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March 17, 2010

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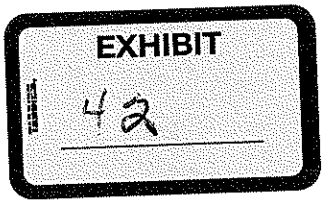

Re: Comments on Proposed Amendments to Water Quality Standards

Dear Ms. Iott:

Enclosed are comments of the General Electric Company (GE) on the Department's proposed revisions to the Connecticut water quality standards. Given the inadequate time for review of the technical bases for the many proposed new and revised standards, these comments focus on a general procedural point (the Department's failure to process these standards as regulations under the Uniform Administrative Procedures Act) and on the basis for one standard (the proposed revised health-based standard for polychlorinated biphenyls), which we show is not scientifically defensible.

Please let us know if you would like additional information relating to these comments.

Very truly yours,

Roderic J. McLaren
Counsel, Pittsfield/Housatonic River Remediation

Enclosure

cc: Betsey Wingfield, CTDEP
Denise Ruzicka, hearing officer
Susan Peterson, CTDEP
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COMMENTS OF THE GENERAL ELECTRIC COMPANY ON PROPOSED REVISIONS TO CONNECTICUT WATER QUALITY STANDARDS

March 17, 2010

Introduction and Background

The General Electric Company (GE) is submitting these comments on the proposed revisions to the Connecticut water quality standards (WQS), which were published by the Connecticut Department of Environmental Protection (CTDEP) on December 22, 2009, pursuant to Section 303 of the federal Clean Water Act (CWA) and Conn. Gen. Stat. § 22a-426.

These proposed revisions consist of an extensive set of major changes to the state WQS, including proposed new aquatic life and/or human health-based standards for over 130 compounds for which such standards did not previously exist and proposed reductions in the level of the standards for over 90 compounds. Given these extensive proposed revisions, together with the fact that CTDEP's technical supporting document was not available until just before the public hearing on these proposed revisions on February 3, 2010, CTDEP has not provided adequate time to comment on the bases for the numerous proposed revisions. In these circumstances, these comments focus on: (1) a key procedural defect in CTDEP's proposal, i.e., its decision not to process or adopt the revised WQS as "regulations" under the Connecticut Uniform Administrative Procedures Act (UAPA) (Conn. Gen. Stat. § 4-166 *et seq.*); and (2) the scientific basis for one proposed standard, the proposed revised human health-based standard for polychlorinated biphenyls (PCBs), based on consumption of organisms or water and organisms.

With respect to the latter, CTDEP has proposed to lower the health-based WQS for PCBs from its current level of 0.00017 µg/L (170 parts per quadrillion [ppq]) to 0.00000056 µg/L (0.56 ppq). That proposed standard is two orders of magnitude lower than the United States Environmental Protection Agency's (EPA's) national recommended water quality criterion for PCBs based on health protection, which is 0.000064 µg/L (64 ppq) (EPA, 2009). CTDEP's technical supporting document (CTDEP, 2010) shows that the proposed revised health-based standard is based on the assumption that PCBs cause cancer in humans. To represent the carcinogenic potential of PCBs, it uses EPA's Cancer Slope Factor (CSF) of 2 $(mg/kg\text{-}day)^{-1}$, listed in EPA's Integrated Risk Information System (IRIS). That document also presents the other assumptions and inputs used in calculating the proposed standard, including a bioconcentration factor (BCF) of 31,200 plus an additional food chain multiplier of 100. However, as discussed below, that document does not provide a defensible rationale for some key inputs.

As we show below, CTDEP is acting contrary to state law by failing to process the proposed revised WQS as regulations subject to the UAPA. As a result, those WQS will not be valid under state law and will not be approvable by EPA under the CWA. In addition, CTDEP's proposed revised health-based standard for PCBs is based on a number of assumptions and

methods that are not scientifically defensible and for which CTDEP has not provided an adequate rationale, in contravention of the requirements of the CWA. The defects in this one proposed standard suggest that there could likewise be scientific deficiencies in other proposed revisions to the WQS.

1. CTDEP Is Acting Contrary to State Law by Refusing to Issue the Water Quality Standards as Regulations Subject to the UAPA.

