baseline ERA is both inconsistent with EPA guidance (EPA 1997) and redundant with the analysis conducted in Phase 1. As the SOW notes, comparisons to AWQCs or SQVs merely indicate that there is a "potential for risk" to aquatic organisms, including invertebrates, fish, and terrestrial receptors, wetland community structure, and habitat value. The results do not provide a quantitative estimate of risk to communities and populations. If the benchmarks are exceeded, it simply indicates that further study is required. Moreover, EPA has already compared sediment and water chemistry to defined benchmarks, including AWQC and generic sediment quality guidelines, such as Long and Morgan (1991), in the Phase 1 investigation (EPA 1991). According to EPA (1997), "requiring cleanup based solely on [a screening-level risk assessment] would not be technically defensible."

The TQ technique set out in the SOW suffers from a number of similar problems. Most important, because the proposed TQ approach typically focuses on an individual organism, it is appropriate only as a first step in the ERA. If this procedure predicts adverse effects on the individual organism, further analysis is needed to assess effects at a higher level of organization. Such additional work may involve obtaining more site-specific exposure information, probabilistic TQ analyses, population-level modeling, or the collection of field data to attempt to verify the predictions.

There are several additional weaknesses with TRVs and the TQ method:

- Exceedance of a TRV (*i.e.*, TQ>1) does not indicate the magnitude of the potential impact or its biological significance.

- There are few published TRVs which correlate body burdens in the relevant species with the toxicological endpoints to be evaluated (survival, growth, and reproduction). Further, in the few cases where body burdens and toxic effects are reported both in a single study, the correlation between the two measurements is either not reported or is weak.

- PCB body burdens can be reported in a variety of ways, such as on a whole body basis, on a lipid-normalized basis, or on an organ-specific basis. When body burdens are reported in the scientific literature, they usually are reported as tissue measurements for target organs (*e.g.*, gonads, brain, liver), rather than for the entire body. Because bioaccumulation factors are rarely reported for those same target organs (bioaccumulation factors most often allow estimation of entire body burden), the ecological risk assessor is often left comparing "apples to oranges" when attempting to derive a TQ from a study which reports body burden rather than dose.

- TRVs are generally based upon No Observed Adverse Effects Levels ("NOAELs"). Appropriate use of TRVs based upon NOAELs depends on the ability of the particular study to demonstrate a dose-response relationship. This, in turn, depends on the dose intervals, which is a factor of the *a priori* characterization of toxicity by the investigator. The variance of the observed effects may inhibit the ability to distinguish a significant effect from a non-significant effect.

2. <u>EPA Must Use Objective Criteria To Select TRVs</u>

Because of their limitations, TRVs must be selected with care using objective criteria. The SOW does not contain any such criteria, proposing instead to select "appropriate" TRVs. While reliance on professional judgment is inevitable, there are more objective considerations that should guide the selection of TRVs:

- Relevance of the endpoint and species measured. The use of studies with the same measurement endpoints as those described in the SOW (*i.e.*, survival, growth and reproduction) and the same species minimizes the need to extrapolate results and will decrease the conservatism and the uncertainty of estimated risk.

- Similarity of test species to receptor species, in terms of sensitivity. The SOW states that TRVs will generally be derived from the most sensitive individual (based on species and age class). This adds unnecessary conservatism to the ERA. For example, much of the information on toxicity of PCBs to fish has been generated using, and reflects the unique sensitivity of, salmonid species. Because the proposed receptors are not salmonids, such studies can not be used to derive TRVs for this Site.

- Degree of chlorination of PCB mixture tested. The PCB mixture tested in the TRV study must be comparable to that found of the Hudson River or in the prey that are consumed by the receptor being evaluated.

- Study duration. Chronic studies provide more relevant information for risk assessment than acute studies. The appropriate duration of the TRV study should be determined by the toxicity test endpoint and the toxicokinetics of PCBs. For example, if the test endpoint is reproductive effects, the duration of the toxicity study should be the entire reproductive cycle of the tested species.

- Exposure pathway. Chronic studies with dietary exposures are the most appropriate mimics of exposure for a receptor species in the field. Acute laboratory studies with unnatural exposure scenarios, such as injection, cannot be used when exposure is modeled on the basis of ingested doses.

- Use of measured vs. estimated responses. Only TRVs related to actual, measured responses by the test organism should be used.

- Nature of dose-response relationship. Unbounded NOAELs should not be used as TRVs. An unbounded NOAEL (a NOAEL for a species for which the lowest observed adverse effect level has not been determined), provides little information on the toxicity of the tested material.

