June _, 2010

BY HAND

EPA Docket Center Public Reading Room
EPA Headquarters West
Room 3334
1301 Constitution Avenue, NW
Washington, DC

Re: Docket ID No. EPA-HQ-OW-2008-0747

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. ("HSIA") offers these comments on the results of EPA's review of existing National Primary Drinking Water Regulations ("NPDWRs"), announced at 75 Fed. Reg. 15499-15572 (March 29, 2010). HSIA represents producers and users of trichloroethylene ("TCE") and tetrachloroethylene (also known as perchloroethylene or "perc"), two of the four compounds whose NPDWRs EPA has identified as candidates for revision.

Implications of Lower MCLs for Public Water Systems

HSIA understands that EPA must implement the Safe Drinking Water Act ("SDWA" or the "Act"), which requires the maximum contaminant level ("MCL") of a contaminant in water delivered to a user of a public water system to be "as close to the maximum contaminant level goal [MCLG] as is feasible." SDWA § 1412(b)(4)(B). Where available treatment technology can reliably remove a contaminant to levels below the MCLG, it is feasible to set the MCL equal to the MCLG. As EPA has recognized, however, "[f]or contaminants with MCLGs at zero (substances in Group A or B), the analysis is somewhat different because detection and achievement of zero concentration in principle cannot be achieved. In the MCL-setting process, therefore, EPA evaluates the feasibility of achieving levels as close to zero as feasible." 52 Fed. Reg. 25690, 25699 (July 8, 1987). "Feasible" is defined as "feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking costs into consideration)." SDWA § 1412(b)(5)

EPA has also recognized analytical constraints in establishing MCLs for substances classified as potential human carcinogens, whose MCLG is zero, "a level which by definition is not 'feasible' because no analytical method is capable of determining whether a contaminant level is zero." 55 Fed. Reg. 30369, 30425 (July 25, 1990). Under existing policy, EPA considers the practical quantitation level ("PQL") to be the lowest level that can reliably be measured, and therefore a "lower-bound constraint in setting the MCL." *Id.* For some programs, EPA uses a single laboratory method detection limit ("MDL"), developed under research conditions, as the baseline for reporting contaminant concentrations. EPA has recognized, however, that:

> "In the drinking water program, standards are applied nationwide to potentially thousands of public water systems instead of a limited number of facilities as for NPDES [National Pollutant Discharge Elimination System] permit limitations. Therefore, it is not practical for EPA to tailor MCLs to the capabilities of the best analytical laboratories. While the MDL may be acceptable for setting permit limitations for carcinogens under the NPDES permits program, the drinking water standards consider the lowest concentration routinely achievable by good laboratories within specified performance limits."

*Id.* at 30426.

For both TCE and perc, EPA appropriately has recognized that its Performance Testing ("PT") data "are insufficient to recalculate a revised PQL for [perc, TCE] because not enough data points are available below the current PQL [5 ppb] to derive a value at the 75 percent passing rate." 75 Fed. Reg. at 15557, 15564. In concluding that it could derive an Estimated Quantitation Level ("EQL") below the PQL, EPA relies on both minimum reporting levels ("MRLs") and MDLs. HSIA supports EPA's stated preference for laboratory performance data. *Id.* EPA also notes that New Jersey uses a PQL for these compounds of 1 ppb, based on a 1987 study of laboratory performance. There has not been sufficient time for HSIA to review the 1987 study. While not disagreeing with the premise that there is potential to lower the current PQL for these compounds, we question the basis for EPA's identification of a PQL of 1 ppb (not to mention selection of 0.5 ppb (the modal MRL) as the EQL), and urge EPA instead to establish a PQL that is demonstrably achievable by public water systems nationwide.

Analytical issues aside, it is clear as noted above that EPA must take cost into account in determining the feasibility of an MCL. At the time that it established the current MCL of 5 ppb for TCE, EPA concluded that Granular Activated Carbon (GAC) and Packed Tower Aeration (PTA) constituted Best Available Technology ("BAT") for it and similar compounds, based on performance and cost. To determine what level was feasible at BAT, EPA examined compliance costs at various levels of contamination. For four compounds with zero MCLGs, EPA estimated total capital costs of $280 million for 1300 community water systems ("CWS") to achieve a 5 ppb MCL. 52 Fed. Reg. 25690, 25699.[1] To achieve 1 ppb, EPA estimated that 3800 CWS would need to install treatment at a total capital cost of $1.3 billion to achieve compliance. Obviously, these costs will need to be reassessed. Among other things, EPA will need to consider the feasibility of modifying existing treatment to comply with lower MCLs, how many systems will need to install additional treatment to comply with lower MCLs, and how many systems will no longer be able to rely on blending to comply with lower MCLs. HSIA does not have access to such information.