Section 4-166(13) of the UAPA defines "[r]egulation" as "each agency statement of general applicability without regard to its designation, that implements, interprets, or prescribes law or policy, or describes the organization, procedure, or practice requirements of any agency." Section 4-168 of the UAPA establishes the procedures to be followed by agencies in adopting regulations, including notice and hearing. It also requires that the agency prepare a fiscal note on the revenue impact of the proposed regulation on the state and any municipality and an analysis of the impact on small businesses. It further provides that no regulation may be adopted, amended or repealed by any agency until it is approved by the Attorney General as to legal sufficiency, approved by the standing Legislative Regulations Review Committee and filed with the Secretary of the State. These procedures are intended to ensure not only that the technical basis for proposed regulations is adequate, but also that the impacts on state and local governments and the regulated community are understood and considered.

Section 22a-424(l) of the Connecticut statutes directs CTDEP to adopt regulations in accordance with the UAPA to implement the state statutes on water pollution control (including Conn. Gen. Stat. § 22a-426) and the federal CWA. Despite this directive, however, CTDEP follows a more limited process in adopting and amending WQS. It complies with some but not all of the notice requirements of Section 4-168, does not prepare a fiscal note, does not prepare an analysis of the impact on small businesses, and does not submit the proposals to the Legislative Regulations Review Committee or the Secretary of the State; and the resulting WQS are not codified in the Regulations of Connecticut State Agencies. It is our understanding that CTDEP intends to follow that limited process in adopting the current set of WQS revisions, thus omitting many of the safeguards provided by the UAPA procedures.

It is clear, however, that the WQS meet the UAPA definition of a "regulation." They are statements of general applicability that prescribe law or policy, because, among other reasons, they (a) form the basis for numerous specific regulatory requirements governing discharges of wastewaters to the waters of the State, (b) are incorporated by reference in the Remediation Standard Regulations governing cleanups (see RCSA § 22a-133k-3(b)(2)), and (c) are applied by CTDEP in issuing water quality certifications under § 401 of the CWA on applications for permits to discharge dredged or fill material into waters of the State pursuant to § 404 of the CWA. The Connecticut Supreme Court has long and consistently held that the only lawful way for an agency to adopt such a policy is through the rulemaking procedure spelled out in the UAPA, and that an agency statement meeting the UAPA definition of a regulation (regardless of how it is designated) may not be applied or enforced unless it has been duly promulgated as required by law. E.g., *Salmon Brook Convalescent Home, Inc. v. Commission on Hospitals and Health Care*, 177 Conn. 356 (1979); *Walker v. Commissioner, Dept. of Income Maintenance*,

187 Conn. 458 (1982). As the Court has stated, under the UAPA: "The criteria that determines whether administrative action is a regulation are neither linguistic nor formalistic. . . . The test is, rather, whether a [policy] has substantial impact on the rights of parties who may appear before the agency in the future." *Sweetman v. State Elections Enforcement Comm'n*, 249 Conn. 296, 317 (1999) (internal quotation marks omitted). Since the WQS have such a substantial impact, the revised WQS will not be valid under state law unless they are issued as regulations under the UAPA.

Moreover, EPA's regulations under the CWA require that, in reviewing a state's WQS for approval, EPA must independently determine "[w]hether the State has followed its legal procedures for revising or adopting standards" (40 C.F.R. § 131.5(a)(3)). If EPA finds that the state did not do so, EPA "must disapprove" those standards under § 131.5(b). See *Fla. Public Interest Research Group Citizen Lobby, Inc. v. EPA*, 386 F.3d 1070, 1087 (11th Cir. 2004). In addition, EPA's regulations require that, as a part of the submission of a state's water quality standards, the state attorney general certify that those standards "were duly adopted pursuant to State law." 40 C.F.R. § 131.6(e). Indeed, unless the standards are "duly adopted," EPA may not consider them for approval under §303 of the CWA. See *Kentucky Waterways Alliance v. Johnson*, 540 F.3d 466, 488, 493-94 (6th Cir. 2008). In this case, if CTDEP does not adopt the revised WQS as regulations under the UAPA, they would not be "duly adopted" in accordance with the State's own legal procedures, and thus would not be approvable by EPA under the CWA.

2. CTDEP's Proposed Health-Based Water Quality Standard for PCBs is Based on Assumptions and Methods That Are Not Scientifically Defensible, Contrary to Clean Water Act Requirements.