- Overall study quality. Demonstration of a relationship between a tested chemical and a toxicity endpoint depends on statistical significance and power. There should be an absence of confounding factors, such as inadequate nutrition in some test groups, and the control population must exhibit normal survival and health.

Only high quality, controlled studies that are consistent with other such studies can be used to provide measurement endpoints.

3. <u>The ERA Must Consider Additional Lines of Evidence</u>

Given the limitations of the TQ approach, the SOW correctly proposes to consider different lines of evidence (page 15). Several lines of evidence not listed in the SOW that should be considered include:

- Benthic invertebrate community biomass, abundance, and diversity compared with a range of these parameters measured in comparable aquatic habitats in the region.
- Fish species abundance, diversity and richness compared with a range of these parameters measured in comparable aquatic habitats in the region.
- Data on the abundance and reproduction of Hudson River birds, including tree swallows collected by the USFWS and nesting bald eagles on the Hudson River.
- Data on the abundance and reproduction of Hudson River mammals.

Each line of evidence is characterized by its own individual strengths and weaknesses; the purpose of using more than one is to reduce uncertainty associated with the overall assessment.

In order to reconcile the different lines of evidence, the Agency must develop at the outset an objective method for identifying and weighing their relative strengths. This method should define specific attributes that will be used to judge the quality of each measurement endpoint. Examples of such attributes (from Menzie *et al.*, 1996) include: strength of association between the measurement endpoint and assessment endpoint; site-specificity; stressor-specificity; quality of data and overall study; availability of an objective measure for assessing environmental harm; sensitivity of the measurement endpoint for detecting changes; spatial representativeness; temporal representativeness; quantitativeness; correlation of stressor to response; and use of a standard method.

In short, a more sophisticated ERA than the approach set out in the SOW is required for this Site. Such an assessment should not rely primarily upon comparisons with benchmarks or TQs but should include site-specific informational and dose/response or concentration/response relationships. Risk assessments based solely on chemistry, body burdens, or model-derived doses are prone to excessive conservatism because the only readily identifiable benchmarks are conservative ones. Consequently, modeled risk estimates must be verified by field data.

IV. Problem Formulation (Section 2)

We discussed our concerns with the assessment and measurement endpoints in the previous section. We identify below some additional problems with the SOW's problem formulation discussion.

EG-8

A. Site Characterization (Section 2.1)

1. The SOW Does Not Acknowledge Significant and Relevant Data Sets

An important element of problem formulation is a detailed review and integration of all available and relevant information concerning the Site. This is particularly important for the type of ERA proposed in the SOW. Where the primary analytical method is the use of exposure and bioaccumulation models and highly simplified risk models, compiling the available data, whether limited or substantial, provides an important means for constraining model results. At this Site, although the Agency has not collected much data for use in the ERA, there is a substantial body of data collected by others, including GE, concerning the general ecological conditions in the Hudson River. The Site Characterization section of the SOW fails to present such a discussion. The Agency should use these data to validate its desktop analyses. We identify and discuss some of the data sources below.

a. Benthic Macroinvertebrates/Phytophilous Macroinvertebrates

EPA's 1993 study of benthic macroinvertebrates (reported as part of its 1995 Database Report) shows that indices of macroinvertebrate community structure are not correlated with PCB concentrations in sediments. NYSDEC's most recent report on macroinvertebrate similarly concludes that there have been no community-level impacts in the Upper Hudson due to PCBs: "High levels of PCBs have been found in the macroinvertebrate tissues downstream of Fort

Edward since analysis began in 1976. . . . No impact at the community level has been observed at any site that can be attributed to high PCB levels" (NYSDEC 1993).

More recent macroinvertebrate community data are available for the Thompson Island Pool ("TIP") and Stillwater regions of the Hudson River. GE sponsored surveys of benthic and phytophilous macroinvertebrates in these areas in September 1997. The mean total invertebrate abundances ranged from approximately 8,000 invertebrates/m^2 to 35,000 invertebrates/m^2, with a maximum of 87,000 invertebrates/m^2 at a vegetated station in the southern end of the TIP (Exponent 1998). Total taxa richness of benthic macroinvertebrates ranged from 33 to 58 invertebrate taxa depending on whether the habitat was vegetated or not and which area was sampled. These results suggest that PCBs have not impaired benthic and phytophilous macroinvertebrate communities in the TIP where concentrations of PCBs in sediment are likely to be highest in the River.

b. Fish

There is a vast database of fish abundance in the Lower Hudson River that suggests that PCBs have not adversely affected relevant populations. While these data are not directly applicable to the upper Hudson because of differences in species and the relatively lower levels of PCBs in the lower river, they do support a conclusion that PCB levels comparable to past and present levels in the lower Hudson are unlikely to affect fish abundance in the upper river.[1] Available information includes:

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[1] Although we explain in the next section that the ERA should not address risks from upper river PCBs to lower river biota, these data provide useful and relevant information for the upper river biota.

