

October 16, 2015

State of New Jersey Department of Environmental Protection Division of Water Supply and Geoscience Drinking Water Quality Institute NJ DEP Main Building 401 East State Street PO Box 420 Trenton, NJ 08625-0420 Comments Submitted Electronically

Subject Response to NJ DWQI September 16, 2015 Request for Information Post-2009 Data and Information Related to 1,2,3-Trichloropropane

Sirs:

Integral Consulting Inc. (Integral) and Environmental Standards, Inc. (Environmental Standards) are industry leaders in health effects assessment, analytical chemistry, and water treatment technology development. In this regard, we have collaborated to provide *new* information relevant to the Drinking Water Quality Institute (DWQI's) 2009 Maximum Contaminant Level (MCL) recommendation for 1,2,3-Trichloropropane (1,2,3-TCP).

In a Public Announcement dated September 16, 2015, the DWQI announced that it is currently reviewing their 2009 MCL recommendation for 1,2,3-TCP. According to DWQI, this review includes evaluating new information. As part of this effort, the DWQI requested submittal of *new* (post-2009) data and information related to three specific topics for 1,2,3-TCP:

- Attachment 1 Health Effects-- data or technical information concerning the toxicology, epidemiology, toxicokinetics, or other studies related to health effects that should be considered in the development of the MCL.
- Attachment 2 Analytical Methods and Practical Quantitation Levels (PQL) -- data or technical information on analytical methods for drinking water and associated Practical Quantitation Levels.
- Attachment 3 Treatment Methods -- data or technical information on methods for treatment or removal from drinking water.

Summary

Based on the attached discussions of post-2009 information on 1,2,3-TCP, Environmental Standards and Integral offer the following summarizing remarks:

 Although the NTP (1993) cancer bioassay remains the only carcinogenicity data available for quantitative evaluation of TCP, a number of toxicology experts have published new (post-2009) studies and agency documents with a reevaluation of this study and have identified extensive technical limitations. This new information is important for DWQI to consider when reassessing their recommended 1,2,3-TCP health-based MCL and affirms that the proposed MCL is overly stringent.

- NJ DEP should not promulgate an MCL for 1,2,3-TCP unless and until such time as a reliable analytical method can be demonstrated by eligible laboratories and certified by NJ DEP.
- NJ DEP must not apply an MCL, regardless of how derived, as a "standard" for non-drinkingwater matrices due to commonly encountered interferences and uncontrollable sampling circumstances.
- The Treatment Report fails to provide the engineering technical evaluation required to support the proposed MCL. There is an insufficient analysis of whether implementable and cost-effective treatment technologies can be installed, operated, and maintained by New Jersey water suppliers to meet the proposed MCL. Additionally, there are issues with the Report's evaluation of technology effectiveness. The implementation issues and economic impact of treatment to the proposed 1,2,3-TCP MCL of 30 ppt for New Jersey water suppliers and private well owners remains unevaluated.

Finally, of the 1,134 New Jersey data points for 1,2,3-TCP the most recently published US EPA UCMR3 CCL3 database (USEPA, June 2015), indicates that the compound has been detected only 4 times at two facilities. Therefore, it appears that widespread exposure through NJ drinking water systems is not a concern and measurable human health protection would not be significantly realized despite the significant expense associated with 1,2,3-TCP MCL requirements.

Integral and Environmental Standards appreciate the opportunity to provide the information in the following Attachments for DWQI's consideration. Should you wish to explore our comments further, please feel free to contact Gerald L. Kirkpatrick by telephone (610.935.5577) or e-mail (<u>gkirkpatrick@envstd.com</u>).

Respectfully Submitted,

y. d. Kulepotisk

Gerald L. Kirkpatrick Managing Partner Environmental Standards, Inc.

With 3 Attachments



ATTACHMENT 1

COMMENTS ON DRINKING WATER QUALITY INSTITUTE REQUEST FOR PUBLIC INPUT FOR 1,2,3-TRICHLOROPROPANE, SEPTEMBER 16, 2015—NEW HEALTH EFFECTS INFORMATION

This comment document, prepared by Integral Consulting Inc., outlines new information on the potential health effects of 1,2,3-trichloropropane (1,2,3-TCP) in response to the request by the New Jersey Drinking Water Quality Institute (DWQI). The following comments support our position that DWQI needs to reevaluate the technical basis supporting their 1,2,3-TCP health-based maximum contaminant level (MCL) derivation to include current best science practices and consensus decisions, which, in our opinion, will result in a less stringent health-based MCL recommendation.

BACKGROUND

1,2,3-TCP is a persistent organic chemical potentially present in groundwater and public water systems in New Jersey. In 2009, DWQI proposed a health-based MCL for 1,2,3-TCP of 0.0013 μ g/L. This is the calculated drinking water concentration associated with NJDEP's default 10⁻⁶ cancer risk level. To derive the health-based MCL, DWQI selected the most stringent oral cancer slope factor calculated from a 1993 National Toxicology Program (NTP) rodent cancer study in which forestomach tumors were observed in female mice at all administered 1,2,3-TCP doses. Because the health-based MCL recommendation is below analytical capability, DWQI ultimately recommended the practical quantitation limit (PQL)-based MCL of 0.03 μ g/L. DWQI is currently reviewing new information that would inform both MCL recommendations and has requested new (post-2009) data and information related to the health effects of 1,2,3-TCP. This would include data or technical information on toxicology, epidemiology, toxicokinetics, or other studies related to health effects that should be considered in the development of the MCL.

