UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
New England Office – Region I
One Congress Street, Suite 1100
Boston, Massachusetts 02114-2023

May 22, 2007

Mr. Andrew T. Silfer, P.E.
General Electric Company
159 Plastics Avenue
Pittsfield, Massachusetts 01201

Sent via US Mail and Electronic Mail

RE: Dispute Resolution on EPA's Conditional Approval Letter for GE's Corrective Measures Study Proposal

Dear Mr. Silfer:

Upon completion of EPA's review of GE's report entitled "*Housatonic River - Rest of River Corrective Measures Study Proposal*" (hereinafter "Proposal") submitted February 27, 2007, EPA issued a Conditional Approval of the Proposal to GE on April 13, 2007. Pursuant to Special Condition II.N.1 of the Reissued RCRA Corrective Action Permit (the "Permit", which is Appendix G to the Consent Decree), GE notified EPA on April 27, 2007 of GE's objections to certain conditions in EPA's Conditional Approval. By that notice, GE invoked dispute resolution with respect to those conditions. As specified in Special Condition II.N.2, the first stage of the dispute resolution is for EPA and GE to have discussions in an effort to resolve the dispute. Upon GE's request, EPA extended the initial 14-day period specified in Special Condition II.N.2 for such discussions for an additional 7 days (until May 18, 2007). In light of the discussions between EPA and GE, EPA has made a number of changes to the disputed conditions based upon the understanding that GE will not go forward with the dispute resolution proceeding initiated on April 27, 2007. The revised conditions are set forth in the Attachment to this letter.

The conditions outlined in the Attachment supersede the conditions denoted by the same number provided in EPA's Conditional Approval letter of April 13, 2007. No other

conditions of that letter are changed by this letter or the Attachment. Pursuant to Special Condition II.N.2 of the Permit, GE shall complete the requirements in the Attachment to this letter.

EPA recognizes that GE submitted a Model Input Addendum on April 16, 2007 as an interim deliverable following the submission of the Proposal. EPA is reviewing that Addendum separately, and EPA reserves all its review and compliance rights regarding that submittal. In addition, in response to EPA's Conditional Approval of April 13, 2007, GE submitted a Supplement to the Proposal (hereinafter "Supplement") on May 11, 2007, for which EPA also reserves all its review and compliance rights. Nothing in this letter or the Attachment shall be interpreted to modify any approval, conditions in a conditional approval, or disapproval of the Addendum or of the Supplement, unless expressly stated as such by EPA in its response to the Addendum or Supplement. In addition, EPA reserves all of its rights regarding any future objections or challenges by GE to EPA actions, as well as any other rights that EPA has under the Permit, the Consent Decree, or applicable law.

This letter or the Attachment do not alter GE's requirement to submit the Corrective Measures Study Report under the terms of the Permit; provided however, in the future, EPA will consider the need for an alternative schedule for the submittal of the CMS Report upon demonstration by GE of the need for such an alternative schedule.

I understand that, based on this letter and the Attachment, GE will not go forward with the dispute resolution initiated by GE on April 27, 2007. Please contact me immediately if GE does not agree with this understanding.

Sincerely,

Susan C. Svirsky

Susan C. Svirsky, Project Manager
Rest of River

Attachment

cc: Mike Carroll, GE
Rod McLaren, GE
Kevin Mooney, GE
James Bieke, Goodwin Procter
Susan Steenstrup, MADEP
Anna Symington, MADEP
Dale Young, MAEOEA
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Tim Conway, EPA
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K.C. Mitkevicius, USACE
Mayor James Ruberto, City of Pittsfield
Thomas J. Hickey, PEDA
Scott Campbell, Weston Solutions
Linda Palmieri, Weston Solutions
Public Information Repositories

ATTACHMENT

Revised Conditions Relating to the Corrective Measures Study Proposal

General Conditions

- GC 13 – GE shall not use the wood frog model to assess the reduction of risk to the amphibian receptors.

  In its Statement of Position, GE claims that use of the population model in the ERA renders the model a "tool for assessing the effects of different remedial alternatives on the sustainability of the local wood frog population." However, the inclusion of the model in the ERA as a supplemental methodology within a much broader risk assessment does not equate to its use as a tool for reliably evaluating or specifying remedial measures. The wood frog population model was presented in the ERA, outside of the weight of evidence evaluation, as an additional analysis of potential risks to wood frogs. It was not considered to be representative of amphibians generally, was not one of the lines of evidence used in the risk assessment, and was not used in the development of MATCs, which in turn were used to develop IMPGs. The population model is therefore not appropriate for stand-alone use in the CMS to evaluate the effectiveness of remedial alternatives.