- Data showing that PCBs have not impacted the abundance of shortnose sturgeon (Kynard 1997). Indeed, the most recent data demonstrate that the Hudson River shortnose sturgeon population is booming (NMFS 1997).

- Numerous studies have showed that the decline in the coastal striped bass population was not the result of Hudson River PCBs, but rather overfishing and water quality conditions in the Chesapeake Bay (NMFS and USFWS 1985; ASMFC 1990) ("given the very healthy status of the Hudson River stock, which is well documented to have relatively high tissue concentrations of PCBs, it would appear that such levels . . . may not pose a threat to striped bass from a population biology perspective"). Far from declining, the spawning stock of striped bass in the Hudson River has shown remarkable growth.

- NYSDEC and the utilities collect data each year on fish abundance in the lower river which reflect generally healthy fish populations unaffected by PCBs.

c. <u>Birds</u>

The ERA does not need to conduct an additional analysis of tree swallows. The data presented in Secord and McCarty (1997) show that even high body burdens of PCBs have not affected the reproductive success of tree swallows. Despite some significant deficiencies in the study design (*e.g.*, lack of suitable reference area), the data from this study support the following conclusions:

- Swallows which are maximally exposed to PCBs in the Hudson River have normal numbers of young, and these young grow normally.

- Evaluation of reproductive parameters relative to tissue residue data shows that tree swallows did not respond to PCBs in a dose-dependent manner. Hatchability and reproductive success were highest, and nest abandonment lowest, at sites with the highest PCB concentrations in eggs and hatchlings.

- Reproductive success, nest abandonment, hatch rates, nest quality and plumage development observed in the experimental tree swallow populations nesting adjacent to the Hudson River were within the range of reference or unexposed populations.

This information shows that PCBs in the Hudson do not affect reproduction in, and thus do not pose population-level risks to, tree swallows.

EPA should not extrapolate Secord's and McCarty's tree swallow data to bird species which have different diets or experience different exposures to PCBs. These species may also be affected by other stressors which have a more demonstrable impact on population dynamics (*e.g.*, lost habitat, human disturbances, other chemicals).

Other relevant information concerning birds that should be considered in the ERA includes:

- Successful breeding by bald eagles in Hudson River habitats appears to be increasing. There were two nesting pairs on the Hudson River in 1996. One pair did not lay eggs; the other pair laid eggs which did not hatch. The cold, wet weather of that year is suspected to have caused the failure of these eagles to produce young (NYSDEC 1997). In 1997, two nests were also present. One juvenile fledged from a nest in Greene County; the other nest was unsuccessful, as it was in 1996. In 1998, three pairs of bald eagles attempted to breed. All three pairs laid eggs. One attempt resulted in three fledged young, another pair produced one fledgling and one unhatched egg, and the third nest had one unhatched egg (Nye 1998).

- Data showing that bald eagles use the Hudson River during winter migration and are breeding successfully in Hudson River habitats. The mid-winter bald eagle survey shows an increase from 29 bald eagles using the Hudson River in the winter of 1979 - 1980 to 103 eagles in the winter of 1995 – 1996.

- Data showing the increasing use of Hudson River habitats by peregrine falcons. Peregrine falcons have established nests on bridges over the Lower Hudson River. While these nests are producing live young, falcons have been injured or killed in accidents with automobiles and from falling off nest sites before they are capable of full flight (Nye 1998).

- Data showing that mallards are "demonstrably secure" throughout the New York Bight watershed and are "widespread, abundant and secure in the state of New York" USFWS (1998). The NYSDEC (1997) reports that, on the basis of breeding surveys, the mallard population using the Hudson River estuary is "stable to increasing." Mid-winter counts of waterfowl show generally increasing numbers of mallards and other species with a peak in the 1995 survey of more than 16,000 birds. (NYSDEC 1997).