COMMENTS

We have reviewed the collective information that has become available since 2009. The NTP (1993) cancer bioassay remains the only carcinogenicity data available for quantitative evaluation of 1,2,3-TCP. However, a number of toxicology experts have published studies and agency documents on the available toxicology study data for 1,2,3-TCP, and have identified extensive technical limitations of the NTP (1993) study. Key conclusions include:

- Administered doses exceeded the maximum tolerable daily limit for 1,2,3-TCP.
- The forestomach tumors identified in rodents are not relevant to 1,2,3-TCP human cancer risk assessments due to species-specific differences in mode of action.
- Dose-response analysis did not include some of the more relevant and appropriate dose response models and methodologies for developing cancer slope factors for 1,2,3-TCP.

This new information is important for DWQI to consider when reassessing the validity of its health-based MCL for 1,2,3-TCP and is summarized for consideration below.

 New publications demonstrate that there are critical limitations with the NTP (1993) study due to administered doses that exceeded the maximum tolerable daily limit for 1,2,3-TCP. DWQI should reinterpret tumor results from NTP (1993) and consider the overt toxicity demonstrated in high dose animals as not relevant to human drinking water exposures.

As stated in guidelines from the U.S. Environmental Protection Agency (EPA), International Life Sciences Institute, and Organisation for Economic Co-operation and Development, when designing a cancer bioassay, high doses should not exceed the maximum tolerated dose to allow a meaningful interpretation of the data (USEPA 2005; OECD 2002; ILSI 1997). It is now well accepted that excessive toxicity at high dose levels compromises the usefulness of the study and/or quality of data generated (Rhomberg et al. 2007). Several recent critical reviews of the NTP (1993) 1,2,3-TCP bioassay have highlighted this key limitation. For example, Tardiff and Carson (2010) contend, contrary to DWQI, that results from the NTP (1993) study are questionable due to substantial premature mortality in the rodents. They go on to suggest that because the administered doses exceeded the maximum tolerated dose for 1,2,3-TCP, less stringent dose-response analyses and safe drinking water exposure levels are more appropriate and yet still health protective. Given that this substantially deviates from the DWQI 2009 analysis, full consideration of this issue raised and technical interpretations made by Tardiff and Carson (2010) need to be included in a revised health-based MCL for 1,2,3-TCP.

Another recent study, Meek et al. (2014), suggested a full weight-of-evidence approach is appropriate for 1,2,3-TCP human health risk assessment. 1,2,3-TCP was used as a case study example in the internationally recognized "mode of action human relevance framework" to systematically evaluate the available 1,2,3-TCP cancer data and apply a weight-of-evidence determination on mode of action and human relevance. Through use of this framework, the study authors highlight the uncertainty (e.g., inconsistent and missing data) for the 1,2,3-TCP cancer mode of action and human relevancy. This is especially important for DWQI to evaluate because it has bearing on the validity of the high administered 1,2,3-TCP doses from NTP (1993) and underlying cancer dose-response modeling assumptions utilized by DWQI (e.g., considering carcinomas to be the cause of death for animals that died prior to sacrifice.)

Combined, the new publications, Tardiff and Carson (2010) and Meek et al. (2014), point to limitations of the high 1,2,3-TCP administered doses-related cancer effects from NTP (1993). These limitations should be fully considered by DWQI when reevaluating the health-based 1,2,3-TCP MCL.

2. New publications present evidence that the 1,2,3-TCP-mediated forestomach tumors from NTP (1993) are not relevant to human health; therefore, DWQI should not include this tumor type in its dose-response modeling and MCL derivation methods.

As demonstrated by several technical experts, although humans have histologically analogous tissue types within the esophagus, the 1,2,3-TCP-mediated forestomach tumors in the rodents from NTP (1993) are not relevant to humans. This issue was first raised by expert peer review during the comprehensive 1,2,3-TCP toxicology review conducted by EPA under the Integrated Risk Information System program and released only months after the initial DWQI 2009 MCL recommendation (USEPA 2009). Peer review comments explained why the forestomach tumors should not be included in the calculation of the oral cancer slope factor. EPA acknowledged the limitations of the NTP (1993) study, which include the following: the bolus dose of high concentration 1,2,3-TCP held by the rodent forestomach does not represent human exposure scenarios; the physiology and function of the forestomach results in prolonged contact with epithelial tissues that would be unrealistic to human exposures; and humans do not have a forestomach or an analogous organ, and given the bolus dosing at extremely high dose levels, tumors in that organ do not represent a human health risk. The EPA assessment demonstrates that excluding results based on forestomach tumors would change (reduce) the oral cancer slope factor by a factor of over 20.

Although DWQI's 2009 support document references IARC (2003) as justification of the human relevancy of the forestomach tumors, more recent evaluations of available health effects information contradict this view. Specifically, Tardiff and Carson (2010) dismiss the forestomach tumors reported in NTP (1993) as not relevant to humans nor appropriate for cancer dose-response modeling. They suggest that tumor types found at sites distant from the dose application (not associated with the GI tract) are most appropriate. They also cite Proctor et al. (2007) to support the argument that 1,2,3-TCP-mediated forestomach tumors that occur particularly at doses exceeding the maximum tolerated dose are not relevant for human health risk assessment. These interpretations of available toxicology data need to be fully and adequately considered by DWQI, as well.

3. New publications provide alternative dose-response modeling methods that result in derivation of less stringent 1,2,3-TCP drinking water protection levels; these innovative approaches should be considered by DWQI in their reevaluation of the health-based 1,2,3-TCP MCL.