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[1] A fifth compound with a zero MCGL, vinyl chloride, was excluded from this analysis because its MCL was set at 2 ppb with no cost increase over 5 ppb, reflecting the treatment capability of PTA.

In addition to the cost issues facing public water systems, there is another significant set of costs that will be imposed by reduction in the MCLs of TCE and perc. Those are addressed below.

Implications of Lower MCLs under Superfund

Lower MCLs will have a direct impact on cleanup costs for groundwater contamination. Under the Comprehensive Environmental Response, Compensation & Liability Act ("CERCLA") remedial action must "require a level or standard of control which at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act . . . where such goals . . . are relevant and appropriate under the circumstances of the release." CERCLA § 121(d)(2)(A). Under the National Contingency Plan that governs Superfund cleanups, potential drinking water sources must be cleaned up to the Maximum Contaminant Level Goal (MCLG), except that "[w]here the MCLG for a contaminant has been set at a level of zero, the MCL . . . shall be attained . . . where the MCL is relevant and appropriate under the circumstances of the release based on [enumerated] factors." 40 CFR 300.430 (e)(2)(i)(C). This greatly enlarges the scope of the feasibility analysis, as there are hundreds of Superfund sites where remediation costs are driven by TCE and/or perc.[2]

It is important to note at the outset that cleanup costs must be considered by EPA in determining feasibility under the SDWA. Section 1412(b)(3)(C)(i) provides:

> "When proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis of . . .
>
> "(III) Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level . . . ."

Nowhere does the Act preclude the consideration of or discount costs that will occur from cleanup required by other statutory authority, even though those costs will not be borne (or intermediated) by public drinking water systems.

To assist EPA's consideration of feasibility of lower MCLs for TCE and perc, HSIA has asked Tetra Tech, a leading provider of consulting, engineering, and technical services with extensive experience in hazardous waste site remediation, to review the cost implications of a range of lower MCLs for TCE (and, by extension, perc) based on available data compiled for the

[2] Virtually all of these sites are legacies of a time when there was no legal/regulatory framework governing the disposal of these and other hazardous wastes. Current laws and regulations, notably the CERCLA ban on land disposal from the early 1980s, and manufacturers' instructions for use and disposal, have for decades prohibited disposal of these compounds in ways that could result in groundwater contamination.

US Air Force. The Tetra Tech paper is attached. Using projected costs to remediate two representative plumes, and extrapolating the cost differentials to an estimated 2000 affected plumes, Tetra Tech conservatively estimates a nationwide cost increase of $212 billion if the MCL for TCE were lowered to 0.5 ppb. As this excludes the cost of additional investigation, redesign of existing treatment systems, or impacts to municipal water treatment facilities to meet a 0.5 ppb MCL, the actual total costs are expected to be significantly higher.

In fact, a lower MCL could either "significantly" or "fundamentally" change a remedy at a site. Either of these types of change to the remedy will increase cost and further delay progress and completion of the remediation. When documenting significant post-Record of Decision ("ROD") changes to the remedy, the lead agency must comply with CERCLA § 117(c) and 40 CFR §§ 300.435(c)(2)(i) and 300.825(a)(2), and issue an Explanation of Significant Differences. A fundamental change to the post-ROD remedy requires the agency to develop and document the change in a ROD Amendment, following the ROD process at 40 CFR §§ 300.435(c)(2)(ii)(A)-(H).

At the very least, the lower MCL is a new Applicable or Relevant and Appropriate Requirement ("ARAR") that will significantly change the remedy. As discussed in the Tetra Tech paper, remediation costs will rise substantially. The lower MCL could also significantly expand the areal extent of contamination at a site by expanding the size of a contaminated groundwater plume. The lower MCL could necessitate a change in the primary treatment method at a site. Finally, if the new MCL cannot be reached and is impracticable from an engineering perspective at a particular site, the agency may have to invoke a Technical Impracticability Waiver of the ARAR. Whether "significant" or "fundamental," a lower MCL will undoubtedly change the remedies, adding significant cost, time and agency oversight responsibility to hundreds of sites across the United States.

