



GE
159 Plastics Avenue
Pittsfield, MA 01201
USA

January 23, 2006

Susan Svirsky
U.S. Environmental Protection Agency
c/o Weston Solutions, Inc.
10 Lyman Street
Pittsfield, MA 01201

**Re: GE-Pittsfield/Housatonic River Site
Rest of River (GECD850)
Dispute Resolution on EPA's Disapproval of GE's Interim Media Protection Goals
Proposal**

Dear Ms. Svirsky:

Pursuant to Special Condition II.N.I of the Reissued RCRA Corrective Action Permit (the Permit) issued by U.S. Environmental Protection Agency (EPA) to the General Electric Company (GE) on July 18, 2000, GE hereby notifies EPA of GE's objections to EPA's disapproval of, and comments on, GE's September 6, 2005 *Interim Media Protection Goals Proposal* (IMPG Proposal) for the "Rest of River" portion of the Housatonic River (as defined in the Permit). EPA's disapproval and comments were set out in EPA's December 9, 2005 letter to GE. In a subsequent letter dated December 21, 2005, EPA agreed, at GE's request, to extend the deadline under Special Condition II.N.I of the Permit for GE to notify EPA of its objections to EPA's December 9, 2005 letter from December 23, 2005 to January 23, 2006.

By this notice, GE is invoking dispute resolution under Special Condition II.N.I of the Permit. As GE has discussed with EPA, GE believes that, pursuant to Special Condition II.N.5 of the Permit, GE is entitled, in a proceeding to review EPA's Permit modification to select corrective measures for the Rest of River, to raise any objections to EPA's disapproval or modification of a prior interim submittal (except for an argument that such action constituted a modification of the Permit), regardless of whether GE invoked dispute resolution on EPA's disapproval or modification of the interim submittal. Nevertheless, GE is invoking dispute resolution at the present time as a protective measure, out of an abundance of caution, to ensure that its objections to EPA's disapproval of the IMPG Proposal are preserved for the record. At the same time, GE is proposing that this dispute resolution proceeding be stayed as described below.

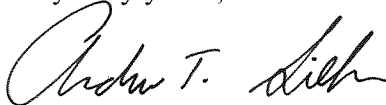
The specific issues on which GE disagrees with EPA's disapproval of and comments on the IMPG Proposal are set forth in the attached Statement of Position. Given the protective nature of this notice and the proposed stay, and based on discussions with EPA, this Statement of Position lists the specific matters in dispute, states GE's basic position on each issue, and provides a brief summary of the main reasons for GE's position. At the expiration of the stay, GE will provide additional rationale and explanations for its positions, as appropriate at that time.

GE proposes that this dispute resolution proceeding be stayed in accordance with the following terms:

- (a) Further dispute resolution proceedings on this notification of dispute of EPA's disapproval of GE's IMPG Proposal shall be stayed until the earlier of: (i) the date on which GE invokes administrative dispute resolution, pursuant to Special Condition II.J of the Permit and Paragraphs 22.o and 141.b of the Consent Decree (CD) for the GE-Pittsfield/Housatonic River Site, on EPA's notification to GE of EPA's intended final decision on the proposed Permit modification, or (ii) if GE does not invoke such administrative dispute resolution or does not raise its objections regarding the IMPG Proposal in such administrative dispute resolution, the date on which GE invokes its right, pursuant to Special Condition II.J of the Permit and Paragraph 22.q of the CD, to seek review of the Permit modification by the EPA Environmental Appeals Board (EAB).
- (b) After expiration of the stay as set forth in the preceding subparagraph, GE shall be entitled to raise its objections to EPA's December 9, 2005 disapproval letter either in a dispute concerning EPA's intended final decision on the proposed final Permit modification or, to the extent consistent with the regulations at 40 CFR Part 124, in the review of the Permit modification by the EAB. In either such proceeding, GE may revise or modify its objections to EPA's December 9, 2005 disapproval letter, to the extent consistent (in the case of an appeal of the final Permit modification to the EAB) with the regulations at 40 CFR Part 124.
- (c) GE will submit the revised IMPG Proposal by March 10, 2006, or by such other date that EPA approves.

Please advise us as to whether EPA agrees to a stay of this proceeding in accordance with the above terms. In the meantime, please let me know if you have any questions about this notice.

Very truly yours,



Andrew T. Silfer, P.E.
GE Project Coordinator

Attachment

cc: Dean Tagliaferro, EPA
Timothy Conway, EPA
Holly Inglis, EPA
Rose Howell, EPA (without attachment)
Susan Steenstrup, MDEP
Anna Symington, MDEP
Robert Bell, MDEP

Thomas Angus, MDEP
Dale Young, MA EOE
Susan Peterson, CDEP
Michael Carroll, GE
Jane Gardner, GE
Roderic McLaren, GE
Kevin Mooney, GE
James Bieke, Goodwin Procter
Samuel Gutter, Sidley Austin

GENERAL ELECTRIC'S STATEMENT OF POSITION ON OBJECTIONS TO EPA'S DISAPPROVAL OF INTERIM MEDIA PROTECTION GOALS PROPOSAL

January 23, 2006

INTRODUCTION

A. General

On September 6, 2005, the General Electric Company (GE) submitted to the U.S. Environmental Protection Agency (EPA) an Interim Media Protection Goals Proposal (IMPG Proposal) pursuant to Special Condition II.C of the Reissued Resource Conservation and Recovery Act (RCRA) Corrective Action Permit that was issued by EPA to GE on July 18, 2000 (the Permit) as part of the comprehensive settlement embodied in the Consent Decree (CD) for the GE-Pittsfield/Housatonic River Site. That Permit applies to releases of polychlorinated biphenyls (PCBs) and other hazardous constituents that have migrated from the GE facility in Pittsfield to the "Rest of River" area (as defined in the Permit and the CD).