The DWQI health-based 1,2,3-TCP MCL was calculated using the NTP (1993) rodent cancer bioassay and the multistage Weibull time-to-tumor model on the incidence of tumors in the forestomach of female mice. DWQI also assumed that in animals that died prior to sacrifice, carcinomas were the cause of death. The resulting cancer slope factor was 26 (mg/kg-day)⁻¹, which translated to a healthbased MCL of 0.0013 µg/L. Using innovative cancer dose-response modeling methodologies (non-linear low dose extrapolation and combined tumors at the 50th percentile), Tardiff and Carson (2010) calculated a cancer toxicity value (comparable to a reference dose) of 0.01 mg/kg-day and a cancer drinking water equivalent level, using a relative source contribution of 50 percent, at 200 μ g/L. The authors demonstrate that calculation methods (such as those utilized by DWQI) are not supported and overestimate the risk of cancer to humans. They justify the nonlinear extrapolation based on proposed weight of evidence for the mode of action of such high bolus doses of 1,2,3-TCP (hyperplasia and inflammation leading to regenerative hyperplasia and tumor promotion.) As mentioned previously, there is support for this mode of action from the NTP (1993) data, and Meek et al. (2014) recommended a full weight-of-evidence evaluation to determine human relevancy and mode of action. Given that the 1,2,3-TCP drinking water equivalent level based on the analysis by Tardiff and Carson (2010) substantially deviates from the DWQI 2009 MCL recommendation, alternative approaches to cancer hazard assessment need to be considered in determining a revised health-based MCL for 1,2,3-TCP.

4. The outdated DWQI-proposed health-based 1,2,3-TCP MCL is inconsistent with more recent agency-derived health effects assessments, which have included calculation of drinking water protection levels at much higher (less stringent) levels after full and appropriate consideration of the limitations with the NTP (1993) data, as described above.

Several states have developed 1,2,3-TCP guidance values for residential drinking water using a range of methodologies. The most recent review of 1,2,3-TCP human health information was conducted by the State of Hawaii Department of Health (HDOH) in 2012. In its assessment, HDOD considers the key limitations of the NTP (1993) cancer bioassay and determines a drinking water protection level of 0.6 μ g/L (Tetra Tech 2012). This is in stark contrast to the DWQI health-based recommended MCL of 0.0013 μ g/L, and is also significantly less stringent than the PQL-based recommended MCL of 0.03 μ g/L. There are several important reasons for the differences between the HDOH and DWQI 1,2,3-TCP assessments. HDOH acknowledges that the different methodologies for cancer dose-response analysis

from the NTP (1993) study can yield cancer slope factors that vary by almost 3 orders of magnitude – 0.06 to 30 (mg/kg-day)⁻¹ – and determined that the most stringent interpretation of the data is not representative of human risk, is overly protective, and, therefore, is not valid. Additionally, HDOH concludes that the human relevance of the NTP (1993) study was highly uncertain given the gavage method of administering 1,2,3-TCP, which results in high bolus doses that do not represent human exposure scenarios. They also disagree with the approach of using the most sensitive dose-response assessment from the NTP (1993) study (as adopted by DWQI), including modeling using rodent forestomach tumors, which they determined does not have human relevance. HDOH further contends that the use of corn oil as a vehicle produces greater incidence of forestomach tumors compared to other routes of administration, causing irritation (hyperplasia and hyperkeratosis of the forestomach) in the rodents not seen in studies using oral administration of 1,2,3-TCP. Ultimately, they conclude that the high dose corn oil gavage administration of 1,2,3-TCP in the NTP (1993) study "exaggerates the toxicological potency of 1,2,3-TCP in human exposures via tap water" (Tetra Tech, 2012, p. 21.)

A recent update to the Agency for Toxic Substances and Disease Registry (ATSDR) 1,2,3-TCP Toxicological Profile represents yet another consensus opinion from agency experts that substantially differs from the outdated 2009 evaluation by DWQI. In 2011, ATSDR issued an addendum to the 1,2,3-TCP Toxicological Profile, originally published in 1992 (ATSDR 2011). The addendum provided a brief qualitative overview and discussion of updated health effects information for 1,2,3-TCP, including cancer. This updated publication recognized and supported the conclusions reached by Tardiff and Carson (2010), including the uncertainty associated with high administered doses from NTP (1993), alternative and less-stringent cancer dose-response modeling, and the determination that the mouse forestomach tumors were not relevant to human health.

CONCLUSION

There have been advances in best practices for human health risk assessment related to the evaluation of the NTP (1993) 1,2,3-TCP cancer bioassay that should be considered by DWQI and used to recalculate a less stringent health-based 1,2,3-TCP MCL. Although the NTP (1993) study remains the only available study from which cancer dose-response modeling can be conducted, there are noteworthy concerns regarding this study and the methodology employed by DWQI in deriving its proposed health-based MCL. The 2009 "Health-Based MCL Support Documents for 1,2,3-TCP" do not address the study limitations nor alternative interpretations of the underlying science and risk assessment

methods. As other agencies have done since DWQI's initial 2009 recommendation, DWQI needs to consider the recent publications that support using the most appropriate cancer endpoints and human-relevant tumors only. Consistent with new information and conclusions of independent and state agency scientists, the available data do not support such a stringent MCL for 1,2,3-TCP. DWQI should consider the new information during its reevaluation of the health-based 1,2,3-TCP MCL.

REFERENCES

ATSDR. 2011. Addendum to the Toxicological Profile for 1,2,3-Trichloropropane. Available at <u>http://www.atsdr.cdc.gov/toxprofiles/1 2 3 trichloropropane addendum.pdf</u>. Agency for Toxic Substances and Disease Registry Division of Toxicology and Environmental Medicine, Atlanta, GA.

IARC. 2003. International Agency for Research on Cancer. Predictive value of rodent forestomach and gastric neuroendocrine tumours in evaluating carcinogenic risk to humans. IARC Technical Publication No 39, Lyon, France.