  GE's claim that use of the population model is consistent with EPA guidance to evaluate effects to populations and communities as a whole rather than individual organisms is without merit because the MATCs/IMPGs were also developed to reflect effects at the population and community level and are considerably more robust than the wood frog population model. GE's statements that the MATCs were solely based on the wood frog study misrepresents the ERA process, in which multiple lines of evidence, some of which involved a different species, were evaluated in reaching the conclusion that the wood frog sex ratio endpoint was the most sensitive, and therefore the most appropriate endpoint for developing the quantitative MATC as per the guidance received from the Peer Review Panel. GE accurately quotes EPA's statement in the ERA that the MATC is "believed to provide adequate protection for other amphibian species," but fails to quote the discussion

immediately following (and similar discussions elsewhere in the risk assessment) in which the uncertainty of the MATC due to potential greater sensitivity of other amphibian species is noted.

In addition to the major reasons for rejecting the proposed use of the wood frog population model discussed above, EPA reviewed GE's proposal to use the model to evaluate the adequacy of potential remediation alternatives with the developers of the wood frog population model. The developers concluded that uncertainties regarding both the model and the input parameters prevent useful conclusions from being drawn if the model is applied as proposed.

Based on these and other considerations, EPA maintains its position that the wood frog population model is not suitable for use in the Corrective Measures Study.

In addition to assessing reduction of risk to amphibians in vernal pool habitats, GE shall assess reduction of risk to amphibians from exposure to PCBs in backwater habitats.

- GC 21 – GE shall evaluate the depth of sediment removal/replacement in the river channel to a minimum depth of 2 to 3 feet, as applicable given the river reach. In the backwaters and impoundments, the removal/replacement depths and/or techniques proposed in the CMS Proposal are acceptable for the purpose of evaluating alternatives in the CMS. Discussion of the assignment of the minimum depths for specific reaches shall be included in the CMS.

  EPA notes that these removal/replacement depths are being used for the sole purpose of evaluating the various remedial alternatives and do not constitute the final depths that will be the outcome of considerations evaluated at the time of design of the remedy, if the remedy were to include such options.

  GE shall revise the depths of removal where necessary, and note the depths in the revised Table 5-1.

- GC 24 – The depth of floodplain soil removal/replacement in "heavily used" areas shall be increased to 3 ft in alternatives FP 3 through FP 7. However, GE may provide justification for the reclassification of specific areas of the parcels designated as "heavily used" that would not meet the "heavily used" designation and therefore would not be subject to the evaluation of 3 ft removal/replacement. Criteria for reclassification shall be unbiased and reproducible (e.g. inundation, accessibility).

  In addition, while the evaluation of floodplain soil removal to 1 foot in non-heavily used areas is adequate for the CMS evaluation, EPA recognizes that there may be other circumstances or unidentified areas of "heavy use" that may require consideration of active remediation of soil to depths exceeding 1 foot in remedy selection or remedial design.

Specific Conditions

- SC 65, Page 5-23 – EPA agrees that the values for the parameters provided in the bulleted list are site-specific and subject to uncertainty. While some of the values for these parameters are provided in the CMS Proposal, others were provided in the Addendum submitted to EPA on April 16, 2007. To best characterize the model estimates of metrics of interest in evaluating the performance of the proposed alternatives, GE shall conduct model simulations in the CMS using alternative values for some of these parameters as specified by EPA in this letter or in the response to the Addendum or subsequent submittals. This will result in two model estimates for some parameters. Model simulations using these bounding estimates will be expected to incorporate the uncertainty surrounding these values.

  In addition to developing attenuation factors for estimating PCB concentrations in Lake Lillinonah and Lake Zoar, GE shall also develop attenuation factors and PCB concentrations estimates for Lake Housatonic.

- SC 67, Page 5-25 – Assumption of PCB concentration in "clean" backfill material – GE shall perform model simulations in the CMS using the proposed PCB concentration of 0.021 mg/kg (½ the detection limit), as well as bounding simulations using 0 mg/kg PCB.

- SC 69, Page 5-26/5-27 – Discussion of the placement of the thin layer cap assumes no instantaneous mixing with the underlying sediment. As demonstrated by GE's preliminary work at Silver Lake, proper placement of cap material/backfill (e.g. thin lifts) can result in little to no mixing. There are few data available from other sediment projects to estimate the amount of mixing that may occur with any degree of certainty.

  GE shall perform model simulations using the assumption of mixing which is approved in EPA's response to the Model Input Addendum, as well as bounding simulations assuming no mixing of the cap material with the residual sediment.

- SC 72, Page 5-29 – Water column metrics shall include PCB concentrations at the two locations proposed and for Bulls Bridge, and Lake Lillinonah, Lake Zoar, and Lake Housatonic (from the CT analysis).