On December 9, 2005, EPA sent GE a letter in which, pursuant to Special Condition II.D of the Permit, EPA disapproved the IMPG Proposal due to certain purported "deficiencies" identified in EPA's letter, and required GE to submit a revised IMPG Proposal that corrects those purported "deficiencies" and includes numerous other specific revisions identified by EPA in Attachment A to its letter. Thereafter, at GE's request, EPA agreed that the deadline under Special Condition II.N.1 of the Permit for GE to invoke dispute resolution on that disapproval would be extended from December 23, 2005 to January 23, 2006.

Pursuant to Special Condition II.J.1 of the Permit, GE is invoking dispute resolution on EPA's disapproval of the IMPG Proposal. As GE has discussed with EPA, GE believes that, pursuant to Special Condition II.N.5 of the Permit, GE is entitled, in a proceeding to review EPA's Permit modification to select corrective measures for the Rest of River, to raise any objections to EPA's disapproval or modification of a prior interim submittal (except for an argument that such action constituted a modification of the Permit), regardless of whether GE invoked dispute resolution on EPA's disapproval or modification of the interim submittal. Nevertheless, GE is invoking dispute resolution at the present time as a protective measure, out of an abundance of caution, to ensure that its objections to EPA's disapproval of the IMPG Proposal are preserved for the record.

In these circumstances, GE is proposing to stay this dispute resolution proceeding until the earlier of either of the following two events under Special Condition II.J: (a) the time when GE can seek administrative dispute resolution regarding EPA's notification of its intended decision on the proposed Permit modification to select a remedy; or (b) the time of appeal of the final Permit modification to the EPA Environmental Appeals Board (EAB) (whose decision is subject to further appeal to the U.S. Court of Appeals for the First Circuit). Given the protective nature of this notice and the proposed stay, and based on discussions with EPA, this Statement of

Position lists the specific matters in dispute, states GE's basic position on each such issue, and provides an abbreviated summary of the main reasons for GE's position.

B. Background

Under the Permit, the IMPG Proposal was required to be submitted following completion of the peer review process on EPA's Human Health Risk Assessment (HHRA) and its Ecological Risk Assessment (ERA) for the Rest of River. Under Special Condition II.C of the Permit, the proposed IMPGs are to "consist of preliminary goals that are shown to be protective of human health and the environment and that will serve as points of departure in evaluating potential corrective measures in the subsequent Corrective Measures Study" (CMS). The proposed IMPGs for human health protection must include numerical concentration-based goals based on direct human contact with affected media and on human consumption of edible biota, and may also include narrative descriptive goals for such pathways. The proposed IMPGs for ecological receptors must include either numerical concentration-based goals or narrative descriptive goals based on exposures and risks to such receptors. The IMPG Proposal must include a justification showing that the proposed IMPGs "would ensure protection of human health and the environment, taking into account EPA's [HHRA] and its [ERA]." Finally, the IMPG Proposal must take into account applicable or relevant and appropriate requirements (ARARs).

GE's September 2005 IMPG Proposal presented a combination of numerical concentration values and narrative descriptive goals. From a human health standpoint, it addressed direct human contact with sediments and floodplain soil and human consumption of fish, waterfowl, and agricultural products from the Rest of River area. From an ecological standpoint, this IMPG Proposal addressed several groups of ecological receptors, including benthic invertebrates, amphibians, fish, and certain birds and mammals. It presented numerical concentration values for PCBs, and, in some cases, dioxin toxicity equivalents (TEQs), in the relevant media.

To allow full evaluation of an appropriate array of remedial alternatives in the CMS, the IMPG Proposal presented ranges of numerical risk-based concentration values (referred to as "Risk-based Media Concentrations" or RMCs). For the health-based values, the range of RMCs included values based on use of both Reasonable Maximum Exposure (RME) and Central Tendency Exposure (CTE) assumptions; and for each set of assumptions, it included values based on three excess lifetime cancer risk levels within EPA's acceptable cancer risk range – 1×10^{-6} , 1×10^{-5} , and 1×10^{-4} – as well as non-cancer-based values using a Hazard Index (HI) of 1. For the ecologically based values, the range of RMCs included various effect thresholds from the site-specific studies used in EPA's ERA or, for species for which there are no site-specific studies, values based on ranges of toxicity reference values (TRVs) from the literature.

Given the Permit requirement to take into account EPA's risk assessments, the September 2005 IMPG Proposal presented two separate sets of RMC ranges. The first set, presented in Section 2, consisted of ranges of numerical concentration values that were calculated based directly on use of the exposure assumptions, toxicity values, and data interpretations used or set forth in EPA's HHRA and ERA. GE noted, however, that, as discussed in prior comments to EPA, GE believes that many of those assumptions, values, and interpretations are not supported by site conditions or the scientific data and substantially overstate exposures and risks to human and ecological

receptors in the Rest of River. Accordingly, the Proposal set forth, in Section 3, an alternative set of concentration ranges that were based on the use of many (but not all) of the inputs used in EPA's risk assessments, combined with certain exposure assumptions, toxicity values, and data interpretations that GE believes are more scientifically supportable and more consistent with actual site conditions and the underlying data.

Finally, Section 4 of the Proposal described potential chemical-specific ARARs for media in the Rest of River area and discussed their relationship with the IMPGs.

In its December 9, 2005 disapproval letter, EPA identified four purported "deficiencies" in GE's IMPG Proposal: (1) the inclusion of the alternative set of RMC ranges, which EPA directed GE to delete in their entirety; (2) the failure to identify any of the RMC values in the ranges as the "point of departure" for the CMS evaluations, which EPA directed GE to correct by identifying the lowest value in each of the ranges as the "point of departure"; (3) the inclusion of narrative goals which EPA asserted use "ambiguous and undefined terms" and which EPA directed GE to modify to add language provided by EPA; and (4) the need to identify chemical-specific ARARs for use in the CMS.¹ EPA also provided, in Attachment A to its letter, numerous specific comments directing GE to make various other changes to the IMPG Proposal.

This Statement states GE's position on the issues on which it disagrees with EPA's directives and comments on the IMPG Proposal. Given the protective nature of this dispute resolution notice, and based on discussions with EPA, this Statement presents only a summary (in bulletized format) of the major reasons for GE's positions. In some cases, that summary refers to, and incorporates by reference, portions of the September 2005 IMPG Proposal and other prior submissions to EPA relating to the issues involved.