ILSI. 1997. *Principles for the selection of doses in chronic rodent bioassays.* Foran, J.A. (Ed.). International Life Sciences Institute. ILSI Press, Washington, DC.

Meek, M.E., C.M. Palermo, A.N. Bachman, C.M. North, and R.J. Davis. 2004. Mode of action human relevance (species concordance) framework: Evolution of the Bradford Hill considerations and comparative analysis of weight of evidence. *J. Appl. Toxicol.* 34(6):595-606.

NTP. 1993. Toxicology and carcinogenesis studies of 1,2,3-trichloropropane (CAS No. 96-18-4) in F344/N rats and B6C3F1 mice (gavage studies). NTP TR 384. National Toxicology Program. Public Health Service, U.S. Department of Health and Human Services.

OECD. 2002. Guidance notes for analysis and evaluation of chronic toxicity and carcinogenicity studies. OECD Series on Testing and Assessment No. 35. Available at: http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/NT00002BE2/\$FILE/JT00130828.PDF. , Organisation for Economic Co-operation and Development, Paris.

Proctor, D.M., N.M. Gatto, S.J. Hong, and K.P. Allamnent. 2007. Mode-of-action framework for evaluating the relevance of rodent forestomach tumors in cancer risk assessment. *Toxicological Sciences* 98(2):313–326.

Rhomberg, L., K. Baetcke, J. Blancato, J. Bus, S. Cohen, R. Conolly, R. Dixit, J. Doe, K. Ekelman, P. Fenner-Crisp, P. Harvey, D. Hattis, A. Jacobs, D. Jacobson-Kram, T. Lewandowski, R. Liteplo, O. Pelkonen, J. Rice, D. Somers, A. Turturro, W. West, and S.

Olin. 2007. Issues in the design and interpretation of chronic toxicity and carcinogenicity studies in rodents: Approaches to dose selection. *Crit. Rev. Toxicol.* 37:729-837.

Tardiff, R.G., and M.L. Carson. 2010. Derivation of a reference dose and drinking water equivalent level for 1,2,3-trichloropropane. *Food Chem. Toxicol.* 48:1488–1510.

Tetra Tech. 2012. Report to the Hawaii Department of Health, Safe Drinking Water Branch, regarding the human health risks of 1,2,3-trichloropropane in tap water. Tetra Tech, Inc. June 18, 2012.

USEPA. 2005. Guidelines for carcinogen risk assessment. EPA/630/P-03/001B. Available at: <u>http://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf</u>. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC.

USEPA. 2009. Toxicological Review of 1,2,3-Trichloropropane (CAS No. 96-18-4). EPA/635/R-08/010F. U.S. Environmental Protection Agency, Washington DC. Available at <u>http://www.epa.gov/iris/toxreviews/0200tr.pdf</u>. U.S. Environmental Protection Agency, Washington, DC.



Attachment 2

Post-2009 Data on 1,2,3-TCP Analytical Methods and Practical Quantitation Levels (PQL)

As part of this review, Environmental Standards, Inc. (Environmental Standards) performed the following tasks:

• Reviewed the (continued to be relied upon) 1999 document, *New Jersey Drinking Water Quality Institute (NJDWQI) Testing Subcommittee PQL Review, Assessment and Recommendations* (March 3, 2009).

• Reviewed the document, *New Jersey Drinking Water Quality Institute Maximum Contaminant Level Recommendations for Hazardous Contaminants in Drinking Water* (March 2009).

• Surveyed in October, 2015, 18 NJDEP accredited laboratories regarding their specific experience with analyzing aqueous samples for 1,2,3-TCP and their NJ DEP-approved method performance.

An MCL of 0.030 μ g/L has been proposed for 1,2,3-TCP by the NJ DWQI. The proposed MCL was derived by multiplying the single New Jersey Department of Health and Senior Services (DHSS) Laboratory's Method 504.1 Method Detection Limit (MDL) of 0.005 μ g/L by a factor of five and then rounding to one significant figure. The NJ DWQI referred to the proposed MCL as being equivalent to a "Practical Quantitation Limit" (PQL), which is, in fact DHSS's (single laboratory) Limit of Quantitation (LOQ).

As an indication of data paucity, NJ DWQI provides and cites only two (2) NJDEP accredited laboratories of the seven listed (New Jersey Drinking Water Quality Institute Testing Subcommittee PQL Review, Assessment and Recommendations March 3, 2009 Table 9, Pg. 21) that have calculated 40 CFR Part 136 MDLs for 1,2,3-TCP \leq 0.005 ug/L and an associated Reporting Limit (RL) using EPA Method 504.1 (see below).

MDL/RLs of Laboratories with New Jersey Certification for Analysis of 1,2,3-TCP

1,2,3-TCP by EPA 504.1 Laboratory	MDL (µg/L)	RL (µg/L)
Analytical Laboratory Services	0.004, 0.006	0.020
ECLS	0.005	0.020

It is noteworthy that NJ DWQI is currently mandating the use of US EPA Method 504.1 as being the most sensitive drinking water method for analysis of 1,2,3-TCP; however, under current federal Safe Drinking Water Regulations, the analytical method, US EPA Method 504.1, is NOT approved for this use. The NJ DWQI Testing Subcommittee *PQL Review, Assessment and Recommendations* document clearly acknowledges issues with using US EPA Method 504.1 for this purpose and states that EPA Method 524.3 is an analytical method *currently under development* and the NJDEP Office of Quality Assurance (OQA) currently does not offer certification for the analysis for 1,2,3-TCP by Method 524.3. US EPA Method 524.3 was, in fact, the standard method applied nationwide for the UCMR3 Contaminant Candidate List (CCL3). Method 524.3 was selected by US EPA for the UCMR/CCL3 program because the method could demonstrably detect 1,2,3-TCP at US EPA's UCMR3 required reporting limit of 0.030 µg/L.