It may be instructive, for purposes of comparison, to compare the cleanup cost estimated for just one of the Armed Services by Tetra Tech to the spending guidelines issued two weeks ago by the Secretary of Defense, intended to effect savings in non-combat programs -- mostly "headquarters and administrative functions, support activities and other overhead" -- that could be used to pay for war-fighting operations.[3] The Booz Allen & Hamilton study relied upon in the Tetra Tech report identifies 1,295 TCE groundwater sites at Air Force bases. The methodology used by Tetra Tech[4] yields a cost increase for Air Force base remediation alone of $137 billion, a number that completely eclipses the combined 2012-2016 combined savings goal of $101.9 billion for all the Armed Services.

Clearly, the cost implications of lower MCLs for TCE and perc are complex and will be orders of magnitude higher than for the typical drinking water contaminant. All the more reason that EPA must meet the statutory directive to prepare an analysis, for the proposed MCL and

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[3] Department of Defense, Fact Sheet: Savings and Efficiencies Initiative, http://www.defense.gov/news/savings.pdf.

[4] 1,295 x 124,455,000 = 161,169,225,000 (cost to remediate to 0.5 ppb) and 1,295 x 18,646,000 = 24,146,570,000 (cost to remediate to 5 ppb).

each alternative, of the "quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level . . . ." SDWA § 1412(b)(3)(C)(i)(III).

Public Health Benefits of Lower MCLs for TCE and Perc

The same SDWA section quoted above regarding costs requires EPA to publish for comment and use in standard-setting an analysis of "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level." SDWA § 1412(b)(3)(C)(i)(I). Moreover, "if the Administrator determines based on an analysis conducted under paragraph (3)(C) that the benefits of a maximum contaminant level promulgated in accordance with paragraph (4) would not justify the costs of complying with the level, the Administrator may, after notice and opportunity for public comment, promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits." SDWA § 1412(b)(6)(A). Thus, the Administrator's judgment as to the costs and benefits of a range of possible MCLs is central to standard setting under the Act.

In assessing the benefits of lower MCLs for TCE and perc, EPA should first consider the determinations it made in the rulemakings in which it adopted the current MCLs. In both cases, EPA observed that "for contaminants in drinking water, the target reference risk range for carcinogens is $10^{-4}$ to $10^{-6}$ and the MCLs EPA is promulgating in this notice generally fall in this range. EPA considers these to be safe levels and protective of public health." 52 Fed. Reg. at 25700-25701 (TCE); *see* 56 Fed. Reg. at 3547 (similar statement for perc). In the case of perc, EPA was more specific on this point:

> "EPA has set the drinking water standard for tetrachloroethylene at 0.005 part per million (ppm) to reduce the risk of cancer or other adverse health effects which have been observed in laboratory animals. Drinking water that meets this standard is associated with little to none of this risk and is considered safe with respect to tetrachloroethylene."

56 Fed. Reg. at 3591.

In the roughly two decades since promulgation of the MCLs for TCE and perc, there has been ongoing testing, study, and review of both the potential non-cancer and cancer health effects of these compounds.[5] This information has been compiled by EPA in extensive (1109- and 556-page, respectively) draft Toxicological Reviews released by EPA for public comment

[5] During this time, EPA has been engaged in reassessments of the potential health risks of each substance. Both reassessments appear to be nearing completion, after reviews by the National Research Council of the National Academy of Sciences and, in the case of TCE, multiple reviews by EPA's Science Advisory Board. The express requirements of the SDWA with regard to these assessments and their peer reviews are discussed in the following section.

and peer review.[6] For purposes of the MCLs, the key features of these assessments are the cancer potency, or slope, factors, for these are the toxicological values that support the statements above that the MCLs for both compounds fall within the target reference risk range of $10^{-4}$ to $10^{-6}$ – thus that drinking water meeting those MCLs is associated with little to no cancer risk or other adverse health effects and is considered safe.[7] If these slope factors are essentially unchanged, it follows that lowering the MCL would not achieve any meaningful public health benefit.