In the event that GE raises these or other issues in a dispute resolution proceeding on EPA's notification of its intended decision on the proposed Permit modification or in an appeal of the final Permit modification, GE will revise or modify the issues as appropriate at that time, and will provide additional rationale and explanations for the reasons supporting GE's positions (consistent, in the case of an appeal to the EAB, with EPA's regulations at 40 CFR Part 124). In addition, GE preserves all positions stated in prior submissions to EPA relating to human health or ecological risk issues, as well as in its September 2005 IMPG Proposal. Finally, GE reserves any other rights it has under the Permit, the CD, or applicable law.

¹ Contrary to the implication in EPA's disapproval letter, GE's September 2005 IMPG Proposal did identify the potential chemical-specific ARARs for PCBs and dioxin TEQs for media in the Rest of River area, although it noted that those criteria would not constitute or affect the IMPGs because GE had developed site-specific RMCs that address the same receptors and pathways. EPA stated that the development of site-specific concentrations is not a substitute for promulgated ARARs, that chemical-specific ARARs must therefore be identified in the IMPG Proposal for use as an evaluative criterion in the CMS, and that if it is determined in the CMS that an ARAR cannot be achieved, then it will be subject to waiver (EPA Letter, pp. 4-5). GE recognizes that the ARARs identified in the IMPG Proposal will be used as an evaluative criterion in the CMS, but believes that they should not also be considered to constitute or affect the IMPGs. In the revised IMPG Proposal, GE will clarify this matter and will identify the chemical-specific ARARs that will be used as an evaluative criterion in the CMS, subject to waiver if they cannot be achieved or if the other conditions for waiver are met.

GE POSITION

1. Alternative Values: EPA erred in requiring GE to remove all IMPGs based on alternative assumptions, input values, and data interpretations, and to base all IMPGs only on the assumptions, values, and interpretations set out in the HHRA and ERA (EPA Letter, p. 2).

- EPA’s position is not required by the Permit. The Permit requirement to “take into account” the EPA risk assessments does not require that the proposed IMPGs must necessarily use all the same exposure assumptions, toxicity values, and data interpretations used in the risk assessments, but rather that they must be considered.
- In developing the alternative values, GE did “take into account” the HHRA and ERA, because GE used the same exposure scenarios and receptors used in the risk assessments and it carefully considered and evaluated the assumptions and other inputs used in those risk assessments, using many of them and providing a rationale for any alternatives used.
- From a scientific standpoint, the presentation of these alternative values was justified because a number of the exposure assumptions, toxicity values, and data interpretations and analyses used in the HHRA and ERA are not supported by site conditions, the underlying data, or the relevant scientific evidence, and substantially overstate exposures and risks to humans and ecological receptors in the Rest of River area. These unsupported assumptions, values, and interpretations were described in GE’s prior comments on the HHRA (AMEC and BBL, 2003, 2005; GE, 2003) and the ERA (BBL et al., 2003, 2005; GE, 2004), as well as summarized in Section 3 of the September 2005 IMPG Proposal – all of which are incorporated by reference herein. They include the following:

Assumptions/Values in HHRA

- Use of RME soil ingestion rates of 200 mg/day for young children and 100 mg/day for older children and adults in recreational direct contact scenarios; more supportable values are 100 mg/day and 50 mg/day, respectively.
- Use of “enhanced” soil ingestion rates of 330 mg/day for utility workers and 200 mg/day for farmers; more supportable value is 137 mg/day for both scenarios.
- In recreational RME scenarios, assumption that 100% of all soil ingested in a day of exposure comes from floodplain; an adjustment should have been made to account for the fraction of total daily soil ingestion that comes from areas not in or near the floodplain.
- Use of overstated exposure frequencies for a number of direct contact RME scenarios (including general recreation, dirt biking/ATVing, and sediment exposure); more supportable frequencies are set out in Section 3 of September 2005 IMPG Proposal.

- Use of RME fish consumption rates of 31 g/day for adults and 16 g/day for young children for bass and 12 g/day for adults and 6 g/day for children for Connecticut trout; more supportable rates for adults are 12 g/day for flowing reaches and 16 g/day for standing reaches, and for children, 4 g/day.
- Assumption that 100% of waterfowl consumed by hunters in the study area were resident birds that spent 100% of their time in the area; more supportable assumption is that only ~ 40% of waterfowl consumed are resident, with the rest being migrants.
- Assumption of no cooking loss in RME waterfowl consumption scenario; cooking loss should have been incorporated.
- Overstated probabilistic analyses of fish and waterfowl consumption, which failed to use distributions for some key parameters and used inflated distributions for others.
- Use of cancer and non-cancer toxicity values derived from studies of laboratory animals, without taking account of the fact that the weight of evidence from human studies shows a lack of credible evidence that PCBs have caused cancer in humans or that PCBs have caused adverse non-cancer effects in humans (with the possible exception of dermal and ocular effects in highly exposed workers).²
- Use of a non-cancer Reference Dose for PCBs of 2E-05 mg/kg-day, when a more supportable value would be 2E-04 mg/kg-day, based on omitting two overly conservative uncertainty factors used by EPA in developing that Reference Dose.
- Inclusion of PCBs in the dioxin TEQ approach, when the current scientific evidence does not support the inclusion of PCBs in that approach.

Interpretations/Assumptions in ERA

- EPA's interpretation of the benthic invertebrate community study as showing significant PCB effects; the more supportable interpretation is that that study did not show any important PCB-related effects on benthic community metrics.
- EPA's interpretation of the wood frog toxicity study as showing significant PCB effects with population-level impacts; the more supportable interpretation is that the effects shown in that study would likely not adversely affect wood frog populations.
- EPA's interpretation of the site-specific population study of short-tailed shrews as showing significant PCB effects on shrew survival; the more supportable interpretation is that that study provides no evidence of significant or meaningful adverse effects on shrews, and that any survival effect was weak and inconclusive.