2. The Site Does Not Extend Below the Federal Dam at Troy **EG-9**

Another error in the site characterization is its definition of the Site as the 200-miles of river from Hudson Falls to the Battery in New York Harbor. As GE has previously informed the Agency,[2] the administrative record supporting the addition of the Site to the National Priorities List ("NPL") limits the Site to the 40 miles above the Federal Dam at Troy. EPA's post-rulemaking statements to the contrary cannot change this limitation. See U.S. v. Asarco, Inc., No. CV96-0122-N-EIL (D. Idaho Sep. 30, 1998) (post-rulemaking statements cannot change scope and size of site from the description provided in the NPL record). GE's disagreement with EPA on the scope of the Site is particularly important in the context of the ERA, which is purporting to assess risks from PCBs to biota and habitats in the Lower River. EPA's Feasibility Study Scope of Work makes it clear that EPA is limiting its analysis to potential remedial actions in the upper river. Assessing ecological risks in the lower river, however, suggests that the Agency may in fact be attempting to justify a remedial action on the basis of benefits to the lower river.

As we have previously explained, the limitation of the Site to the upper river means that the Agency cannot seek to justify any remedial action in the upper river on the basis of benefits to the lower river. If the Agency attempts to do so, it would be obligated to investigate and evaluate remedial alternatives, such as source control, in the lower river; consider the additional sources of PCBs (and other contaminants and stressors) to fish and other biota in the

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[2] See Nov. 6, 1997, letter from Angus Macbeth to Richard Caspe; May 5, 1998, letter from Angus Macbeth to Douglas Fischer.

lower Hudson; and identify the much wider group of parties who rightfully should be classified as PRPs. The presence of other dischargers of PCBs in the lower river is well known to EPA; the Agency has conducted recent studies of PCB discharges into New York Harbor, including sampling outfalls. The Agency made the importance of other contaminants plain in its 1984 ROD, concluding "that detectable levels of dioxin, dibenzofurans, mercury and chlordane (from known and unknown sources) have also been identified in Hudson River fish, and that even if PCBs decrease to an acceptable level, the fishing bans would continue on the basis of these other types of contaminants."

EPA cannot have it both ways. The Agency cannot describe the Site as encompassing the 150 miles from Troy to the Battery and then address only one contaminant and one or two PRPs outside that 150 miles as the sole subjects for remedial consideration. The scope of EPA's Superfund activity at the Site is circumscribed by the characterization and definition of the site which EPA promulgated in its NPL rulemaking years ago.

B. Contaminants of Concern (Section 2.2) **EG-10**

The SOW proposes to limit the ERA's consideration to PCBs. There are other chemical and physical stressors in and along the Hudson River, which also must be considered. For example, sediment concentrations of cadmium, copper, lead, mercury and zinc measured in the 1993 EPA survey in the Upper Hudson exceed NYSDEC sediment quality values. Fish sampling in the upper Hudson reveals that fish there have DDE and DDT concentrations that have been shown to impair bald eagle reproduction elsewhere (Anthony et al. 1993). Similarly, it is likely that habitat loss and alteration, modification to landscape for agriculture and urbanization, and recreational hunting and trapping have impacted wildlife populations and communities in the Hudson River watershed.

The presence of other contaminants and stressors is important. EPA (1998b) provides that ERAs should assess "an array of stressors that may be influencing the assessment endpoints and describing the diversity of potential effects." In the limited instances where EPA intends to consider site-specific data, such as benthic macroinvertebrates in the upper Hudson, other contaminants and stressors may confound observations and/or have additive or antagonistic interactions with PCBs. Even where the SOW proposes to rely primarily on exposure modeling for its assessment, other stressors are relevant. Although exposure modeling avoids issues associated with confounding stressors, it still is necessary and appropriate to place the estimated risks associated with PCBs against the backdrop of other stressors. Unless other stressors are considered, the remedial decision-maker will be unable to determine whether a remedial action directed at PCBs will have any beneficial effect. The ERA should interpret any stresses to ecological receptors that may be due to PCBs in the context of all anthropogenic stresses to the Hudson River. In essence, EPA must determine what the conditions in the Hudson would be but for PCBs.

C. Site Conceptual Model (Section 2.4) **EG-11**

The site conceptual model has several problems. First, it identifies exposure pathways, but neglects environmental fate processes such as burial and dechlorination that act to reduce exposure over time. Second, it fails to include other stresses on the Hudson River ecosystem, including other chemicals, conventional water-quality degradation and other human impacts. Third, the conceptual model diagram (Figure 5) ignores aquatic vegetation, which is an important component of the aquatic food web and which supports invertebrates that are important for forage fish. This is important because the potential impacts of remediation activities on aquatic vegetation and therefore on the ecosystem as a whole must be considered.