NJ Drinking Water Quality Institute Attachment 2 Comments on Post-1999 1,2,3-TCP Data Analytical Methods and PQLs October 16, 2015 Page 2

Unless NJ DWQI can realistically coordinate certification of NJ DEP-approved laboratories for 1,2,3-TCP analysis using Method 524.3, then adoption of any proposed lower MCL may be problematic for the regulated community, environmental stakeholders, and NJ DEP.

Environmental Standards has reviewed the available technical supporting documents published with the 2009 proposed MCL rulemaking and recommends that NJ DEP evaluate and address the following issues as they relate to the analytical feasibility of NJ DEP-accredited laboratories reliably achieving low μ g/L (*i.e.* part-per-trillion) sensitivity for 1,2,3-TCP.

Issue 1 – The 1,2,3-TCP PQL was derived from a single laboratory calculated MDL

The NJ DEP Testing Subcommittee derived the proposed MCL for 1,2,3-TCP by simply multiplying the NJ DHSS Laboratory's Method 504.1 calculated MDL of 0.005 μ g/L by a factor of five. Erroneously, the Testing Subcommittee then chooses to refer that arithmetic construct as an MCL equivalent to a PQL.

By standard environmental analytical chemistry definition, the value calculated by the Testing Subcommittee is a single-laboratory Limit of Quantitation (LOQ). It is not a PQL. A PQL is a quantitation limit that any reputable laboratory should be able to achieve with reasonably current instrumentation. This PQL must be achieved by following a carefully prescribed and defined method, not the method merely followed by the DHSS laboratory or any other single laboratory.

Accordingly, at a minimum, the calculated MDLs for 1,2,3-TCP by a certifiable method from all NJ DEP accredited laboratories must be subjected to statistical analysis and only using that analysis, can a properly defined PQL be derived. Statistical bootstrapping is not necessary, as a sufficient number of laboratories accredited for 1,2,3-TCP analysis exists using Method 524.2. For consistency with the UCMR3 CCL3 program, Method 524.3 should be more carefully considered by the NJ DWQI.

NJ DEP and the NJ DWQI should undertake US EPA Method 524.3 method development and certification. Until that time, no MCL for 1,2,3-TCP should be proposed.

<u>Issue 2 - Using the 40 CFR Part 136 MDL Procedure as the Basis for Proposing a Maximum</u> <u>Contaminant Level for 1,2,3-TCP</u>

While the NJ DWQI is using the PQL concept to propose a 1,2,3-TCP MCL (See Issue 1 above), the underpinning of the proposed MCL is the 40 CFR Part 136 procedure for calculating the MDL for 1,2,3-TCP by EPA Method 504.1.

The determination of MDLs by 40 CFR Part 136 has been criticized by the scientific community as a flawed procedure for deriving an expression of analytical sensitivity. The MDL procedure is misunderstood, and invalid MDL determinations are common. As long ago as 1993, the Wisconsin Department of Natural Resources conducted an inter-laboratory survey of compound detection limits and of the 56 laboratories surveyed, 23 incorrectly calculated their MDLs (more than 40 percent). "*Meaningful detection limits are a critical first step toward meeting the agency's data needs of the future, where toxicology is expected to continue to push the boundaries of analytical science*" (Wisconsin DNR, April 1996).

At the federal level, the US EPA was sued in 2003 (Engineering and Analysis Division Office of Science and Technology Office of Water (4303T) U.S. Environmental Protection Agency, EPA-821-B-04-005, October 2004) by several trade associations, and as part of the subsequent settlement, there was an

acknowledgement by US EPA that the 40 CFR Part 136 procedure is flawed and needs to be altered if those limits are to be reliably used for regulatory rulemaking.

As a result of the 2003 litigation and subsequent agreement, US EPA chartered a Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs (Committee) in 2005. This committee was formed specifically due to the scientific community's concerns with the Method Detection Limit (MDL) procedure as published in 40 CFR Part 136, Appendix B. The charge to the Committee was "*to provide advice and recommendations on approaches for the development of detection and quantitation procedures and uses of these procedures in Clean Water Act programs.*" Ultimately, one important recommendation provided by Committee was that "*to maintain consistency and minimize effects on the environmental laboratory community, EPA programs that reference the present Part 136 Appendix B procedure consider adopting a new procedure that would replace it*" (Report of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses In Clean Water Act Programs, December 2007).

Furthermore, the US EPA now recognizes that there are flaws in current instrument calibration methods, which influence how an ML (method limit) is determined, and that improvements in these methods are needed. These improvements should be made before US EPA requires permittees to make decisions on use of test methods based on their MLs (<u>http://www2.epa.gov/measurements</u>).

It is well documented in both state and federal citations that the MDL procedure used by NJ DEPaccredited laboratories and the Testing Subcommittee might be problematic. Certain issues with the 40 CFR Part 136 MDL procedures are acknowledged as a footnote in the NJ DWQI Testing Subcommittee PQL Review, Assessment and Recommendations document. "*During this PQL review and development process, the Testing Subcommittee would like to acknowledge the ongoing work being done by various groups including the EPA in addressing the issue of the MDL process, its relationship to quantitation limits and possible alternatives.*" (http://www2.epa.gov/measurements).

A fundamental concern with proposing a 1,2,3-TCP MCL at this time is that a "PQL" (again, this is actually a single-laboratory LOQ) based on a 40 CFR Part 136 MDL for 1,2,3-TCP represents a value that cannot be reliably detected and accurately quantitated by a laboratory on a day-to-day basis.