² The fact that the animal-based toxicity values overstate the human health effects of PCBs was confirmed in a recent study by Silkworth et al. (2005), who showed that human cells are many times less sensitive than the cells of the laboratory animals used in developing the PCB toxicity values (rats and rhesus monkeys) to the gene expression that is believed to lead to toxicity from PCB exposure.

- EPA's interpretation of the mink feeding study as showing effects of PCBs and TEQs on mink kit survival at 6 weeks after birth; the more supportable interpretation is that that study did not provide definitive evidence of a dose-related adverse effect on kit survival due to PCB exposure.
- EPA's assessment of potential PCB risks to osprey and wood ducks based on a TRV derived from a literature study of chickens, when the evidence indicates that chickens are far more sensitive to PCBs than these wild avian species and thus are not an appropriate surrogate for these species, and when PCB toxicity information exists on more suitable surrogate species and even on osprey themselves.
- Assessment of risks to breeding osprey based on the assumption that they forage 100% of their time in the Rest of River area, when the evidence indicates that osprey do not breed in this area and that the only osprey observed in the area are transient (i.e., migrants).
- The alternative RMCs proposed in the September 2005 IMPG Proposal, which use more supportable input values and interpretations on the above issues, are protective of human health and the environment for the scenarios, receptors, and risk or effect levels to which they apply.

2. Points of Departure for Health-Based IMPGs: EPA erred in directing GE to identify, as points of departure for health-based IMPGs, the RME values based on a 10^{-6} cancer risk and a non-cancer HI of 1 (EPA Letter, pp. 3-4).

- The National Contingency Plan (NCP) and EPA's RCRA corrective action guidance (EPA, 1990, 1996) specify that, for carcinogens, concentrations will be considered protective if they reflect a cancer risk in the range of 1×10^{-6} to 1×10^{-4} .
- While the NCP and RCRA guidance state that the 10^{-6} risk level should be "the point of departure *for determining remediation goals*" (emphasis added), EPA's guidance makes clear that that risk level need not be the target goal for remedial evaluations in all situations, and thus is not equivalent to or consistent with the Permit definition of IMPGs as "points of departure *in evaluating potential corrective measures*" (emphasis added).

3. Narrative IMPGs for Human Health: EPA erred in directing GE to revise the narrative IMPGs for human health to include statements regarding the methods for achievement of the IMPGs and definitions of key terms that are the same as those used in the HHRA (EPA Letter, p. 4; Att. A, pp. 2, 6, 7).

- EPA's comments directed GE to add to these narrative IMPGs statements that the exposure point concentrations that will be used in applying the RMCs in the CMS will be the 95th Upper Confidence Limit (UCL) of the mean, derived in some cases using inverse distance weighting (IDW). However, it is premature to specify the method for achieving the IMPGs in the IMPG Proposal; that should be left to the CMS.

- EPA also directed GE to include in these narrative IMPGs statements that the definitions of significance of risks, accessibility, actual and future uses, frequency of consumption (for edible products), and edible portions of fish must be those used in the HHRA. This directive is not required by the Permit, which, as discussed above, requires only that GE “take into account” the HHRA.

4. Points of Departure for Ecological Receptors: EPA erred in directing GE to identify, as points of departure, the Maximum Acceptable Threshold Concentrations (MATCs) identified in the ERA or (for receptors for which MATCs were not calculated) values representing a 20% effect level or a 20% probability of exceeding the literature-based TRV identified in the ERA for the most sensitive surrogate species, and to eliminate reference to all other endpoints (EPA Letter, pp. 3, 4; Att. A, pp. 15, 23-29).³

- For ecologically based values, there is no EPA regulation or guidance on numerical levels of risk reduction that should serve as remediation goals.
 - Neither the NCP nor EPA’s RCRA corrective action guidance contains any such quantitative criteria on risk levels or risk ranges for remediation goals.
 - EPA’s guidance on *Ecological Risk Assessment and Risk Management Principles for Superfund* (EPA, 1999) recognizes that there is “no magic number” for determining “the acceptable level of adverse effects for the receptors to be protected,” and that goals are best set on a site-specific basis, considering the overall goal “to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota” (pp. 7, 8, & 3).
- EPA stated that “[t]he point of departure for ecological IMPGs has been defined in practice in making remedial decisions at other contaminated sites and as a level of concern in other EPA programs as a contaminant concentration that falls within the range of the No Observed Adverse Effect Level (NOAEL) to the Lowest Observed Adverse Effect Level (LOAEL)” (EPA Letter, p. 3).
 - EPA did not provide any citations for that proposition, and in any event, did not dispute the fact that there is no regulation or EPA-published guidance so providing.
 - EPA’s *Ecological Risk Assessment Guidance for Superfund* (EPA, 1997) does state that the description of risks at Superfund sites “identifies a threshold for effects on the assessment endpoints as a range between the contamination levels identified as posing no ecological risk and the lowest contamination levels identified as likely to

³ EPA’s comments directed GE to limit the RMCs for ecological receptors only to the MATCs or to values representing a 20% effect level or a 20% probability of exceeding the TRV for the most sensitive surrogate species. However, even if EPA accepted some limited ranges of RMCs for some ecological receptors, there is no sound basis (as discussed in this section) for specifying the foregoing levels as points of departure or initial target goals for evaluating potential remedies in the CMS or for eliminating reference to other endpoints. Moreover, in Section 7, we present the position that, for several specific receptor groups, EPA’s rejection of broader ranges (such as those proposed in the September 2005 IMPG Proposal) was unwarranted.

produce adverse ecological effects” (p. 7-6). However, it does not indicate that this threshold for effects should be used as the remediation goal for a site. In fact, it states that this risk description can “provide information to help the risk manager judge the likelihood and ecological significance of the estimated risks” (p. 7-4).