D. Receptors (Section 2.6) **EG-12**

EPA should take into account the following points on the receptors identified in the SOW:

- The feeding habits and habitat use of smallmouth bass, which are listed as a receptor in Table 1, are similar to those of largemouth bass. Analysis of smallmouth bass as a receptor is therefore redundant and unnecessary.

- Some of the threatened and endangered species listed do not use the habitats of the Hudson River. For example, the whorled pogonia is an orchid which grows in highly acidic, peat-like soils characteristic of bogs, not riparian wetlands; northern harrier is not closely linked to aquatic habitats but forages for mammals over meadows and older wetlands. Therefore, these species should not be considered in the ERA.

- Striped bass and shortnose sturgeon do not occur in the Upper Hudson River and are therefore not appropriate as receptors for this ERA.

V. Exposure Assessment (Section 3)

EG-13

A. Exposure Pathways (Section 3.1)

The SOW contains several errors and inconsistencies in its description of exposure pathways. In many instances, the SOW does not consider all the available site-specific and species-specific information that can reduce uncertainty and improve exposure estimates.

1. Fish

The SOW is inconsistent and incorrect in its characterization of fish diets. Site-specific, empirical information on fish diets is available (*e.g.*, Exponent 1998) and should be used as the basis for determining the relative proportions of different prey in the diets of fish.

2. Birds

As noted above, there is no need to conduct further assessments of tree swallows because Secord and McCarty (1997) shows that PCBs in the Hudson are not affecting tree swallow reproduction. In any event, the SOW incorrectly states that worms are consumed by tree swallows. Most studies of tree swallow diets report that insects make up the majority of the tree swallow diet (*e.g.*, McCarty 1995) and that tree swallows also rely on plant materials, particularly during winter (Robinson 1992). Secord and McCarty (1997) also contains information on the concentrations of PCBs in tree swallows for 1994, and the authors have similar data for 1995 and 1998. EPA should use this site-specific data.

Empirical, site specific information on the diets of bald eagles is also available. Peter Nye of NYSDEC has found remains of grebes, eels, pickerel, bullhead, herring and carp in eagle nests. Information on the PCB concentrations in some of these prey, including bullhead and eels, are available (Secor 1998). Moreover, NYSDEC has collected samples of the blood of juvenile eagles, eagle eggs, and the remains of prey in nests from the eagles breeding on the Hudson River. Samples are being stored for analysis of organochlorines. EPA should work with NYSDEC to determine actual PCB concentrations in the samples of bird tissue and their prey.

3. Mammals

The SOW characterizes the diet of raccoons and mink incorrectly. Both species consume a variety of foods. The diet of mink includes mammals, birds, and amphibians, and the raccoon diet includes terrestrial insects and plant material. EPA should use the references cited in the EPA Wildlife Exposure Factors Handbook (EPA 1993) to estimate the relative importance of each prey type in the diets of mammalian receptors and develop exposure models accordingly. EPA must also consider the specific use of Hudson River habitats by these receptors and weight exposures accordingly. For example, mink or raccoons may favor small streams and wetlands for foraging over the main stem Hudson River.

B. Quantification of PCB Fate and Transport (Section 3.2)

1. The ERA Should Rely Exclusively on Time-Variable, Mechanistic Models Such as GE's

The SOW describes EPA's plan to use the fate, transport and bioaccumulation models and geochemical analyses presented in the DEIR/PMCR in the ERA. These models are critical components of the reassessment, especially with regard to risk prediction under alternative remedial scenarios. GE has previously submitted comments on these documents, identifying a number of serious problems (GE 1996, 1997). The peer review group convened to review the PMCR echoed many of GE's concerns. EPA must address the recommendations of GE and the peer review group before using the models in the ERA.

GE has developed an Upper Hudson River sediment transport model that is mechanistic and uses data-based formulations to describe resuspension and deposition processes realistically. This model has been rigorously calibrated and validated and should be considered for use in the fate and transport modeling.

Appendix A to the SOW describes how the Agency intends to use the different bioaccumulation models for the Site: the Bivariate Statistical Model ("BSM," used to compute average PCB levels), the Probabilistic Food Chain Model ("PFCM," used to compute average levels and variability), the Gobas Model, and the time-variable, mechanistic bioaccumulation model developed by QEA for GE. As GE has explained previously (and as the peer review panel confirmed), EPA should not rely on the two steady-state statistical models in the reassessment because they do not provide an appropriate basis for predicting average PCB levels in the Upper Hudson River.

