American Water Works Association

The Authoritative Resource on Safe Water℠

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U.S. Environmental Protection Agency
Office of Water Docket (Mailcode 2822T)
1200 Pennsylvania Ave. NW
Washington, DC 20460

RE: Drinking Water: Perchlorate Supplemental Request for Comments
Docket EPA-HQ-OW-2009-0297

The American Water Works Association appreciates the opportunity to comment on the supplemental request for comments regarding perchlorate as detailed in the August 3, 2009 *Federal Register* notice (74 FR 41883). AWWA is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 57,000 members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, engineers, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,700 utilities that supply roughly 80 percent of the nation's drinking water. Based on this broad membership base, these comments should be considered as representative of the drinking water community in general.

These comments represent a restatement of the position submitted to the Agency in response to preliminary regulatory determination for perchlorate as detailed in the October 10, 2008 *Federal Register* notice (73 FR 60262). Given the weight of evidence available at that time and AWWA's independent assessment of occurrence and exposure we concurred with Agency's preliminary determination that regulation of perchlorate would not present ''a meaningful opportunity for health risk reduction for persons served by public water systems.'' We continue to support that preliminary determination. AWWA also concurs with the Agency's Inspector General[1] in stating that regulatory action under the Safe Drinking Water Act (SDWA) is not the appropriate or effective way to address the overarching public health issue - iodide deficiency. The National Research Council (NRC) assessment[2] of perchlorate also recognized iodide deficiency as the larger public health issue.

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1 Wilson, M. 2008. *Scientific Analysis of Perchlorate*. US Environmental Protection Agency, Office of Inspector General. Available at http://www.epa.gov/oigearth/reports/2009/20081230-2008-0010.pdf

2 National Research Council (NRC). 2005. Health Implications of Perchlorate Ingestion. National Academy Press, Washington, DC.

Interpretation of the Physiologically-Based Pharmacokinetic (PBPK) Modeling

AWWA recognizes the value of using models for risk assessment purposes. The Agency, in response to concerns raised in October 2008, elected to reassess exposure to life stages and broaden the scope of "the most sensitive population" which previously had been defined by the National Research Council (2005) as "the fetuses of pregnant women who might have hypothyroidism or iodine deficiency." The assessment appropriately follows EPA's Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants (USEPA, 2005) which recommends the following 10 age groups be considered in exposure assessments for children.

- Less than 12 Months old: birth to < 1 month, 1 to < 3 months, 3 to < 6 months and 6 to < 12 months.
- Greater than 12 months old: 1 to < 2 years, 2 to < 3 years, 3 to < 6 years, 6 to < 11 years, 11 to < 16 years, and 16 to < 21 years.

AWWA recognizes these important subpopulations, yet is troubled by the lack of recognition in the modeling efforts to incorporate the findings from the most recent and well designed epidemiological studies. These studies provide direct dose-response assessments that should be included into the Agency's modeling effort rather than making presumptive calculations for purposes of estimating a Health Reference Level (HRL) for each life stage examined. The majority of these studies have shown no adverse health effects to women of child bearing age, newborns, and school age children who were exposed to significant amounts of perchlorate via drinking water at levels below and above the EPA accepted Reference Dose (RfD) of 0.0007 mg/Kg-day), as well as to other goitrogens. These studies also address the request for comment regarding the use of the PBPK model to "explore the relative sensitivity of various life stages".

In previous exposure assessments conducted by the EPA, such as arsenic, all available epidemiological data was factored into the modeling assumptions, including sensitive subpopulations. EPA has clearly omitted significant peer-reviewed studies that provide a significant weight of evidence finding that there is no adverse impact from exposure to perchlorate in drinking water in the subpopulations that are a focus of this reassessment as summarized in Table 1. This omission represents a significant deficiency that countermands the Agency's stated commitment[3] and obligation under the SDWA to use the "best available peer reviewed science" for supporting sound and technical regulatory determinations.