- EPA also asserted that the MATCs “are generally equivalent to LOAELs” (EPA Letter, p. 3). However, this is not the case for some of the receptor groups. For example, for omnivorous and carnivorous mammals represented by the short-tailed shrew and for piscivorous mammals represented by the mink, the MATCs established in the ERA are at or below the level of the NOAEL. For such groups, even accepting that the point of departure should be in the range between the NOAEL and the LOAEL, there is no basis for limiting it to the MATC.
- Moreover, EPA’s directive fails to allow use of effect thresholds or effect sizes that could also be useful in the CMS. Most of the MATCs are based on calculated 20% effect levels (EC20s) for the most sensitive endpoints evaluated in the studies. However, other endpoints and effect sizes may also serve as appropriate receptor-specific cleanup goals, depending on the type and size of effect to be prevented and the relevance of the endpoints to the overall goal of protecting local populations and communities.
- For receptors for which there are no site-specific or species-specific effects data and for which MATCs were not calculated (namely, piscivorous and insectivorous birds represented by the osprey and wood duck, respectively), EPA’s directive to base the IMPG on a 20% probability of exceeding the TRV for the most sensitive surrogate species (in this case, a chicken) or a 20% effect level for that species is unjustified.
 - For these receptor groups, the ERA itself specified ranges of literature-based TRVs for surrogate species, ranging from the most sensitive to the most tolerant species, and it calculated hazard quotients (HQs) based on those ranges. This approach appropriately acknowledges the uncertainty about which other species best represents the receptor species in question.
 - Selecting a threshold effect value for the most sensitive species (chickens) as the sole basis for the IMPGs or even as the point of departure is overly conservative, given the documented extreme sensitivity of chickens to PCBs relative to other avian species, including wild piscivorous species. Doing so means that the goals for wild piscivorous and insectivorous birds would be based on small effect levels for a species that is hundreds to thousands of times more sensitive than those wild species.
 - This approach also fails to take into account the existence of studies on PCB effects on piscivorous and insectivorous avian species that are more closely related to the selected representative species than is the chicken.
 - Given the lack of site-specific and species-specific effects data for these receptors, use of a range of RMCs based on TRVs for various avian species is more appropriate than selection of a single point of departure. It would allow for evaluation in the

CMS of the extent to which remedial alternatives can achieve various levels in that range.

5. Narrative IMPGs for Ecological Receptors: EPA erred in directing GE, in these narrative goals, to define significant impairment of a subpopulation or community as a 20% or greater response relative to reference (EPA Letter, p. 4; Att. A, pp. 15, 23-28).

- EPA’s comments stated that, although the EPA Superfund program has not established numerical levels for risk reduction, “other guidance exists” for the establishment of an approximate 20% effect level as the threshold for ecological significance, relying primarily on a paper by Suter et al. (1995).
- The Suter et al. (1995) paper and other papers cited by EPA do not constitute Agency guidance. EPA cannot selectively choose among various papers in the literature and decide to call some of them “guidance.” In any event, even if it were guidance, Agency guidance does not impose binding requirements or criteria.
- From a scientific standpoint, the use of a 20% response relative to reference is not a bright line for determining a significant impairment of local populations and communities. The potential consequences of exceeding a 20% effect level will vary depending on the reproductive strategy of the receptor species and the nature of the endpoint being measured.
 - Some species, such as fish and many species of frogs and benthic invertebrates, have evolved reproductive strategies that are based on the production of many more offspring than will ultimately survive. Such “resilient” species will tolerate a 20% or even higher reduction in fecundity or survival better than a mammalian or avian species that produces only a few young per year. EPA recognizes this in the case of fish by specifying that a 50% effect (EC50) should be used to judge the significance of juvenile deformities (EPA Att. A, p. 24). However, EPA does not recognize that the same is true when dealing with malformations in frogs or in evaluating bioassays of benthic invertebrate species with similar reproductive strategies.
 - The use of an effects level to judge population-level impairment also depends on the endpoint involved. For endpoints with less relevance to the maintenance of healthy local populations, a 20% effect level may not have a population-level impact. The ERA recognized this in the case of sex ratio effects in frogs, for which it concluded that the EC20 was not biologically relevant and likely not of concern to local populations (ERA, Vol. 5, pp. E-116, E-142). However, the same is also true for other endpoints, such as a 20% reduction in growth of invertebrates in a laboratory bioassay or a 20% but transient effect on the growth of bird offspring.

6. Focus on Ecological Population/Community-Level Studies and Effects: EPA erred in directing GE to remove statements emphasizing population- and community-level studies and effects (EPA Att. A, pp. 12, 15, & 9).

- EPA’s comments agreed that the overall ecological goal (except for threatened and endangered species) is “to reduce ecological risks to levels that will result in the recovery and maintenance of healthy local populations and communities of biota” (EPA Att. A, p.10, quoting EPA, 1999, p. 3). However, it stated that it does not agree that all measurement endpoints must be at that level of ecological organization, and it noted that effects on individuals can be extrapolated to local subpopulation and community responses (EPA Att. A, p. 12). It thus directed GE to revise the text on ecological goals “to remove any bias toward a particular level of organization” (*id.*, p. 12), and to eliminate statements emphasizing certain field studies of local populations or communities – namely, the benthic invertebrate community study (*id.*, p. 15) and the field fish population surveys (*id.*, p. 9). These directives are unwarranted and inconsistent with EPA (1999) guidance, as discussed further below.
- GE has not claimed that all measurement endpoints must be at the population or community level of organization. It recognizes that effects on individuals can be extrapolated to local populations and communities. In doing so, however, to be consistent with EPA (1999) guidance, it is critical that the individual-level effects be evaluated in terms of how they would translate into impacts on local populations and communities. Thus, it is entirely appropriate for ecological goals to focus on local populations and communities.⁴
- Similarly, it is appropriate to emphasize well-conducted site-specific field studies that focus on the populations and communities of interest (such as the benthic invertebrate community study and the fish population surveys), because such studies directly examine the actual status of such populations and communities that have been exposed to the contaminants over many generations.
- EPA also erred in directing GE to remove the statement that “the predicted risks are uncertain given the absence of any obvious effects on the fish and wildlife populations and communities in the Rest of River area, which appear to be abundant, diverse, and thriving” (EPA Att. A, p. 13). Since PCBs have been present at elevated levels in the Primary Study Area (PSA) (between the confluence and Woods Pond Dam) for approximately 70 years, the facts that the field studies did not reveal any obvious large-scale population effects and that EPA’s own ecological characterization showed abundant, diverse, and thriving fish and wildlife throughout that area create uncertainty

⁴ The EPA (1999) guidance and EPA’s comments (EPA Att. A, pp. 10-11) note, as an exception to this general goal, that threatened and endangered species should be evaluated on an individual-organism basis. However, this does not affect the basic principle that ecological goals should focus on local populations and communities. Rather, it recognizes that, given the already stressed nature of the population of these species, individual-level effects could adversely impact the local population.

about the risks predicted in the ERA and should be considered in evaluating potential remedies.

