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ORIGINAL BY EMAIL

May 16, 2013

Department of Environmental Protection
Bureau of Waste Site Cleanup
One Winter Street, 6th Floor
Boston, MA 02108
Attn: Elizabeth Callahan

Re: Proposed Revisions to the Massachusetts Contingency Plan, 310 CMR 40.0000, et seq.

Dear Ms. Callahan:

Associated Industries of Massachusetts (AIM) is pleased to comment on the above proposed regulations. AIM is the largest trade association in Massachusetts, with over 5000 member companies, many of whom will be impacted by these proposed regulations.

In that regard, AIM would like to go on record supporting the entire comments of NAIOP and those of Dominion Energy Brayton Point, L.L.C which relate to the change in the Vanadium standard and the proposed definition of historic fill. AIM would also like to add one additional comment regarding the Massachusetts Department of Environmental Protection (MassDEP) proposal to change its long-standing Method 1 S-1 soil standard for PCBs from 2 mg/kg to 1 mg/kg.

MassDEP has explained that the prior standard for PCBs (like those for lead and zinc) was set to equal the Massachusetts Water Resources Authority (MWRA) regulatory limit for PCB in the land application of sludge, but that "[o]ver time, … the actual concentrations of these chemicals in sludge have been well below the limits applied to the soil standards," and besides "the MCP contains a specific notification exemption for such residuals." Proposed MCP Amendments – Redline/Strikeout Version at p. 128. Thus, MassDEP is proposing "to discontinue using sludge limits as the basis for these standards," and, instead, to set the Method 1 S-1 soil standard for PCBs at 1 mg/kg "to be consistent with the remediation goal used by U.S.EPA at many sites where MassDEP has joint jurisdiction with that agency." *Id.*

This proposed change is unjustified. One of the cornerstones of the MCP is certainty. The default Method 1 soil standard of 2 mg/kg for unrestricted use has been in place since 1993, and has been

applied as the cleanup level at many sites in Massachusetts. MassDEP should not change such a long-standing default standard unless there is a compelling, risk-based justification for doing so.

In this case, changing the standard simply to be consistent with a remediation goal used by EPA at many sites (which is not even a regulatory limit) is not justified by the science. As shown below, EPA's remediation goal is based on an outdated PCB toxicity value and a key exposure assumption that is not applicable in Massachusetts.

EPA established the 1 mg/kg level for PCBs in soil as a "starting point action level" or "preliminary remediation goal" for unlimited exposure scenarios in guidance issued in 1990, more than 20 years ago (EPA, 1990, p. 26). That guidance document stated, based on a risk analysis done at that time using a residential land use scenario, that a PCB concentration of 1 mg/kg "equates to approximately a 10^{-5} excess cancer risk assuming no soil cover or management controls" (*id*. at p. 28). Thus, EPA concluded that that concentration reflects a "protective, quantifiable concentration for soil" in residential scenarios, and "should therefore be *the starting point for analysis* at PCB-contaminated Superfund sites where land use is residential" (*id*.; emphasis added).[1] The risk calculations in the 1990 guidance used a cancer slope factor (CSF) of 7.7 $(mg/kg\text{-}day)^{-1}$ (*id*. at Appendix B, p. 4). However, in 1996, EPA issued a revised dose-response assessment of PCBs, which was incorporated in EPA's Integrated Risk Information System (IRIS), establishing a range of lower CSFs for PCBs, the highest of which is 2 $(mg/kg\text{-}day)^{-1}$ (based on PCB Aroclor 1254). That alone indicates that the 1 mg/kg goal is overly conservative by 3-4 times at the same target risk level. Moreover, the risk calculations in EPA's guidance were based on various default exposure assumptions that would apply nationwide, including an assumed exposure frequency of 365 days per year for soil ingestion (see *id*. at Appendix B, p. 1). Conditions in Massachusetts will be different, in particular because both EPA and MassDEP assume that direct contact with soil in New England will not occur during the winter months when the ground is frozen or snow-covered, and thus it typically evaluates direct contact with soil in a residential scenario for the seven warmer months of the year (i.e., 5 days per week for 30 weeks, or 150 days per year).[2]