While it generally is good scientific practice to check for consistency among different approaches to a given problem, this is true only insofar as the approaches are developed properly and (at least to some degree) independently and add useful information. As described in GE's original comments concerning the PMCR, there are serious limitations to the BSM and PFCM approaches that limit their utility:

- The Hudson River has exhibited extreme variation in exposure levels as well as lipid content of fish. PCB levels in the food web do not respond immediately to changes in these parameters, so PCB levels measured in fish at any point in time may be in the process of responding to changes in exposure levels. That is, the steady state assumption in the BSM and PFCM is violated.

- The BSM has no predictive power within the Thompson Island Pool, based on the observation that there is no relationship between observed and computed largemouth bass Aroclor 1254 levels (Figure 9-12 of the PMCR). The pattern of observed vs. BSM predicted values differs among reaches. Without further study into the mechanisms underlying bioaccumulation, it is not clear why the bioaccumulation model should differ in its predictions among reaches. Finally, the BSM overpredicts at low concentrations (Figure 9-12). PCB levels are now declining in the Hudson River. Thus, it is anticipated that model predictions will overestimate the PCB levels in biota in the future.

- The PFCM confuses uncertainty with variability. For example, the computed distribution of biota-sediment bioaccumulation factors ("BSAFs") should provide a representation of the distribution of invertebrate PCB levels as seen by the fish. The BSAF distribution used in the PFCM was determined directly from the data, even though the variance in the data is due in large part not to the true variability in the sediment/invertebrate relationship, but to uncertainty. This uncertainty is a result of the sediment and invertebrate samples not being collected at exactly the same location, because the species composition of the samples may not be the same as the species composition of the diet of the forage fish, and because of analytic uncertainty. Because of this confusion, the resulting distribution of BSAF values has no physical meaning.

- The PFCM requires the answer to solve the problem. The predator/forage fish bioaccumulation factor ("PFBAF") was determined using the observed distribution of predator PCB levels. However, the whole purpose of the model is to compute the distribution of predator PCB levels. Similarly, the parameters that determine the spread, or variance, of the computed PCB levels are constants that are validated by comparison with the distribution of the data. The computed spread and shape of each distribution will not change in the future, even as average sediment and water column PCB levels decline. The model provides no additional information beyond what the data already provide.

In contrast, a mechanistic model avoids these problems and incorporates *all* of the information that is in the steady state models (that is, measured PCB levels, dietary information), *as well as* ancillary information (bioenergetics, toxicokinetics, and time-variable processes) in computing average PCB levels. Therefore, EPA should use a time-variable mechanistic model to compute average levels, such as the one developed by QEA for GE. The distributions of PCB levels should be estimated directly from the data.

2. EPA Should Not Hold Initial Concentrations Steady Over an Extended Period

The SOW states that the exposure model parameters will be assumed to remain constant for extended periods of time (*e.g.*, 5-10 years). No justification for this approach is provided, and given the observed declines in PCB concentrations in sediment, water and biota, this assumption runs counter to the available evidence. Initial concentrations should not be assumed to hold steady over five-to ten-year increments. Time-variable fate, transport and bioaccumulation models, like GE's, should be used to generate this information.

C. Observed Exposure Concentrations (Section 3.3) **EG-15**

The SOW proposes to characterize exposures and body burdens based on 95 percent upper confidence limits on averages, an approach that will result in a conservative estimate of actual Site conditions. Although this approach might be appropriate for a screening-level assessment, the ERA is a baseline risk assessment. The ERA should use mean exposure levels with appropriate quantification of uncertainty.

The traditional measure of uncertainty (mean +/- $t_{0.05,n-1}$ × standard error) is not the most appropriate for all data sets. The best measure depends on the shape of the distribution of the data (*e.g.*, normal, lognormal). The ERA should consider other techniques including Land's method for lognormal populations and nonparametric bootstrap methods.

1. <u>Benthic Invertebrates</u>

EPA has collected data on benthic invertebrate communities and PCB body burdens at a number of stations in the Upper Hudson River. According to the SOW, the ERA will use these data to calculate site-specific biota-sediment accumulation factors for use in food-chain modeling. BSAF values should be used along with sediment PCB data to estimate invertebrate PCB levels. Because of the potentially large uncertainties associated with field measurements of benthic invertebrate BSAFs, the ERA should compare the site-specific values with other field and lab measurements for consistency.

