6/1/2003

CHARGE FOR THE HUMAN HEALTH RISK ASSESSMENT PEER REVIEW FOR THE REST OF THE HOUSATONIC RIVER

Background

In October 2000, the U.S. District Court approved and entered a Consent Decree agreed to by the General Electric Company (GE), the U.S. Department of Justice, the U.S. Environmental Protection Agency (EPA), the Commonwealth of Massachusetts, the State of Connecticut, the U.S. Department of the Interior, the National Oceanic and Atmospheric Administration, the City of Pittsfield, and the Pittsfield Economic Development Authority for the remediation and restoration of the GE facility in Pittsfield, MA, and other properties and areas affected by releases of polychlorinated biphenyls (PCBs) and other contaminants of potential concern (COPCs) from that facility, including the Housatonic River.

Under the Consent Decree, EPA is to conduct a Human Health Risk Assessment (HHRA) for the portion of the Housatonic River and its floodplain beginning at the confluence of the East and West Branches of the river (approximately two miles downstream of GE's facility in Pittsfield) and continuing downstream, excluding those portions of current residential properties in the floodplain that are or could be used as lawns (which are subject to separate remediation requirements under the Consent Decree). That stretch of the river and floodplain is known in the Consent Decree as the Rest of River. EPA has completed the HHRA for the Rest of River. The Consent Decree provides that the HHRA will be subject to Peer Review by a Peer Review Panel. This document provides the charge for the Peer Review of the HHRA for the Rest of River.

Objective and Scope of HHRA

The objective of the HHRA is to assess the current and future potential cancer risks and non-cancer hazards to human health in the absence of remediation or institutional controls from exposure to PCBs and other hazardous constituents from the GE facility that are found in the sediment, river bank and floodplain soil (excluding the actual and potential lawn portions of current residential properties), and biota in the Rest of River area. The reasonable maximum exposure (RME) and central tendency exposure (CTE) were evaluated for each scenario. The

RME is the high-end exposure (90^{th} to 99.9^{th} percentile) and the CTE is an estimate of the average exposure.

Due to the large area of concern and the number of properties in the Rest of River, the HHRA was performed in two phases. Phase 1 was a risk-based screening evaluation of floodplain and riverbank soils and river sediments based on potential human exposure to PCBs from direct contact under current land use conditions. In Phase 1, contaminant concentrations in the soil of floodplain properties (or areas) and in the riverbank soil and sediment of various segments of the river were compared to screening risk-based concentrations (SRBCs) for contaminants of potential concern (COPCs) to determine which areas required further data collection and evaluation, and those which could be eliminated from further consideration. These comparisons were made using the maximum concentration detected at each property (or area) or the 95% upper confidence limit on the mean (95% UCL) for that property (or area), whichever was lower.

Phase 2 consisted of a comprehensive baseline risk assessment, including evaluation of exposures to COPCs from:

- direct-contact exposure to floodplain and river bank soil and sediment in those properties and areas that were not screened out in Phase 1,
- consumption of fish and waterfowl, and
- consumption of agricultural products, and other food items in the Rest of River.

Summary of Charge to Peer Review Panel

The Consent Decree specifies that the Peer Review Panel is to review EPA's HHRA to evaluate: "(1) consistency with EPA policy and guidance; (2) the exposure scenarios and parameters used; (3) the toxicity assessment; (4) the risk calculations; and (5) the report conclusions." In addition, Appendix J to the Consent Decree specifies that an opportunity will be provided for GE and other members of the public to submit written comments and to make oral presentations to the Peer Review Panel on issues relevant to the charge for the Panel members' consideration.

Questions To Be Addressed by Peer Review Panel

In evaluating the general items specified in the Consent Decree listed above, the Peer Review Panel members shall give specific consideration to the questions listed below. In considering these questions, the Panel members shall evaluate the following (hereinafter the "evaluation criteria"): the objectivity, consistency, and reasonableness of the procedures and inputs used by EPA both in the application of existing EPA guidelines, guidance and policy (see Attachment A for list of relevant EPA guidance and policy documents), or in the absence of Agency guidance, guidelines, or policy. If significant errors are observed in the application of the appropriate methodologies, the Panel members shall provide specific comments, describing the error(s) and suggested improvements. The suggested improvements must be specific, clear, and consistent with existing EPA methodologies and guidelines.