For TCE, the oral slope factor upon which EPA relied for the statement above was $1.1 \times 10^{-2}$ $(mg/kg/day)^{-1}$.[8] EPA's current preferred oral slope factor for TCE is $4.6 \times 10^{-2}$ $(mg/kg/day)^{-1}$.[9] Using a cascade of conservative assumptions, an EPA "sample calculation for total lifetime cancer risk based on the kidney unit risk estimate, adjusting for potential risk at multiple sites and for potential increased early-life susceptibility and assuming a constant lifetime exposure to 1 µg/mL of TCE in drinking water" yields a lifetime risk of only $1.9 \times 10^{-6}$.[10] An equivalent 5 ppb lifetime risk would be $9.5 \times 10^{-6}$. This compares to EPA's determination 23 years ago that a 5 ppb lifetime risk would be $2 \times 10^{-6}$.[11] In any event, the 4-fold difference in these worst case estimated upper bound lifetime cancer risks does not alter the earlier EPA determination that the potential risk of drinking water contaminated with TCE at or below the MCL falls within the target reference range.

For perc, the oral slope factor upon which EPA relied for the statement above was $5.1 \times 10^{-2}$ $(mg/kg/day)^{-1}$.[12] EPA's current preferred oral slope factor for perc is a range of $1 \times 10^{-2}$ to $1 \times 10^{-1}$ $(mg/kg/day)^{-1}$.[13] As noted in the current draft Toxicological Review, the 1985 oral slope factor "falls near the center of the range developed in the current assessment."[14] Thus there is no

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[6] Toxicological Review of Trichloroethylene (External Review Draft) (EPA/635/R-09/011A) (October 2009); Toxicological Review of Tetrachloroethylene (Perchloroethylene) (External Review Draft) (EPA/635/R-08/011A) (June 2008).

[7] By definition, these are plausible upper-bound risk estimates that are believed to be health-protective under EPA's Guidelines for Carcinogen Risk Assessment. 70 Fed. Reg. 17766-17817 (April 7, 2005).

[8] Health Assessment Document for Trichloroethylene (EPA/600/8-82/006F) (July 1985), Table 8-37.

[9] Toxicological Review of Trichloroethylene (External Review Draft) (EPA/635/R-09/011A) (October 2009), 5-146.

[10] *Id.*, Table 5-43.

[11] *See* 52 Fed. Reg. at 25700, Table 2, indicating that 0.03 mg/l of TCE in drinking water equates to a $10^{-5}$ upper bound lifetime cancer risk.

[12] Health Assessment Document for Trichloroethylene (EPA/600/8-82/006F) (July 1985), Table 8-37.

[13] Toxicological Review of Tetrachloroethylene (Perchloroethylene) (External Review Draft) (EPA/635/R-08/011A) (June 2008), 5-71.

[14] *Id.*, 5-73. It should be noted that the only change likely to this range is a reduction of the high end, based on the majority position of the National Academy review committee on the mononuclear-cell leukemia (MCL) endpoint from which the highest potency factors were derived. They "judged that the uncertainties associated with

change in the slope factor for perc, and no quantifiable benefit in the reduction of the current MCL.

For both TCE and perc, there was little disagreement among the reviewers as to the potency factors, save for the concern noted above that may result in a lowering of the high end of the range for perc. HSIA has maintained that nonlinear methodologies are more appropriate in light of available mechanistic and mode of action data, but any such methodology would indicate less risk at low concentrations. Thus, there appears to be no change in EPA's cancer risk assessments of the two compounds that would indicate a need to lower the current MCL of 5 ppb, or any public health benefit to doing so. None of the noncancer endpoints of concern come close to projecting any noncancer risk at those levels. Reduction of the MCLs does not appear to provide any public health benefit.

SDWA Requirements for EPA's Use of Science in Decisionmaking

The SDWA is very specific in its direction to EPA as to how scientific evidence is to be used in selecting and establishing MCLs:

> "In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use –
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> (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
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> (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

SDWA § 1412(b)(3)(A).

Agency-wide risk assessments (actually re-assessments) have been underway for both TCE and perc since 1990, when EPA withdrew the carcinogenicity assessments for the compounds from their Integrated Risk Information System (IRIS) entries.[15] Both are expected to be completed shortly. Whether these assessments, when completed, may be used in support of EPA's MCL decision-making will depend on the extent to which they reflect "the best available, peer-reviewed science."