2. <u>Fish</u>

It is not clear whether or to what extent the ERA will use the significant data on PCB concentrations in fish collected by NYSDEC, GE, and others. To the extent they are available and valid, the ERA should use all the site-specific data on fish body burdens to calibrate and validate the models.

3. <u>Birds</u>

The approach to be used to assess exposures to insectivorous birds is not clearly described. According to the SOW, data collected by the USFWS will be used to evaluate tree swallow body burdens "for those locations at which data are available." What approach will the ERA use for other locations? If the ERA uses BSAFs, what specific diet assumptions will the

Agency employ? Employing unvalidated assumptions will create substantial uncertainty in the ERA.

D. Modeled Exposure Concentrations (Section 3.4) **EG-16**

Given the failure to collect data to support its ERA, the Agency is left to rely primarily on modeling approaches to determine PCB concentrations in biota. Without sufficient data for validation and calibration, modeling compounds uncertainty and often leads to unnecessary conservatism. This is particularly true for the modeling proposed to support the ERA. If models are used, the Agency must use the available data to develop and then calibrate and validate them.

First, in the case of the Hudson River, outside of the substantial database on PCB concentrations in fish, there are few data against which to calibrate and validate the proposed models. Where data could readily be developed, as for PCB concentrations in the eggs of eagles, EPA has chosen to ignore the relevant information. Without validation, the level of certainty in the results is unknown.

Second, the SOW provides a general model to describe ingested dose,[3] but does not explain how the ERA will translate such doses to body burdens. For example, the SOW refers to assimilation and metabolic efficiency terms, stating that dose (meaning exposure) will be expressed as a body residue or as an ingested dose rate, depending on the TRV. The SOW does not provide a model for determining bird and mammal bioaccumulation, examples of assimilation

[3] The ERA presents two ingestion exposure algorithms for birds and mammals: one for water and one for food. The units for the ingestion rate term (IR_i in the equation on p. 33) should be kg wet weight/day. The units for concentration of PCBs in food items (C_i) should specify that concentration is expressed on a wet weight basis.

and metabolic efficiency terms, or data to support such terms. Similarly, the ERA states that biomagnification factors ("BMFs") may be used to predict concentrations of PCBs in eggs of piscivorous birds. With the exception of bald eagles, there are limited data to support the development of BMFs for piscivorous birds. This is particularly inappropriate because, for most of the bird and mammal receptors, the toxicity database provides TRVs in terms of ingested dose, not body burden. Compounding uncertainty by extrapolation of a modeled ingestion rate to a body burden, only to compare body burdens to the limited TRVs available for this endpoint, cannot be justified, and will lessen the value of the risk assessment for decision-makers.

Turning to the specific inputs to the models, it is important to understand and assess the relative proportions of different prey items in the diet in order to determine the proper dose. For example, Salyer and Langler (1949) and Davis (1980) report that more than 75 percent of the kingfisher's diet is comprised of cyprinid species, with crayfish comprising another thirteen percent of the diet. Additional foods, such as lizards, frogs, small snakes, salamanders, insects, small mammals, young birds and berries, have been reported in the literature. Landum et al. (1993) and Kaufman (1996). The ingestion models must also incorporate the correct size of consumed prey species. Inclusion of larger prey, which may have higher PCB body burdens, would overestimate exposure through the diet. This type of information and site-specific PCBs in prey are needed to construct a food-web model that is truly representative for the Hudson River.

Similarly, the SOW states that PCB concentrations in benthic invertebrates will be averaged using all samples to obtain exposure point concentrations ("EPCs") for fish. It is more appropriate to estimate average BSAFs and then multiply this result by average surface sediment PCB concentrations because surface sediment PCB levels vary considerably over long and short spatial scales. Therefore, PCB levels measured in a few locations are not necessarily representative of pool-wide surface sediment concentrations.

EG-17

VI. Effects Assessment (Section 4)

The SOW proposes two different approaches for estimating the toxicity of PCBs: (1) using total PCBs and Aroclor toxicities and (2) using congener-specific toxicities and toxic equivalency factors ("TEF"). There are many factors which favor the use of total PCBs or Aroclor-based concentrations at this Site. First, most of the data for the Hudson River are presented in total or Aroclor-based concentrations. The available capillary column data do not quantify many of the congeners relevant to a TEF analysis. Using Aroclor or total PCB-based effects data are preferable to estimating congener compositions of aged Aroclor mixtures (with attendant problems of selective depletion and enrichment) and comparing the resulting toxic equivalent ("TEQ") values to TEQ-based effects data.