A decade after EPA's issuance of the above-referenced guidance, EPA Region I conducted a risk analysis of a 2 mg/kg cleanup level for residential areas in Massachusetts, using conservative residential exposure assumptions that would apply in Massachusetts, including an exposure frequency of 150 days per year, together with EPA's current toxicity values for PCBs set forth on IRIS (EPA, 1999). That analysis showed that a cleanup level of 2 mg/kg in soil equates to an excess cancer risk of $4x10^{-6}$ and a non-cancer hazard quotient of 0.8 (*id*. at p. 11). Thus, EPA's 1999 analysis demonstrates that a 2 mg/kg standard in Massachusetts is in fact *more* protective than was indicated by EPA's nationwide analysis of a 1 mg/kg goal in its 1990 guidance.

The lack of justification for reducing the existing Method 1 soil standard for PCBs is further demonstrated by the scientific evidence showing that even the current the PCB cancer and non-cancer toxicity values set forth on IRIS, which are based on studies of laboratory animals, substantially overstate both the carcinogenic potential and the non-cancer impacts of PCBs in humans. Detailed reviews by Golden et al. (2003) and Golden and Kimbrough (2009) of the human epidemiological studies on cancer have shown that there is no causal relationship between

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[1] The guidance noted further that lower concentrations "are generally not quantifiable and in many cases will be below background concentrations" (*id*.)

[2] For EPA, see the risk analysis discussed below. For MassDEP, see the MassDEP spreadsheets used for derivation of Method 1 S-1 soil standards.

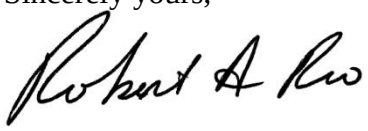
PCB exposure and any form of cancer.[3] Similarly, a comprehensive review of the non-cancer data by Bernier et al. (2001) demonstrates that, with the possible exception of dermal (skin) and ocular (eye) effects in highly exposed PCB workers, there is no reliable evidence that PCB exposure has caused adverse non-cancer health effects in humans.

Moreover, studies have demonstrated clearly that human cells are many times less sensitive to PCBs (particularly the most potent PCB congener, PCB 126) than the cells of the laboratory test animals (rats and monkeys) used in the studies on which EPA's toxicity values are based, potentially by several orders of magnitude (Silkworth et al., 2005; Westerink et al., 2008; Carlson et al., 2009; Sutter et al., 2010). In addition, the 2006 report by the National Research Council on EPA's Dioxin Reassessment concluded that the evidence on dioxins, including the "dioxin-like" PCB congeners, favors a threshold below which those compounds would not have carcinogenic effects, rather than the EPA assumption that those compounds cause such effects in a linear fashion that is directly proportional to exposure at any and all exposure levels (NRC, 2006, pp. 121-22, 141-42). These studies confirm that the animal-based PCB toxicity values on IRIS are overly conservative in representing the toxicity of PCBs to humans.

In any event, regardless of the debate on the appropriate toxicity values for PCBs, EPA's 1999 analysis mentioned above demonstrates that, even using EPA's values, the current Method 1 soil standard of 2 mg/kg is wholly adequate to protect public health in Massachusetts. Given that showing, together with the fact that the regulated community has relied on that standard for 20 years and that many sites in the Commonwealth have achieved a Permanent Solution and Class A Response Action Outcome based on achievement of that standard, there is no risk-based justification for now reducing that standard to 1 mg/kg, with its attendant additional costs.

Thank you for allowing us to comment on these proposed regulations. Should you have any questions please do not hesitate to contact me at 617-488-8308.

Sincerely yours,



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[3] For example, Kimbrough et al. (1999) and Kimbrough et al. (2003) studied a cohort of over 7,000 occupationally exposed workers in two General Electric capacitor plants and found no statistically significant increase in deaths due to cancer regardless of the degree of PCB exposure of the workers or the length of their employment in the plants.

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