In summary, multiplying a theoretically calculated MDL value by a multiple of 5 is incorrectly referenced by NJ DWQI as a PQL and should not be proposed as an MCL.

Issue 3 - The Use of EPA Method 504.1 as the basis of proposing the 1,2,3-TCP MCL

The NJ DEP Testing Subcommittee references US EPA Method 504.1 as having the lowest 40 CFR Part 136 calculated MDL. Notwithstanding the flaws associated with the MDL procedure itself (see above), it is notable that US EPA's Method 504.1 is a gas chromatographic (GC) method that relies on a chromatographic peak retention time between sample and standard on a gas chromatographic column.

While this GC method is potentially acceptable for screening purposes, a variety of sample interferences are known to result in false positives detections being reported by laboratories. In fact, Section 2.3 of US EPA Method 504.1 states that confirmation of *tentatively* positive results should be obtained as follows: "*Confirmatory evidence should be obtained for all positive results. This (sic) data may be obtained by using retention data from a dissimilar column, or when concentrations are sufficiently high by GC/MS.*"

The US EPA recognizes this limitation of using a *non-definitive* analytical technique for proposing MCLs, and in all cases the US EPA's CCL3 program specifies the use of Method 524.3 for the analysis of 1,2,3-TCP in water samples. Since it is clear that proposing an MCL has a significant impact on the stakeholder community, we suggest the use of analytical methods in which interferences and false positives are minimized. Further, during a recent survey of 18 NJ DEP accredited laboratories, Environmental Standards learned that 9 of those laboratories (50-percent) "*periodically or routinely*" encounter interferences when performing analysis by US EPA Method 504.1. It is noteworthy that under current federal Safe Drinking Water Regulations, the analytical method, US EPA Method 504.1, is NOT an approved drinking water method, unlike Method 524.3.

Using a better analytical method such as a GC/MS technique is prudent and responsible with regard to proposing and ultimately promulgating an MCL for 1,2,3-TCP. In that regard, we note that NJ DEP currently does not accredit laboratories using drinking water Method 524.3 for 1,2,3-TCP. Accordingly, MCL rulemaking for 1,2,3-TCP should be deferred, at least until such time as NJ DEP's Office of Quality Assurance (OQA) offers certification for the analysis of 1,2,3-TCP in drinking water by US EPA Method 524.3.

Finally, during a recent surveying of 18 NJDEP accredited labs, Environmental Standards observed that 15 laboratories are accredited to perform 1,2,3-TCP using approved drinking water GC/MS EPA Method 524.2. Hypothetically, taking the average reported MDL across these laboratories (calculated to be 0.2 ug/L) and multiplying by 5 (as was done by NJ DEP previously), a concentration of 1 ug/L is observed. Method 524.2 has an established PQL of 0.5 ug/L. Accordingly, a proposed MCL of 0.030 ug/L is more than 33-times greater than the calculated hypothetical MCL and a factor of 17-times greater than the established PQL of EPA Method 524.2.

Issue 4 – Using Drinking Water Methods for Non-Drinking Water Matrices

For some, there is a presumption that an MCL, based on the use of US EPA's 500-Series drinking water methods (like 524.3), would only have application when a party is submitting finished potable water samples for analyses. However, MCLs are routinely applied as an upper-bound water quality "limit" or "bright-line standard" in a variety of non-potable water circumstances. Examples of aqueous samples analyzed using US EPA 500 Series drinking water methods abound.

Using US EPA Method 500 series drinking water methods for non-drinking water testing purposes is neither feasible nor practical. If the long-term intention of NJ DEP is to enforce the 1,2,3-TCP MCL on non-potable aqueous samples, but not potable water supplies, the water quality standard should be derived based on some other testing series, such as US EPA's 40 CFR Method 624 and/or EPA Method 8260. Using the ideal and hypothetically "*most sensitive*" drinking water method to propose an MCL and then attempting to enforce that MCL on parties who collect non-potable water samples, is not realistic because the interferences, sampling and field handling techniques of such samples are so variable and uncontrollable.

References Cited

New Jersey Department of Environmental Protection, Drinking Water Quality Institute, 2015, *Request for Public Input for 1, 2, 3, -Trichloropropane.* September 16, 2015. At http://www.nj.gov/dep/watersupply/g boards dwqi.html

New Jersey Department of Environmental Protection, Drinking Water Quality Institute, 2009, *New Jersey Drinking Water Quality Institute Maximum Contaminant Level Recommendations for Hazardous Contaminants in Drinking Water. March 4, 2009. At <u>http://www.nj.gov/dep/watersupply/pdf/dwgi mcl 09 recommend report final.pdf</u>*

New Jersey Department of Environmental Protection, Drinking Water Quality Institute, 2009, *New Jersey Drinking Water Quality Institute Testing Subcommittee PQL Review, Assessment and Recommendations. March 3, 2009. At <u>http://www.nj.gov/dep/watersupply/pdf/last_final_iplq_testing.tt.pdf</u>*

Wisconsin Department of Environmental Resources, 1996, Laboratory Certification Program, PUBL-TS-056-96. At <u>http://dnr.wi.gov/regulations/labcert/documents/guidance/-lodguide.pdf</u>

United States Environmental Protection Agency, 2004, Report of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs. Engineering and Analysis Division Office of Science and Technology Office of Water (4303T) U.S. Environmental Protection Agency, EPA-821-B-04-005, October 2004. At <u>http://water.epa.gov/scitech/methods/cwa/det/upload/final-report-200712.pdf</u>