  The sediment metric shall be calculated for the subreach-specific FCM exposure concentration as simulated by EFDC. It is unclear from the text if sediment concentrations are proposed to be calculated for Lake Housatonic. GE shall calculate these concentrations.

  GE shall use the wet weight ratio of 5:1 to convert modeled whole-body PCB concentrations for largemouth bass to their equivalent fillet ratio for comparison with human health IMPGs for fish consumption.

  In its Statement of Position, GE states that "it was reasonable for GE to rely [only] on the site-specific GE largemouth bass dataset, and it was unjustified for EPA to direct GE not to do so." GE has referenced "unrealistically low lipid levels in some of the EPA fillet samples and high variability in the reported relationships between whole-body and fillet

concentrations" to justify exclusion of the entire EPA data set. For the reasons discussed below, EPA maintains its position that all appropriate data should be considered in the development of the whole-body:fillet conversion factor.

Low Lipid Results for Some Samples

With regard to the issue of questionable lipid results for some samples, EPA's position is that data should be excluded only after detailed technical scrutiny for quality assurance, and exclusion of data should be minimized. This position is consistent with EPA Quality Guidance for Data Quality Assessment (EPA 2000), which states that "discarding an outlier from a data set should be done with extreme caution, particularly for environmental data sets." The Guidance further recommends that, if a data point is found to be an outlier, the analyst may: (1) correct the data point; (2) discard the data point from analysis; or (3) use the data point in all analyses. Discarding the entire data set that contains the outlier is not among the recommended actions, and is contrary to common scientific practice.

Analytical Variability

GE's argument regarding purported high variability in the whole body:fillet ratios calculated from the EPA data fails to consider the important distinction between variability, imprecision, and bias in analytical measurements. Variability refers to the diversity of values for a given characteristic that is a normal and inherent property of natural systems. Imprecision is random error in the measurement of those values, observed as different results from repeated measurements of similar samples (*e.g.*, splits, replicates). Bias is systematic error, and is of greater importance for establishing a scaling factor. Neither the quality control procedures (e.g., interlaboratory splits) nor the comparison of GE and EPA data on a lipid-normalized basis suggest analytical bias that would preclude use of the EPA dataset for calculation of a scaling factor.

EPA disagrees that the higher variability in individual whole body:fillet (WB:F or "ratio") contaminant ratios in the EPA data set compared to the GE data set provides a basis for ignoring the EPA data. The reasons for this conclusion are summarized below:

- The EPA samples reflect a greater diversity of fish sizes, ages, and reaches than the GE samples (the latter were all from large fish in a single sampling event at two locations).
- The regressions conducted by GE using the EPA data did not exclude the few samples that EPA agrees have questionable lipid results, which would reduce the variability and result in an increase in the r^2.
- The *variability* in the relationship for EPA data cannot be taken as evidence of systematic *bias* in the mean ratio between fillet and whole body concentrations. Even if analytical variability and/or sampling variability is greater in the EPA data set, this does not render the EPA data unusable for calculation of scaling factors. To the contrary, observation of analytical variability and/or natural variability indicates that the largest possible data set should be used to capture the natural stochasticity and provide the most reliable representation of the mean value. Use of a single study, even when within-study variability is low, has potential to misrepresent the long-term average, which is why use of all studies and all appropriate data is essential.

Discussion of the variability in analytical measurements of lipid content was included in the RFI (BBL and QEA 2003; Section D.1), where it was noted that the Rest of River (ROR) program included analysis of splits of fillet samples (n = 18), with EPA and GE samples submitted to different laboratories (GERG and NEA, respectively). The lipid extraction methods differed between the two laboratories, such that the split analysis provided an evaluation of the analytical variability associated with extraction method. The results of the split analyses indicated *no systematic differences* in lipid percentages. The RFI (BBL and QEA 2003) concluded that "no bias in either laboratory's methods was detectable and both laboratories reported at least one lipid value at or below 0.3%".

The results of the split-sample analyses indicate that the analytical method used by GE yielded similar results to the method used by EPA, and also yielded some results that fell below the threshold identified by GE to be "of concern". Also, as noted in the RFI, the EPA lipid data were produced under both laboratory-specific and programmatic QA/QC

procedures, and no quality control problems were identified (BBL and QEA 2003). Therefore, although concerns with specific individual data points were identified and required evaluation, discarding the entire EPA data set is not scientifically justified.