It is not expected or intended that the Peer Review Panel members will reach consensus on all issues. For those issues for which consensus is not reached, the range of opinions of the reviewers should be stated and summarized. The Panel members should identify any major data or methodological gaps that may impact the use of this risk assessment for decision-making. However, it must be realized that, while additional long-term research may be desirable to address some questions, it is outside the purview of both the Risk Assessment and this Peer Review.

In the questions listed below, the term EPA guidance is used in the context of representing any EPA policies, guidelines, methodologies, directives or other Agency procedures.

In evaluating the general items specified in the Consent Decree listed above, the Peer Review Panel members shall give specific consideration to the following questions:

A. Phase I – Direct Contact Exposure Screening

Were the procedures used in Phase 1 of the HHRA to screen out properties and areas from further evaluation as well as the application of those procedures appropriate under the evaluation criteria? In addressing this question, consider:

- the general procedures used;
- the SRBCs used for the COPCs; and

- the land use and exposure categories considered and the classification of particular parcels and areas into those categories.

B. Phase 2 – Direct Contact Exposure Assessment

1. Were the following aspects of the direct-contact exposure assessment appropriate under the evaluation criteria?

   - The exposure scenarios which were evaluated.
   - The exposed populations which were selected for each scenario.
   - The exposure areas identified based upon potential current and future use(s).
   - The routes of exposure for each scenario.

   Consider the following when addressing this question:

   – Current and reasonably anticipated future land uses, physical conditions, and accessibility;

   – Locations, concentrations, and distribution of COPCs in the sediment, bank soil, and floodplain soil; and

   – Ages of the selected exposed populations.

2. Have the most important exposure pathways been identified and evaluated?

3. Were the approaches and methods used to calculate and apply exposure point concentrations (EPCs) for the direct-contact exposure assessment appropriate under the evaluation criteria?

4. Were the values used to represent the exposure and absorption parameters used in the direct-contact exposure assessment appropriate under the evaluation criteria, specifically:

   - Exposure duration for each scenario;
   - Exposure frequency and area use factors for each scenario and exposure area;
   - Soil ingestion rates;
   - Exposure assumptions affecting dermal contact (e.g., soil adherence rates, skin surface areas assumed to contact soil or sediment); and

- Oral and dermal absorption factors.

In addressing this question, please consider the same factors listed in Question 1 (as relevant).

5. Is the approach used to estimate a Reasonable Maximum Exposure (RME) and a Central Tendency Exposure (CTE) for the direct-contact exposure assessment appropriate under the evaluation criteria?

6. Were the uncertainties adequately characterized and expressed?

7. Overall, was the approach used to estimate risk from direct contact reasonable for evaluating the baseline risk?

C. Phase 2 - Fish and Waterfowl Exposure Assessment

1. Were the approaches and methods used to calculate EPCs for the fish and waterfowl consumption scenarios appropriate under the evaluation criteria?

2. Were the exposure assumptions and parameters used in both the assessments of fish and waterfowl consumption appropriate under the evaluation criteria?

3. Was the basis for the selection of point estimate RME and CTE exposure parameter values appropriate under the evaluation criteria, and were they clearly described and referenced?

4. Were the probabilistic approaches used clearly described, and were they appropriate under the evaluation criteria?

5. Were the distributions used in the probabilistic assessments clearly described, and were they appropriate under the evaluation criteria?

6. Were the uncertainties in the data and models adequately characterized and expressed?

7. Were variability and uncertainty in the risk estimates adequately characterized and expressed?

8. Overall, was the approach used to assess risk from consumption of fish and waterfowl and other wild food items reasonable for evaluating the baseline risk?

D. Phase II – Agricultural Exposures

1. Were the exposure scenarios evaluated appropriate and reasonable for current and reasonably foreseeable future use of the floodplain?

2. Were the approaches used to estimate transfer of COPCs from soil to plants appropriate under the evaluation criteria?

3. Were the approaches used to estimate the bioaccumulation of COPCs in animal tissue appropriate under the evaluation criteria?

4. Were the exposure assumptions and parameter values appropriate under the evaluation criteria?

5. Was the basis for selection of values clearly described and referenced?

6. Is the approach used to estimate the RME and CTE appropriate under the evaluation criteria?

7. Were the uncertainties in assessment adequately characterized and expressed?

8. Overall, was the approach used to assess risk from consumption of agricultural products and other wild food items reasonable for evaluating the baseline risk?