United States Environmental Protection Agency, 2015, Forum on Environmental Measurement, At <u>http://epa.gov/fem/calibration.htm</u>

United States Environmental Protection Agency, 2015, Contaminant Candidate List 3, 2015, Home page and attending support documentation, <u>http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3</u>

United States Environmental Protection Agency, 2015, Unregulated Contaminant Monitoring Regulations, Contaminant Candidate List 3, Occurrence Database 2015. At <u>http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/data.cfm</u>

United States Environmental Protection Agency, June 2015, The Third Unregulated Contaminant Monitoring Rule Data Summary., 2015. At http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/upload/UCMR3 Data-Summary June-2015 508.pdf



ATTACHMENT 3

COMMENTS ON DRINKING WATER QUALITY INSTITUTE REQUEST FOR PUBLIC INPUT FOR 1,2,3-TRICHLOROPROPANE—TREATMENT OPTIONS FOR DRINKING WATER

This comment document, prepared by Integral Consulting Inc., outlines new information on the treatment methods for 1,2,3-trichloropropane (1,2,3-TCP) in response to the request by the New Jersey Drinking Water Quality Institute (DWQI), Treatment Subcommittee, dated September 16, 2105 (DWQI 2015). The basis for these comments is the treatment methods evaluation for 1,2,3-TCP outlined in Appendix C of the 2009 maximum contaminant level (MCL) recommendation, *Evaluation and Assessment of Removal Technology for Specific Organic Contaminants in NJ Drinking Water* (the Treatment Report; Black & Veatch 2008).

The Treatment Report does not appear to provide the appropriate level of technical and cost evaluation to support rule-making. DWQI is considering an MCL for 1,2,3-TCP of 30 parts per trillion (ppt). This MCL and related testing and treatment requirements would be imposed on all water companies, municipalities, private well owners, and other New Jersey water providers. The nature and extent of 1,2,3-TCP impacts in New Jersey groundwater has not been assessed. As such, the Treatment Subcommittee cannot provide information on how many water suppliers or drinking water sources in New Jersey may be required to implement treatment in response to the proposed MCL. In addition, information cannot be provided on the range of expected influent 1,2,3-TCP concentrations to treatment facilities, data critical to evaluating technology effectiveness, implementability, and cost.

The Treatment Report's analyses are very general. Treatment options for 15 different organic constituents are discussed, without consistent specificity to 1,2,3-TCP. Several treatment options are discussed that are ineffective or have not yet been proven effective for removal of 1,2,3-TCP to the proposed MCL (e.g., air stripping, biological degradation, and membrane filtration). Based on our assessment of effectiveness, we have focused on the technologies provided in Table 5-1 of the Treatment Report, including granular activated carbon (GAC) as viable, and advanced oxidation and membrane treatment (using reverse osmosis as a representative technology) as potentially applicable.

General and specific comments are provided below.

GENERAL COMMENTS

The Treatment Report *fails* to:

- **1.** Fully evaluate applicable treatment technologies and address the lack of robust treatment data for reverse osmosis and advanced oxidation processes (AOP).
- 2. Evaluate the implementability and cost (e.g., availability of technologies, pretreatment requirements, ease of retrofitting existing water treatment plants, permitting, and maintenance requirements) of the proposed MCL on water suppliers across New Jersey, especially in light of the lack of 1,2,3-TCP occurrence and magnitude data.
- 3. Analyze the treatment costs and implementation challenges for private well owners including potentially required point-of-entry treatment systems.

SPECIFIC COMMENTS

Granular Activated Carbon

- 1. The Treatment Report is incomplete in that it relies upon generic costing models for the selected best available technology—GAC. Alternatively, lifecycle cost evaluation is a robust approach that considers the full cost of all anticipated recurring and non-recurring costs for the predicted life span of an operation, structure, or system. The Treatment Report considers a limited set of capital, operations and maintenance costs based on generic models for organic contaminant treatment. While limited vendor data exist and demonstrate GAC is applicable (Babcock 2015; Jordan 2015, pers. comm.), 1,2,3-TCP appears to have a much lower adsorption capacity than more common volatile organic compounds (e.g., trichloroethene [TCE] and tetrachloroethene [PCE]), which may result in earlier breakthrough given similar influent concentrations (CH2M Hill 2005). Therefore, effectiveness, implementability, and cost evaluations should be completed based on specific evaluation of required 1,2,3-TCP removal rates for the anticipated influent concentrations found in New Jersey water supply systems.
- 2. The Treatment Report does not fully evaluate pretreatment and residuals management costs or implementability issues. These costs can be very significant, and their omission from the Treatment Report's analysis is not explained. For example, required GAC backwashing is included in the capital costs; however, the management of backwash water is not included in the operating costs (Treatment Report, Appendix A). Also, while the capability to backwash vessels and GAC regeneration requirements are mentioned, the liability implications of various

disposal methods, including the potential need for land disposal, and the costs associated with such liabilities are not explored.

3. The Treatment Report should fully evaluate capital and operational costs on a unit cost basis for 1,2,3-TCP treatment including all related implementation costs.

Generic costs for a standard GAC system are provided in the Treatment Report, with a cost basis provided in Appendix A.1.1. However, these costs are incomplete and are not specific to 1,2,3-TCP. In addition, there is no evaluation of financial and logistical requirements (and associated economic impacts) to implement GAC systems for water suppliers across the state and private well owners, who may not have the resources to absorb such costs.