Amrhein et al. (1999) and other Published Studies

GE cites Amrhein *et al.* (1999) to support a conversion factor of 1.7 on a wet weight basis. Amrhein *et al.* (1999) documents PCB ratios (whole fish to fillet) of 1.70 ± 0.80 and 1.47 ± 0.60 for **coho salmon and rainbow trout** [emphasis added], respectively. These salmonid species have considerably higher lipid content in fillet tissue (on the order of 3 to 5 times higher) than largemouth bass and other ROR species of primary interest for human consumption; the higher lipid content in fillet tissue results in a lower WB:F tissue ratio for contaminants, as predicted by EqP theory. Amrhein *et al.* (1999) also documents *lipid-normalized* ratios of 0.98 ± 0.31 and 0.85 ± 0.23, values which are consistent with EqP theory and with data from Housatonic River fish, indicating that the wet-weight ratio of 1.7:1 is due to high lipid content in edible tissue of salmonids, which are not representative of the ROR species of interest.

Burman and Rygwelski (2006) provide information of greater relevance to development of a scaling factor for the Housatonic River. This study illustrates the sensitivity of WB:F ratios to the *lipid content of the sampled fish*. The smallmouth bass and yellow perch samples evaluated by Burman and Rygwelski (2006) yielded lipid contents similar to those observed in Housatonic River adult largemouth bass (i.e., approximately 4% lipid), and also yielded WB:F PCB ratios greater than 5:1 for both species. Examination of data for all species presented in Burman and Rygwelski indicates that while the wet weight conversion factor of 1.7 proposed by GE might be appropriate for fatty fish (>10% lipid) in other systems, it is not applicable to fish species with the lipid contents typical Housatonic River sport fish. The data in the appropriate range of lipid content are supportive of a WB:F PCB ratio for largemouth bass of approximately 5:1.

EPA notes that the RETEC (2002) data table presented by GE in its Statement of Position includes only the lowest value (1.5 for lake trout) from Burman and Rygwelski. Higher

values associated with species more representative of ROR species (e.g., smallmouth bass and yellow perch) were excluded on the rationale that these ratios were not based on matched fillet and offal from same fish. Values for these latter species were nearly exactly the same as the 5:1 ratio proposed by EPA. The rationale provided is sufficient to suggest that there is additional uncertainty in the Fox River ratios, but it is highly improbable that lack of such matching would introduce a systematic bias of 300%.

With respect to the Hudson River ratio of 2.5:1 mentioned in GE's Statement of Position, the RI/FS for the Hudson River (TAMS, 2000) indicates that "available data are almost entirely for fish fillets"; therefore, this value of 2.5 was largely derived from the literature and therefore is less relevant to the ROR than the value of 5:1 derived from the site-specific data.

References

Amrhein, J.F., C.A. Stow, and C. Wible. 1999. Whole-Fish Versus Fillet Polychlorinated Biphenyl Concentrations: An Analysis Using Classification and Regression Tree Models. *Environ. Toxicol. Chem.* 18:1817-1823.

BBL (Blasland, Bouck & Lee, Inc.) and QEA (Quantitative Environmental Analysis, LLC). 2003. *Housatonic River – Rest of River RCRA Facility Investigation Report.* Prepared for General Electric Company.

Burman, B. and K.R. Rygwelski. 2006. "Derivation of a Hypothetical Lake Michigan Lake Trout Fish Consumption Criteria for PCBs." Appendix 3.4.1 of Ronald Rossmann, (Ed.), *Results of the Lake Michigan Mass Balance Project: Polychlorinated Biphenyls Modeling Report.* Prepared for U.S. Environmental Protection Agency, Great Lakes National Program Office, Chicago, Illinois. EPA-600/R-04/167. December 2006.

EPA. 2000. Quality Guidance for Data Quality Assessment - Practical Methods for Data Analysis. EPA QA/G-9, QA00 Update. United States Environmental Protection Agency, Office of Environmental Information, Washington, DC. July, 2000. EPA/600/R-96/084.

RETEC (The RETEC Group Inc.). Final Baseline Human Health and Ecological Risk Assessment, Lower Fox River and Green Bay, Wisconsin, Remedial Investigation and Feasibility Study. Section 7 – Sediment Quality Thresholds. Prepared for Wisconsin Dept. of Natural Resources, Madison WI. December 2002.

TAMS (TAMS Consultants, Inc.). 2000. Hudson River PCB Reassessment RI/FS – Phase 3 Report: Feasibility Study. Prepared by TAMS Consultants, Inc. for U.S. Environmental Protection Agency Region 2 and U.S. Army Corps of Engineers, Kansas City District. Book 1 of 6 (Report Text). December 2000.

Assumptions for fish abundance, size, species preferences, etc. used in the CMS shall be the same as those identified in the ERA.

- SC 77, Page 5-40/5-57 – This condition is eliminated.