Section 303 of the CWA and EPA's regulations thereunder require that a state develop its water quality standards using sound scientific methods and base those standards on a sound scientific rationale. See 40 C.F.R. § 131.11(a) (WQS must be based on "sound scientific rationale"); see also *Pennaco Energy, Inc. v. U.S. Envtl. Prot. Agency*, 2009 WL 6024157, slip op. at 34 (D. Wyo. 2009) (requiring EPA, on review of a state's WQS, to determine whether that standard was supported by appropriate scientific data). EPA's regulations require further that, when a state establishes numeric criteria that deviate from EPA's national recommended criteria for a given pollutant, as CTDEP proposes to do here in the case of the health-based standard for PCBs, those criteria must be based on "scientifically defensible methods." 40 C.F.R. § 131.11(b)(1)(iii). Further, in submitting revised standards to EPA for review, the state must include, as minimum requirements for that submission, the "methods used and analyses conducted to support water quality standards revisions." 40 C.F.R. § 131.6(b).

The proposed health-based standard for PCBs does not meet these requirements for the following reasons.

a. The proposed PCB standard assumes that PCBs cause cancer in humans, which is not supported by reliable scientific evidence.

The proposed health-based standard for PCBs is based on assumed carcinogenic effects of PCBs in humans, as represented by EPA's CSF of 2 $(mg/kg\text{-}day)^{-1}$, which was based on studies of laboratory rats (EPA, 1996). While that CSF comes from IRIS, it assumes that PCBs cause cancer in humans. In fact, the vast body of human epidemiological studies has provided no reliable evidence that PCBs cause cancer in humans. These studies include both highly exposed worker populations and populations exposed to lesser environmental background levels.

In total, more than 50 peer-reviewed, epidemiological cancer studies specific to PCBs have been published over the past 30 years. Many of those studies involved thousands of workers with occupational exposures far greater than those that would result from environmental exposures. None of those studies supports a finding that PCBs are human carcinogens.

One study, Kimbrough et al. (1999), as updated by Kimbrough et al. (2003), is particularly noteworthy. That study represents one of the largest studies ever conducted of workers who were heavily exposed to PCBs. The cohort consisted of 4,062 men and 3,013 women who worked between 1946 and 1977 at two GE capacitor manufacturing facilities. The average follow-up time for the workers was 31 years, providing the longest latency period of any PCB-exposure occupational study. Kimbrough et al. (1999) reported the findings on following this cohort through 1993. They found that, among all workers, including those classified as having the highest PCB exposure, there was no statistically significant increase in deaths due to cancer or any other disease compared to the general U.S. population. Kimbrough et al. (2003) followed the same cohort through 1998. That update similarly found that, among all workers, including those classified as having the highest PCB exposure, there were no statistically significant increases in deaths due to cancer. There were also no statistically significant increases in cancer or other mortality associated with length of employment or latency.

Golden et al. (2003) prepared a technical monograph that discusses the findings of Kimbrough et al., as well as all of the other human evidence relating to the potential carcinogenicity of PCBs. In all cases where isolated instances of cancer had been reported and putatively associated with exposure to PCBs, subsequent studies that were better designed, more appropriately controlled for potential confounders, statistically more powerful, encompassing longer latency periods and otherwise more robust, did not confirm the original findings. This paper concluded that "[a]pplying a weight-of-evidence evaluation to the PCB epidemiological studies can only lead to the conclusion that there is no causal relationship between PCB exposure and any form of cancer."

Recently, Golden and Kimbrough (2009) conducted a weight-of-evidence evaluation of PCB carcinogenicity in humans as a follow-up to the earlier evaluation (Golden, 2003), incorporating new studies that had been published in the intervening years. These authors again concluded that "the weight of evidence does not support a causal association for PCBs and human cancer."

In a separate line of evidence, Silkworth et al. (2005) investigated whether the animal bioassays accurately predict the human carcinogenicity of PCBs. These studies showed that human cells respond differently to PCBs than do rat cells. Human cells require higher doses to elicit a response, and the potency of the most potent PCB congener is much less than what is predicted via rat bioassays. These results provide empirical evidence that the assumption that humans have an equivalent carcinogenic response to PCBs, which underlies the use of the rodent-derived CSF in assessing risks to humans, is incorrect.

All of this information indicates that application of the PCB CSF, as used in deriving CTDEP's proposed health-based WQS for PCBs, is based on an erroneous assumption of PCB carcinogenicity in humans.

b. CTDEP's application of a Food Chain Multiplier of 100 in deriving its proposed health-based WQS for PCBs is scientifically inappropriate and unjustified.