In addition, the report does not address or evaluate the following items that may have significant costs:

- All GAC systems require influent-specific and complete evaluations of competing regulated and non-regulated adsorptive species to fully evaluate operational unit costs. Therefore, GAC usage (and, thus, cost) under actual conditions is likely underestimated in the Treatment Report.
- Pretreatment is commonly required to make the water suitable for GAC treatment (e.g., particulate filtration, soluble iron removal, pH adjustment) and should be evaluated to provide a range of potential unit costs. Because every water supply system, and every well or source within each system, may differ in its pretreatment needs, every well or source should be separately evaluated with respect to the balance of the well or source and related infrastructure to understand the full range of pretreatment options and costs. Iron removal is a particularly common pretreatment requirement in New Jersey. The Treatment Report neither evaluates nor acknowledges these issues.
- Spent GAC residuals management and disposal costs are not thoroughly evaluated in the Treatment Report and can be very significant. For example, not all GAC vendors have the ability to regenerate spent GAC, which reduces competitiveness in the GAC regeneration marketplace. Additionally, to regenerate at all is dependent on the influent concentration of the contaminant of concern as well as other compounds that will be removed by GAC: if the mass loading onto the GAC is too high, or other regulated species with different loading thresholds exist, a vendor may not be able to regenerate the GAC without violating their permits. In these cases, spent GAC must be sent to a landfill, which significantly increases costs and has its own regulatory limitations. Also, the removal of naturally occurring radioactive materials in source water, a situation common in New Jersey, can complicate and increase costs for disposal.

Advanced Oxidation

- 1. The Treatment Report suggests an effective AOP exists for 1,2,3-TCP, yet the information presented in the Treatment Report cites a single application of AOP for treatment of 1,2,3-TCP. A number of AOP technologies exist. Our research and vendor communications indicate that proven AOP options for 1,2,3-TCP are likely limited to the combined ozone and hydrogen peroxide (O₃/H₂O₂) AOP; however, these data are limited and dated (Treatment Report, Section 4.1; Haas and Keep 2015, pers. comm.; Jordan 2015, pers. comm.). AOP processes are heavily influenced by overall water quality, including pH, total dissolved solids, metals, and organics, so the technology may perform with one water source, but not another, and/or require significant pretreatment. Finally, no field-scale tests appear to have been performed, which are required to fully evaluate the technology's effectiveness, implementability, and costs.
- 2. Proposed AOP costs are misaligned and incomplete. Costs are provided for two AOP processes: ozone (Table 3-4) and ultraviolet light plus hydrogen peroxide (UV/ H₂O₂) (Table 3-5). However, no cost basis is provided, and our research does not indicate either of these AOPs are effective for 1,2,3-TCP, especially at the proposed MCL. In addition, based on the report discussion preceding the cost estimates, it appears the costs are based on treatment of PCE, TCE, methyl *tert*-butyl ether, and geosmin and, thus, are not specific to 1,2,3-TCP. Moreover, and confusingly, the costs provided are not for the one potentially applicable AOP—O₃/H₂O₂.

Membrane Filtration

- 1. **Reverse osmosis is not fully evaluated.** Reverse osmosis is briefly discussed in the Treatment Report as potentially applicable for the removal of 1,2,3-TCP (up to 85 percent removal; Table 2-4); however, additional information is required to evaluate its effectiveness, at field scale.
- 2. **Residuals management is not addressed.** The Treatment Report does not address the implementability and costs of waste disposal for reverse osmosis rejectate. There are typically significant management and cost issues associated with this technology.
- 3. **Capital and operational costs should be completely evaluated on a unit cost basis.** A thorough and comparable evaluation of costs is especially important for membrane filtration technologies because historically unit costs have been significantly higher than GAC. Costs for membrane technologies are not evaluated in the Treatment Report.

CONCLUSION

The Treatment Report provides an insufficient analysis of whether implementable and cost-effective treatment technologies can be installed, operated, and maintained by New Jersey water suppliers and private well owners to meet the proposed MCL. In addition, there are issues with the Treatment Report's evaluation of technology effectiveness. Overall, the implementation issues and economic impact of treatment to the proposed MCL of 30 ppt for 1,2,3-TCP for New Jersey water suppliers and private well owners remains unevaluated. Thus, the Treatment Report fails to provide the engineering technical evaluation required to support the proposed MCL.

REFERENCES

Babcock, R. 2015. Evaluation of six GACs for 1,2,3-trichloropropane removal using rapid small scale column tests. Platform Presentation. 2015 Pacific Water Conference AWWA & HWEA. University of Hawaii at Manoa. Department of Civil/Environmental Engineering Center. February 4, 2015.

Black & Veatch. 2008. Evaluation & assessment of removal technology for specific organic contaminants in NJ drinking water. Black & Veatch Corporation, NY. November.

CH2M Hill. 2005. Interim guidance for investigating potential 1,2,3-trichloropropane sources in San Gabriel Valley Area 3. Prepared for U.S. Environmental Protection Agency, Region IX. CH2M Hill. Southern California Regional Office, CA. July 27, 2005.

DWQI. 2015. Drinking Water Quality Institute Request for Public Input for 1,2,3-Trichloropropane. New Jersey Drinking Water Quality Institute, NJ. September. 1 pp.

Haas, R., and T. Keep. 2015. Personal communication (e-mails from R. Haas and T. Keep, Project Engineering Manager and Engineering Sales Manager, respectively, Trojan UV, to A. Frankel, Principal Engineer, Integral Consulting Inc., dated October 7, 2015, regarding 1,2,3-TCP Treatment). Trojan UV, London, Ontario, Canada .

Jordan, D. 2015. Personal communication (e-mails from D. Jordan, Technical Sales Development, Evoqua Water Technologies LLC to A. Frankel, Principal Engineer, Integral Consulting Inc., dated October 7, 2015, regarding 1,2,3-TCP Treatment). Evoqua Water Technologies LLC, Warrendale, Pennsylvania.