7. Ranges for Ecological Receptors: EPA erred in rejecting ranges such as those proposed by GE for several groups of ecological receptors.

Benthic Invertebrates

- EPA position:
 - EPA’s comments directed GE to base the RMC for benthic invertebrates on the PCB MATC (EPA Att. A, p. 15). That MATC is 3 mg/kg in sediments, which was based on a combination of: (a) a chronic toxicity threshold of 2 mg/kg, based primarily on the lowest EC20 calculated for any test organism in the chronic toxicity tests (*Chironomus tentans* 20-day ash-free dry weight, a measure of growth); and (b) the geometric mean of the five lowest EC20 values calculated from the benthic invertebrate community study for both coarse and fine sediments together (which was 5.6 mg/kg) (ERA, Vol. 1, pp. 3-41, 3-57, 3-59).
 - In addition, the ERA identified an acute “intermediate-risk” toxicity threshold of 10 mg/kg, based on the geometric mean of the calculated 20% survival values (LC20s) from three *in situ* toxicity tests (10-day *Hyallela*, 10-day *Chironomus*, and 48-hour *Daphnia magna*) (ERA, Vol. 1, pp. 3-42, 3-59; Vol. 4, p. D-62).
 - EPA rejected GE’s proposal to include in the range of RMCs any EC50 values from either the toxicity tests or the benthic community study, as well as EC20 values for benthic community metrics other than the five lowest.
- GE position:
 - The use of EC50s, at least for some endpoints and species, is appropriate for benthic invertebrates based on their reproductive strategy (see Section 5 above).
 - For the benthic invertebrate community study, the EC20s derived from coarse sediments should not be applied to fine sediments, for which the EC20s were considerably higher.
 - In the event that the LC50s or other results from the *in situ* toxicity tests were used in developing an RMC range, the results of the 48-hour test with *Daphnia* should not be included. That test is less relevant than the 10-day *Hyallela* and *Chironomus* tests, since *Daphnia* is not a sediment-dwelling organism.
 - The use of a range of RMCs encompassing various species, endpoints, and effect sizes is appropriate to allow evaluation of the ability of remedial alternatives to achieve various cleanup goals within these ranges, depending the type and size of effect to be prevented, the relevance of the endpoints to local benthic communities, and the type of sediments present.

Amphibians

- EPA position:
 - EPA's comments directed GE to revise the RMC for amphibians to be the PCB MATC (EPA, Att. A, p. 23). That MATC is 3.27 mg/kg in vernal pool sediments, which was based on the calculated EC20 value for metamorph malformations in Phase III of EPA's wood frog toxicity study (ERA, Vol. 1, p. 4-53; Vol. 5, p. E-144).⁵
 - EPA rejected GE's proposal to include in the range of RMCs the EC50 value for metamorph malformations in Phase III of the wood frog study (38.6 mg/kg) and the EC20 and EC50 values for larval malformations in Phase I of that study (> 32.3 mg/kg).
- GE position:
 - The use of the EC50 for Phase III malformations is appropriate due to the reproductive strategy of frogs, which, like fish, produce many more offspring than will survive (see Section 5 above). It is thus consistent with EPA's use of the EC50 for juvenile malformations in the development of the MATC for fish.⁶
 - That level is also supported by the fact that the same study showed no PCB-related effects on survival, growth, or metamorphosis of the wood frogs. Although EPA stated that those endpoints are less sensitive (EPA Att. A, p. 20), survival and metamorphosis are more directly relevant to the potential impact of PCBs on local frog populations than the endpoints used by EPA to develop the MATC, in that they are a measure of the number of individuals that actually reach the next life stage.
 - The Phase I malformation data are relevant. Although EPA stated that those data were limited to external malformations whereas the Phase III data included both external and internal malformations (*id.*, p. 20), the Phase I data did include some internal malformations (ERA, Vol. 5, p. E-81, Table E.3-8) and thus are suitable for developing a range of RMCs.
 - EPA has erroneously rejected GE's analysis of net abnormality-free metamorph output in Phase I, which indicates that, even assuming that all malformations result in mortality, the rates of malformation observed did not significantly affect the net

⁵ All sediment PCB concentrations specified in this discussion of amphibians are based on the ERA's calculated spatially weighted mean concentrations.

⁶ EPA argues that this is not so because many of the observed internal malformations in frogs were malformations of female gonadal tissue, which can lead to sterility (EPA Att. A, p. 22). Even accepting that there could be a link between such malformations and lack of reproductive output in those females (which is a supposition), it is likely, given the reproductive strategy of these frogs and the strong density-dependence in frogs, that the local wood frog populations can readily tolerate a subset of females that are not reproductively active. See also note 7 below.

output of healthy metamorphs and thus would be unlikely to adversely affect the local frog populations.⁷

- The ERA acknowledged that the EC20 for sex ratio effects in Phase III of the study was too small to be biologically relevant (ERA, Vol. 5, pp. E-116, E-142). However, even the EC50 for sex ratio effects is inappropriate for development of RMCs, because the sex ratio data do not provide clear evidence of PCB-related adverse effects.
- Despite EPA's assertion that its community field surveys provide indications of potential harm to resident wood frog populations and are thus consistent with the wood frog study results (EPA Att. A, pp. 19-20), those surveys in fact provide multiple indications of no effects. The reported effects were likely artifacts of small sample size or inappropriate comparisons among ponds of different sizes, and observed malformations were not consistent with a PCB exposure-response relationship.
- In any event, the scientific literature suggests that both malformations and skewed sex ratio in frogs may result from numerous environmental conditions unrelated to PCB exposure.
- EPA's suggestion that other amphibian species, such as leopard frogs and salamanders, may be more highly exposed to PCBs than wood frogs due to differences in their life history (*id.*, p. 19) fails to recognize that several other factors besides length of time in a pond environment determine exposure.