E. Phase II – Integrated Risk Evaluation

1. Were the bases for the toxicity assessment adequately described including the cancer slope factors, reference doses, and calculations of TEQ?

2. Did the risk characterization describe the methods and risk summary at an adequate and appropriate level of detail?

3. Were the potential risks associated with exposure to a combination of pathways and COPCs (direct contact, fish and waterfowl consumption, and agricultural product consumption) adequately characterized?

4. Were the uncertainties associated with both cancer and non-cancer health effects adequately characterized and expressed?

F. General

1. Were the EPA toxicity approaches and values (e.g. IRIS and HEAST) used for the COPCs applied appropriately under the evaluation criteria?

2. Were the important assumptions for estimation of dose (i.e., toxicity and exposure) and risk identified?

3. Were the calculations of carcinogenic and non-carcinogenic risks performed properly and consistent with EPA guidance?

4. Were the significant uncertainties inherent in the risk evaluation properly addressed and characterized? If not, please identify those that were not properly addressed or characterized and how they should be addressed in the HHRA.

5. To the best of the Panel's knowledge, have relevant peer-reviewed studies that support, are directly relevant to, or fail to support any estimate of risk been identified and considered, and has an appropriate methodology been used to reconcile inconsistencies in the scientific data?

6. To the best of the Panel's knowledge, is there other pertinent information available that was not considered in the HHRA? If so, please identify the studies or data that could have been considered, the relevance of such studies or data, and how they could have been used in the HHRA.

7. With respect to the conclusions in the HHRA report:

    - Are the conclusions (risk characterization) supported by the information presented in the other sections of the report?

    - Do the conclusions (risk characterization) objectively and reasonably characterize potential current and reasonably foreseeable future risks to human health in the Rest of River area?

ATTACHMENT A

List of Relevant Human Health Risk Assessment Guidance/Policy Documents

EPA. 1989. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*. Interim Final. Office of Solid Waste and Emergency Response. Washington, D.C. EPA/540/1-89/002.

EPA 1990 *National Oil and Hazardous Substances Pollution Contingency Plan, Final Rule*. 40 CFR 300.55, Federal Register, 8666-8865. 8 March

EPA 1991. *Role of the Baseline Risk Assessment. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions*. Memorandum from Don R. Clay to Division Directors. 22 April.

EPA. 1991. *Human Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors.* OSWER Directive 92856-03. 25 March.

EPA. 1991. *Risk Assessment Guidance for Superfund, Volume I – Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals). Interim.* Office of Emergency and Remedial Response. Washington, D.C. Publication 9285.7-01B. December.

EPA. 1992. *Guidance for Data Usability in Risk Assessment (Part B); Final*. USEPA PB92-963362.

EPA. 1992. *Dermal Exposure Assessment: Principles and Applications. Interim Report*. Office of Research and Development, Washington, D.C. EPA/600/8-91/011B. January.

EPA. 1992. *Implementing the Deputy Administrator's Risk Characterization Memorandum*. Henry L. Longest II, Director, Office of Emergency and Remedial Response, and Bruce Diamond, Director, Office of Waste Programs Enforcement. 26 February.

EPA. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors*. Memorandum from F. Henry Habicht II to Assistant and Regional Administrators. 26 February.

EPA. 1992. *Guidance for Data Usability in Risk Assessment (Part A). Final*. OERR. Publication 9285.7-09A. April.

EPA. 1992. *Supplemental Guidance to RAGS: Calculating the Concentration Term*. Office of Solid Waste and Emergency Response, Publication 9285.7-081. May.

EPA. 1992. *Guidelines for Exposure Assessment*. 57 Fed. Reg. 22888. 29 May.

EPA. 1993. Memo from W.H. Farland and H.L. Longest to Regional Directors, Re: *Use of IRIS Values in Superfund Risk Assessment*. USEPA. OSWER Directive #00285.7-16.

EPA. 1994. *EPA Risk Updates, Number 2, August 1994*. US EPA Region 1, Waste Management Division.

EPA. 1995. *Guidance for Risk Characterization*. USEPA. Science Policy Council. Washington, D.C. February.