Even with use of EPA's CSF, CTDEP's proposed standard of 0.56 ppq for PCBs is not based on a scientifically defensible method because it is based on use of an unjustified food chain multiplier (FCM) of 100 in addition to the bioconcentration factor (BCF). Use of these combined factors results in double-counting the bioaccumulation of PCBs as they move through the food chain.

In deriving all of its proposed WQS for human health protection, CTDEP has used both a BCF and an FCM (CTDEP, 2010). This was apparently done without consideration, on a chemical-specific basis, of whether the application of an FCM in addition to the BCF was appropriate. A BCF is used to represent the ratio of a chemical concentration measured in organisms to that measured in water – i.e., the increase in concentration in going from water to organisms. In many cases, the BCFs are based on the relationship between the concentration of a constituent in water and the concentration of that constituent measured in organisms that are low in the food chain, such as benthic invertebrates, and not consumed by humans (EPA, 2000). In such cases, an FCM is used to reflect the increase in tissue concentration as constituents move up the food chain from lower-level organisms to the higher-level organisms that are consumed by humans. Tissue concentrations of lipophilic compounds, such as PCBs, generally increase as they move up through the food chain into higher-trophic-level organisms, such as game fish. As a result, concentrations in those fish are generally greater than concentrations in the lower-level organisms for which BCFs are typically measured. Since WQS for compounds that bioaccumulate in fish tissue are based largely on the exposure that is assumed to result from human consumption of that tissue, an FCM is meant to adjust for those differences and provide an estimate of the concentration of those chemicals in the edible portions of the upper-trophic-level fish that humans consume.

For each constituent for which CTDEP has developed a proposed WQS, CTDEP has selected an FCM. But it does not appear to have considered whether application of such a factor is necessary or appropriate for individual compounds. While it may be appropriate to apply an additional factor if the BCF value used in deriving the WQC is a measure of the concentration in organisms that are not consumed by humans, that is not the case for PCBs.

The BCF value of 31,200 L/kg that was used by CTDEP for PCBs is the same value that has been used by EPA since 1980 (EPA, 1980, 2009) to develop its ambient water quality criteria for PCBs. That value was based on data for upper-trophic-level fish species including rainbow trout, brook trout, white sucker, bluegill, and channel catfish (EPA, 1980).[1] These are species of fish that are commonly targeted for consumption by anglers. Therefore, this BCF value already provides a measure of the difference between the concentration of PCBs in the water column and the concentration of PCBs in the tissues of edible fish, thereby accounting for movement of PCBs up the food chain. In other words, the BCF already accounts for the increase in PCB concentration from the water column to the edible tissue of game fish that are consumed by humans.[2] In this situation, there is no need or justification to make a further adjustment by the addition of an FCM, as was done by CTDEP. Thus, CTDEP should not have applied an FCM at all in deriving the PCB WQS.

In its technical support document, CTDEP (2010) has not provided any justification for the double-counting that results from using an FCM in situations like this where the BCF is already based on the organisms consumed by humans. As such, that document does not meet the CWA requirement to provide scientific support for its proposed revised PCB standard.

As previously mentioned, the above-described scientific deficiencies in the proposed revised PCB standard suggest that there could likewise be scientific deficiencies in other proposed revisions to the WQS.

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[1] EPA evaluated the available BCF data for fish tissue in such species; and since bioaccumulation in fish tissue is affected by the percent lipid in that tissue, EPA normalized the BCFs for the individual studies to derive an adjusted BCF for each, at a 1% lipid level, so that the values for all studies would be directly comparable. Then EPA averaged those lipid-normalized BCFs to calculate an average lipid-normalized BCF of 10,385 L/kg at the 1% lipid level. Finally, EPA evaluated the available data on lipid levels in fish and shellfish that were consumed nationwide, determined that the average lipid content was 3%, and then adjusted the value of 10,385 L/kg (based on 1% lipid) to reflect this higher lipid content, resulting in the final value of 31,200 L/kg.

[2] In fact, this BCF is conservative in its estimate of the level of PCBs in the edible portions of fish. That BCF was based on a combination of BCF data from whole body fish as well as fish fillets. Only 3 of the 10 BCF values for game fish that were included in the calculation were BCFs for the fillet portions of the fish, while the remaining 7 values were based on whole body fish samples. Lipid contents and PCB levels in whole body samples are known to be higher than those in the fillets. As a result, this BCF likely overestimates actual accumulation in the fillet portion, which is the portion that is generally consumed.

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