Piscivorous Mammals, Represented by Mink

- EPA position: EPA's comments directed GE to revise the RMC for these mammals to be the MATC (EPA Att. A, p. 27). That MATC is 0.984 mg/kg in diet, based on a probit analysis of the 6-week kit survival data from the mink feeding study conducted by Bursian et al. (2003), for which the ERA calculated an LC20 of 0.984 mg/kg (ERA, Vol. 2, pp. 9-51, 9-54; Vol. 6, p. I-106). The comparable TEQ level is 16.2 ng/kg.
- GE position:
 - As noted above (in Section 1), the Bursian et al. (2003) study did not provide definitive evidence of an adverse effect on kit survival due to PCB exposure, even at the highest dose level.

⁷ Although Phase I could not have assessed gonadal development since that system would not have differentiated in Phase I, most of the female gonadal malformations observed in Phase III were associated with other, more obvious malformations which likely would have been observed in Phase I. The number of such gonadal malformations that would have been unaccounted for in the analysis of net abnormality-free metamorph output in Phase I is thus likely low, which further supports the conclusion that the malformations would be unlikely to affect the populations.

- Even accepting the Bursian et al. (2003) conclusions, the NOAEL from that study was 1.6 mg/kg PCBs (16.1 ng/kg TEQ) and the LOAEL was 3.7 mg/kg PCBs (68.5 ng/kg TEQ) (see ERA, Vol. 6, p. I-61). In these circumstances, it is reasonable to present a range of RMCs from the NOAEL to the LOAEL, as EPA (1997) guidance recognizes with respect to effect thresholds (see Section 4 above).

Omnivorous and Carnivorous Mammals, Represented by Short-Tailed Shrew

- EPA position: EPA's comments directed GE to revise the RMC for these mammals to be the PCB MATC (EPA Att. A, p. 28). That MATC is 21.1 mg/kg in floodplain soil, based on EPA's hockey stick regression of the arithmetic mean soil concentrations versus shrew survival from the site-specific shrew demography study conducted by Boonstra and Bowman (2003) (ERA, Vol. 2, p. 10-43; Vol. 6, pp. J-54 - J-55, Figure J.4-9).
- GE position:
 - As noted above (in Section 1), the Boonstra and Bowman (2003) study did not provide clear evidence of adverse PCB-related effects on shrew survival in any of the study grids. Although the ERA's statistical method indicated such an effect, other statistical methods of analyzing the data showed no PCB effect on survival.
 - Review of the ERA's hockey stick regression model (Figure J.4-9) shows that the MATC is at or below the NOAEL (since it lies on the zero slope phase of the curve reflecting background mortality and is in fact below two other data points that also lie on that curve), and that the LOAEL based on the arithmetic mean soil data is 34.3 mg/kg. Thus, the range of RMCs should at least encompass the range from the NOAEL to the LOAEL.
 - However, in this case, the upper bound of the range should extend higher, to at least 43.5 mg/kg, because: (a) even accepting EPA's regression method, use of the spatially weighted mean data (instead of the arithmetic mean data) would not support the above threshold levels based on the hockey stick regression; and (b) 43.5 mg/kg is the spatially weighted mean concentration of a grid that falls on the zero slope of the mortality curve representing background mortality.
 - The data show a very high abundance of short-tailed shrews in the PSA. Although EPA argued that abundance is not evidence of lack of effects (EPA Att. A, p. 28), it is a valid population-level assessment endpoint (EPA, 2003) and speaks to the success of the local population in the face of both natural and anthropogenic stressors.

Piscivorous Birds, Represented by Osprey

- EPA position:
 - EPA's comments stated that, for receptors for which MATCs were not calculated, the RMCs should be constrained to a concentration representing a 20% effect level or a 20% probability of exceeding the TRV for the most sensitive species identified in the

- ERA (EPA Letter, p. 4). For osprey specifically, EPA directed GE to base the RMC on the TRV for the most sensitive avian species (chicken) and a dietary exceedance probability of 20% (EPA Att. A, p. 25).
- For PCBs, the TRV identified in the ERA for chickens was 0.12 mg/kg-day, based on a 7% transient reduction in growth weight of chicks in the Lillie et al. (1974) study (see ERA, Vol. 6, p. H-46). Calculation of a 20% probability of exceeding that TRV in fish consumed by osprey would yield an extremely low PCB level, 0.16 mg/kg, in fish tissue.
 - Alternatively, calculations using a < 20% effect level for chickens from the same study – specifically, a TRV of 1.2 mg/kg-day, representing effect levels of 10-14% – would yield an RMC of 3.2 mg/kg in fish consumed by osprey.
- EPA rejected the use of a range of RMCs based on data for any species other than the chicken.
- GE position:
 - As noted in Section 4 above, basing the RMCs on a threshold effect value for chickens is highly over-conservative, given the documented extreme sensitivity of chickens to PCBs relative to other avian species, including wild piscivorous species, as well as the minor effects observed in chicken at those levels by Lillie et al. (1974).
 - This is particularly true since there are studies of potential PCB effects on piscivorous birds (e.g., bald eagles, which are more closely related to osprey than are chickens), as well as more recent studies on osprey themselves. The range of RMCs for piscivorous birds should include values based on PCB TRVs derived from such studies.
 - Use of a range of RMCs based on TRVs for various avian species (from the most sensitive to the most tolerant) is appropriate because it would allow for evaluation in the CMS of the extent to which remedial alternatives can achieve various levels in that range, depending on the species selected for protection.