Second, there are significant problems in using the TEF approach. While the TEF approach has provided significantly improved understanding of the relative toxicities of different PCB congeners and of the aggregate toxicity of PCB mixtures, its value for ecological risk assessment is limited because the endpoints of TEF studies are often cellular or biochemical indicators. Benchmarks derived from these studies are even more conservative than screening benchmarks derived from studies in which the endpoint is survival, growth, or reproduction.

As a result, GE recommends limiting the analysis to total or Aroclor-based concentrations.

VII. Risk Characterization (Section 5)

As we have noted previously, use of the TQ approach as the only line of evidence for certain receptors as described in the SOW is insufficient for a baseline ERA at a site the size and scope of the Hudson River PCBs Superfund Site. One significant limitation of the TQ method is that it only provides information about individual level effects. To be useful, these results must be translated to effects at the community or population level.

The SOW presents a model which it claims achieves such a translation. Although the model purports to be based on Suter's (1993) approach for characterizing population-level risks, it, in fact, misrepresents Suter's work. As discussed in Chapter 8 of Suter (1993), population-level risk assessments require, at a minimum, integration of toxicological information with information on the survival rates and reproductive rates of the exposed population. The model described in the SOW merely characterizes the distribution of exposures within a population. No attempt is made to characterize actual changes in rates of survival, growth, or reproduction. As long as the exposure distribution is being compared to a TRV, population-level risk is not being addressed.

Moreover, the model will provide only the value of a normal cumulative distribution function (the probability for a given value from a normal cumulative distribution) for the standardized mean of the linear combination of two random variables. This is not the same as estimating the probability that any given individual from one distribution is greater than any one individual from the other distribution, as stated in the text. The model estimates the probability that the average body burden is greater than the average TRV. This formula does not estimate the probability that the tissue chemical concentration of any given individual fish from a population will exceed a TRV.

Chapter 8 of Suter (1993) discusses a range of methods for extrapolating individual-level effects to population-level effects. The simplest approach is to (1) estimate dose or exposure-response relationships for survival (by life stage) and reproduction, (2) calculate the effects of exposure on the rates of survival and reproduction of the exposed species, and then (3) translate changes in survival and reproduction into changes in the intrinsic rate of increase (*r*) of the exposed population. This approach, however, is more suitable for comparative risk assessments than for site-specific assessments because it does not consider the influence of density-dependent processes that would be expected to partially offset PCB-related reductions in survival or reproduction. Age-structured population models that incorporate density-dependence are described in Chapter 8 of Suter (1998) and in Barnthouse et al. (1990). The time available to EPA since the Preliminary Assessment would have been sufficient to collect site-specific data for Hudson River fish populations for input into these types of models. Models developed using data collected from comparable populations in other ecosystems could still be used, although the uncertainty would be higher. Regardless, the results would be more meaningful than the TQ approach proposed by EPA because they would address the actual magnitude of ecological responses to PCB exposures, not just the absence or potential presence of a response.

VIII. Uncertainty (Section 6) EG-19

The SOW's description of uncertainty includes (1) general categories of uncertainty as described in EPA guidance and (2) methods for Monte Carlo analysis of exposure models. It fails to mention the greatest single source of uncertainty in the assessment, which is the virtual absence of site-specific ecological data. The principal consequence of this absence is that the assessment might be able to suggest risk to individuals, but it will be unable to shed light on the magnitude of actual risks to communities or populations related to past, present or future PCB exposures. In fact, the results of the proposed ERA will be so uncertain that they will be of little use in the remedial analysis.

EG-20

While it is true that sensitivity analysis is one approach to assessing uncertainty, the example provided in the first paragraph of page 53 is not a true sensitivity analysis. Rather, running the avian and mammalian models using the upper bound on the ingestion rate of a prey item represents a Maximum Exposed Individual (MEI) evaluation. To conduct a sensitivity analysis, the model would have to be repeatedly executed, each time varying one parameter by the *same degree* (*e.g.*, +/- 10%) while holding all other parameters constant. Once all parameters have been varied, the effects on the model output can be compared in order to draw conclusions regarding the relative sensitivity of the model to the different parameters and the relative uncertainty associated with each parameter.

IX. Conclusion

The ERA proposed in the SOW has a number of significant deficiencies. The basic approach is to conduct screening-type or TQ analyses that are subject to substantial uncertainty. The result will be a highly uncertain estimate of risks to individuals; no information will be provided to address the critical assessment endpoint of sustainability of biological communities or populations. In these circumstances, EPA can not place substantial reliance on the ERA in its remedial decision-making.

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