EPA. 1995. *Policy for Risk Characterization at the U.S. Environmental Protection Agency*. USEPA, Office of the Administrator, Washington, D.C. March.

EPA. 1995. *Land Use in the CERCLA Remedy Process*. Memorandum from E.P. Laws to EPA Regional Offices. OSWER Directive 9355.7-04. 25 May.

EPA. 1995. *EPA New England, Risk Updates, Number 3*. August.

EPA. 1996. *Guidance for Data Quality Assessment. Practical Methods for Data Analysis. EPA QA/G-9. QA96 Version*. EPA/600/R-96/084. January.

EPA. 1996. *PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures*. National Center for Environmental Assessment. Office of Research and Development. Washington, D.C. EPA/600/P-96/001F. September.

EPA. 1996. *EPA, Region 1, New England, Risk Updates, Number 4*. November.

EPA. 1997. *Special Report on Environmental Endocrine Disruption, An Effects Assessment and Analysis.* Office of Research and Development. EPA/630/R-96/012. February.

EPA. 1997. *Guiding Principles for Monte Carlo Risk Analysis*. Office of Research and Development, Risk Assessment Forum. EPA/630/R-97/001.

EPA. 1997. *Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency*, Fred Hansen, Deputy Administrator. 15 May.

EPA. 1997. *Health Effects Assessment Summary Tables (HEAST), FY-1997 Update*. Office of Solid Waste and Emergency Response. Washington, D.C. EPA-540-R-97-036. PB 97-921199. July.

EPA. 1997. *Exposure Factors Handbook, Volume 1 – General Factors*. Office of Research and Development, Washington, D.C. EPA/600/P-95/002Fa. (Update to *Exposures Factors Handbook, May 1989*). August.

EPA. 1997. *Exposure Factors Handbook, Volume II – Food Ingestion Factors*. Office of Research and Development, Washington, D.C. EPA/600/P-95/002Fb. (Update to *Exposures Factors Handbook, May 1989).* August.

EPA. 1997. *Exposure Factors Handbook, Volume III – Activity Factors*. Office of Research and Development, Washington, D.C. EPA/600/P-95/002Fc. (Update to *Exposures Factors Handbook, May 1989*). August.

EPA. 1998. *Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites*. Timothy Fields, Jr.Acting Assistant Administrator to Division Directors. 13 April.

EPA. 1998. *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities. Peer Review Draft: Volumes 1-111. EPA/530-D-98-001a,b,c.* Office of Solid Waste and Emergency Response. July.

EPA. 1999. *Draft Guidelines for Carcinogen Risk Assessment*. NCEA-F-0644. July.

EPA. 2000. *Exposure and Human Health Reassessment of 2,3,7,8 Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds. Part 1; Estimating Exposure to Dioxin-like Compounds. Volume 4: Site Specific Assessment Procedures (Draft Final). EPA/600/P-00/001Bb.* Office of Research and Development. September.

EPA. 2001. *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites, Peer Review Draft*. OSWER 9355-4.24, March.

EPA SAB. 2001. *Dioxin Reassessment – an SAB Review of the Office of Research and Development's Reassessment of Dioxin. Review of the Revised Sections (Dose-Response Modeling, Integrated Summary, Risk Characterization and Toxicity Equivalent Factors) of the EPA's Reassessment of Dioxin by the Dioxin Reassessment Review Subcommittee of the EPA Science Advisory Board (SAB).* EPA-SAB-EC-01-006. May 2001.

EPA. 2001. *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment). Interim.* Public Comment Draft.

EPA. 2001. *Risk Assessment Guidance for Superfund (RAGS), Volume III: Part A – Process for Conducting Probabilistic Risk Assessment.* OSWER 9285.7-45. EPA 540-R-02-002. December.

EPA. 2002. *Integrated Risk Information System (IRIS)*. Peer-reviewed toxicity database maintained by the U.S. EPA. Washington, D.C.

EPA 2002. *Role of Background in the CERCLA Cleanup Program*. OSWER 9285.6-07P. April.

EPA. 2002. *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency*. EPA/260R-02-008. December.

EPA 2002. *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites. Office of Emergency and Remedial Response*. OSWER 9285.6-10. December.

EPA 2003 *Draft Final Guidelines for Carcinogen Risk Assessment* (External Review Draft). NCEA-F-0644A. Risk Assessment Forum. 3 March.