Insectivorous Birds, Represented by Wood Ducks

- EPA position: As noted above, EPA's comments stated that, for receptors without MATCs, the RMCs should be constrained to a concentration representing a 20% effect level or a 20% probability of exceeding the TRV for the most sensitive species identified in the ERA (EPA Letter, p. 4). For wood ducks specifically, EPA directed GE to base the RMC on the TRV for the most sensitive avian species and a dietary exceedance probability of 20% (EPA Att. A, p. 26).
 - For PCBs, using the TRV identified in the ERA from the Lillie et al. (1974) chicken study (0.12 mg/kg-day), calculation of a 20% probability of exceeding that TRV would be 0.39 mg/kg in wood ducks' insect prey.

- Alternatively, calculations using a < 20% effect level for chickens from the same study (i.e., a TRV of 1.2 mg/kg-day, representing effect levels of 10-14%) would yield a PCB RMC of 4.4 mg/kg in wood duck prey.
- For TEQs, the ERA identified a range of TEQ concentrations in eggs (20-50 ng/kg) judged to have reproductive effects in the White and Seginak (1994) study of wood ducks (see ERA, Vol. 5, p. G-83). Calculation of a 20% probability of exceeding the lower bound of that TRV range (20 ng/kg) would yield an RMC of 14 ng/kg in wood duck prey.
- GE position:
 - Limiting the RMC for PCBs to a threshold effect value for chickens is highly over-conservative for the same reasons discussed above. In addition, for insectivorous birds, it would be appropriate to include in the range a PCB RMC based on a study by Custer and Heinz (1980) on mallards, which are closely related to wood ducks. Such an RMC would be 30 mg/kg in prey.
 - For TEQs, the RMC range should extend at least to a value based on the upper bound of the lower range of egg concentrations with reproductive effects in the White and Seginak (1994) study (i.e., 50 ng/kg), which would yield an RMC of 41 ng/kg in wood duck prey.

8. RMCs for Transient Osprey and Bald Eagles: EPA erred in directing GE to remove the calculations of RMCs for transient osprey and bald eagles, and to base all RMCs for these receptors on the assumption of 100% foraging time in the Rest of River area (EPA Att. A, pp. 24-25, 29).

- Ospreys are not a relevant representative receptor species for resident piscivorous birds since most osprey that breed in Massachusetts nest along the coast and there is no evidence of breeding or resident osprey in the Rest of River area. Rather, all osprey observed in this area were migratory transients. As a result, RMCs for transient osprey are more appropriate for this species than are RMCs for resident osprey.
- In any event, regardless of whether RMCs are calculated for resident osprey and bald eagles, it is useful to have a set of RMCs for transient osprey and eagles (i.e., those migrating through the Rest of River area), so as to allow evaluation in the CMS of the extent to which remedial alternatives would achieve either of those sets.

9. TEQ RMCs for Bald Eagles: EPA erred in directing GE to calculate RMCs for TEQs in bald eagles (EPA Att. A, p. 9).

- EPA's directive to generate an RMC for bald eagles for TEQs, as well as PCBs, was based on the assertion that the TEQ HQ (~5) exceeded the PCB HQ (~4) (see ERA, Vol. 2, Figures 12.2-3 & 12.2-4). It was not based on differences in the overall risk characterization for PCBs and TEQs from the weight-of-evidence analysis.

- The slight differences in HQs are not meaningful when modeling uncertainty is considered.
- More significantly, the bald eagle PCB TRV was based on a measure of reproductive impairment, whereas the TEQ TRV was based on a no-effect level for induction of a biomarker (CYP1A) in a bald eagle study that found no adverse effect of TEQs on any reproductive endpoint, but only elevated biomarkers of exposure. The use of such biomarkers to estimate risks or to develop ecological goals conflicts with the ERA's selected assessment and measurement endpoints and with basic tenets of ecological risk assessment.

10. Attaining Designated Uses in MA and CT Water Quality Standards: EPA erred in directing GE to state, in the narrative goals for human health and ecological receptors, that the “desired outcome” is that, for PCBs, the Rest of River area will attain the designated uses defined in the Massachusetts and Connecticut Water Quality Standards (EPA Att. A, pp. 2, 6, 10), insofar as that directive required GE to treat that “desired outcome” as a separate IMPG.

- The Permit requires that the IMPG Proposal show that the proposed IMPGs would ensure the protection of human health and the environment, taking into account the EPA risk assessments. It does not require a showing that the proposed IMPGs would result in attainment of any particular designated uses.
- Thus, to the extent that EPA's directive requires that GE separately evaluate, as an IMPG, the ability of remedial alternatives to attain EPA's stated “desired outcome,” it is unwarranted because the other IMPGs are adequately protective of human health and the environment.
- While the Permit also requires that the IMPG Proposal must take into account ARARs, GE's September 2005 IMPG Proposal identified potential chemical-specific ARARs for the Rest of River, and GE's revised IMPG Proposal will likewise identify such ARARs for use as an evaluative criterion in the CMS, subject to waiver if the conditions for waiver are met. See note 1 on page 3 above.

11. Impact of Traditional Schaghticoke Fish Consumption Practices: EPA erred in directing GE to discuss the quantitative impact of “the traditional fish preparation practices of the Schaghticoke Reservation” on the RMCs for fish consumption (EPA Att. A, p. 6).

- The HHRA stated that members of the Schaghticoke Tribal Nation “have expressed a desire to return to traditional fish cooking practices, which include slow cooking whole fish (minus the head) coated with mud and then wrapped in foil” (HHRA, Vol. IV, p. 7-32).

- That expressed desire during EPA's oral interviews of a few individuals is not sufficiently objective to constitute a "reasonably anticipated" future exposure scenario (see EPA, 1995), and thus does not justify EPA's directive.
- Moreover, it is not clear whether the Schaghticoke Tribal Nation (whose members were interviewed by EPA) or the separate Schaghticoke Indian Tribe is in fact the actual tribe entitled to the Schaghticoke Reservation; and neither of those tribes has received federal recognition. In these circumstances, the results of the interviews cannot be considered to constitute reliable evidence of historic practices and customs of indigenous communities, such as to warrant separate evaluation in the IMPG Proposal or the CMS.

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