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MCL (particularly the high background incidence, uncertainty about the dose-response relationship, and poor understanding of mode of action) were too great to support using MCL data rather than data on hepatic or renal cancer for determining quantitative estimates of risk." Review of the Environmental Protection Agency's Draft IRIS Assessment of Tetrachloroethylene (National Academies Press) (2010), 8.

[15] At the time, EPA's Science Advisory Board had advised EPA that the evidence was not adequate to support EPA's proposed classification of TCE and perc as "probable human carcinogen" under the Guidelines for Carcinogenic Risk Assessment in place at the time; how this resulted in removal of the qualitative and quantitative assessments has never been explained.

In the case of perc, the completion of the assessment should be relatively straight-forward. EPA's 2008 draft Toxicological Review was reviewed by the National Research Council of the National Academy of Sciences, which released a report outlining a number of deficiencies, including:

- "One of the overarching weaknesses of the draft assessment was the lack of critical analysis of the data on which EPA relied in evaluating methodologic strengths and weaknesses."

- "Overall, it appears that the procedure was to accept the results of positive studies with little critical evaluation of validity and to dismiss null studies of similar or better methodologic rigor as flawed."

- "The draft's critiques of studies are often uneven; studies that found no association are criticized more often than studies that found a positive association even if they had similar methodologic limitations."[16]

If EPA is guided by the Academy's recommendations, its final Toxicological Review for perc should meet the SDWA requirements for use of science in decision-making.

The situation for TCE is more complex. EPA first produced a draft Toxicological Review in 2001. The draft was seriously flawed, as revealed in a 2002 Science Advisory Board review and reflected by an interagency request to the National Research Council of the National Academy of Sciences to provide independent guidance on scientific issues to support an objective and scientifically balanced health risk assessment. The report that resulted[17] led to issuance of a substantially revised draft in 2009. The revised draft was improved in some respects but departed substantially from the Academy's guidance in others. Moreover, in the meantime an exhaustive assessment of the impacts of TCE and perc contamination of drinking water at a major Marine Corps base was published by yet another committee of the National Research Council.[18] This report places every cancer outcome reviewed in relation to exposure to TCE, perc, or a mixture of the two into categories, taken directly from a 2003 report entitled The Gulf War and Health by the National Institute of Medicine. For TCE, the highest category any cancer outcome received was "limited or suggestive evidence of an association."[19]

The draft Toxicological Review, on the other hand, took the position that there was convincing evidence of a causal association between TCE exposure in humans and kidney

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[16] Review of the Environmental Protection Agency's Draft IRIS Assessment of Tetrachloroethylene (National Academies Press) (2010), copy attached.

[17] Assessing the Human Health Risks of Trichloroethylene (National Academies Press) (2006) (hereinafter "2006 Report"), copy attached.

[18] Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects (National Academies Press) (2009) (hereinafter "Camp Lejeune Report"), copy attached.

[19] *Id*., Boxes 1, 2, at 6, 8.

cancer. Although the Camp Lejeune Report was referenced in the draft Toxicological Review, this major inconsistency was not explained or addressed in any way. Moreover, the epidemiologic study on which this conclusion was primarily based was used as the basis for estimating the TCE slope factor, even though the 2006 Report concluded that "[t]here appear to be insufficient epidemiologic data to support quantitative dose-response modeling for trichloroethylene and cancer."[20]

EPA's Science Advisory Board reviewed the draft Toxicological Review at meetings May 10-12, 2010. It is uncertain whether and to what extent its advice to EPA will address the advice previously provided by the National Research Council reports on the same subject. In any event, it appears that EPA will have to make substantial changes to the 2009 draft if its final assessment is to reflect "the best available, peer-reviewed science" as required by the Act.

Comments from HSIA and others on the draft Toxicological Reviews for TCE and perc are attached.

Conclusion

The SDWA provides explicit direction to EPA on how it is to use the available scientific information in establishing or revising MCLs. It is also very clear as to the analysis of benefits and costs EPA must conduct and provide for public comment at the time it proposes revised MCLs. Given the enormous spending outlay, much of it by the public sector, that would result directly from lower MCLs for TCE and perc, it will be incumbent upon EPA to show the lower MCLs would have substantial public health benefit. For the reasons expressed above and in the attached National Academy reviews and comments, there does not appear to be any appreciable public health benefit to be gained by dropping the MCLs below 5 ppb, and certainly none corresponding to the huge cleanup costs that would result.

Attachments

[20] 2006 Report, 327-328.