[3] Memo to Employees from EPA Administrator Lisa Jackson, entitled "Scientific Integrity: Our Compass for Environmental Protection". May 9, 2009. http://www.epa.gov/Administrator/scientificmemo.html

Table 1. Epidemiological Studies Assessing Effect of Perchlorate Exposure on Children

Epidemiological Studies	Study Design	Findings
Crump et.al., 2000[4]	Study investigated the potential effects of perchlorate in drinking water on thyroid function in newborns and school-age children. A total of 162 school-age children and 9,784 newborns were studied in the proximate cities in northern Chile: Taltal (100 to 120 µg/L), Chañaral (5 to 7 µg/L), and Antofagasta (non-detectable to <4 µg/L).	No evidence was found that perchlorate in drinking water at these concentrations is associated with thyroid suppression in newborns or school-age children. Among school-age children no evidence was found of adverse effects on thyroid, bone marrow, liver, or kidney function.
Tellez et.al., 2005[5]	Authors conducted a longitudinal epidemiologic study among pregnant women from three cities in northern Chile: Taltal with 114 µg/L, Chañaral with 6 µg/L, and Antofagasta with 0.5 µg/L, perchlorate in the public drinking water. Study was designed to test long-term exposure to perchlorate at levels that may cause a situation analogous to iodine deficiency.	Perchlorate in drinking water at 114 µg/L did not cause changes in neonatal thyroid function or fetal growth retardation. Median breast milk iodine was not decreased in the cities with detectable perchlorate. Analysis of maternal urinary perchlorate excretion indicates an additional dietary source of perchlorate.
Amitai et.al., 2007[6]	Thyroxine (T_4) values were compared among newborns in Ramat Hasharon, Israel, whose mothers resided in suburbs where drinking water contained perchlorate ≤340 µg/L (very high exposure, n = 97), 42–94 µg/L (high exposure, n = 216), and <3 µg/L (low exposure, n = 843).	This study finds no change in neonatal T_4 levels despite maternal consumption of drinking water that contains perchlorate at levels in excess of the National Research Council reference dose (RfD). Therefore the perchlorate RfD is likely to be protective of thyroid function in neonates of mothers with adequate iodide intake.

Alternative HRLs Based Upon Body Weight and Water Consumption of Other Life Stages

AWWA believes that it is unnecessary for the Agency to adjust for Relative Source Contribution (RSC) when calculating a HRL, since the RfD is based on a No Observed Effects Level (NOEL) and the Greer[7] study only measured the incremental exposure to drinking water. The body of data on which the National Research Council (NRC) based their conclusions produced a No Observed Effects Level (NOEL) (not considered a No Observed Adverse Effects Level [NOAEL]because the biochemical changes measured were not considered adverse in and of

[4] Crump, C., Michaud, P., Téllez, R., Reyes, C., Conzalez, G., Montgomery, E., Crump, K., Lobo, G., Becerra, C., and J. Gibbs. 2000. Does perchlorate in drinking water affect thyroid function in newborns or school-age children? *Journal of Occupational and Environmental Medicine.* 42:6:603.

[5] Téllez, R., Chacón, P.M., Abarca, C.R., Blount, B.C., Landingham, C.B, Crump, K.S., and J.P. Gibbs. 2005. Long-term environmental exposure to perchlorate through drinking water and thyroid during pregnancy and the neonatal period. *Thyroid.* 15:9:963.

[6] Amitai, Y., Winston, G., Sack, J., Wasser, J., Lewis, M., Blount, B., Valentin-Blasni, L., Israeli, A., and A. Leventhal. 2007. Gestational exposures to high perchlorate concentrations in drinking water and neonatal thyroxine levels. *Thyroid.* 17:9:843.

[7] Greer, M., Goodman, G., Pleus, R., and Greer, S. 2002. Health effects assessment for environmental perchlorate contamination: the dose-response for inhibition of thyroidal radioiodine uptake in humans. *Environmental Health Perspectives*, 110:927.

themselves) of 0.007 mg/Kg-day. The NRC further recommended a total uncertainty factor of 10 for intraspecies extrapolation (the data were from humans), resulting in a recommended RfD of:

RfD = 0.007 / 10 = 0.0007 mg/Kg-day

The Agency[8] accepted the NRC's RfD. Typically the RfD would be multiplied by the RSC for ingestion of drinking water to obtain a limit on exposure. However, this practice arose from the common use of clinical, epidemiological, or experimental animal studies in which individuals were exposed solely through the route of interest (e.g. ingestion of water). Given a sole route of exposure it is necessary to correct for the fact that individuals in the general population would likely be exposed to a compound through multiple routes. As a result, the application of an RSC in the regulatory process is based on the (often unstated, but nonetheless implicit) assumption that the study population was NOT exposed through routes other than the one of interest, while the general population was exposed through ALL routes.

This assumption is not fully warranted in the case of perchlorate because the individuals in the Greer study maintained a normal diet during the period of the study.[9] Therefore, they should have been exposed to perchlorate from non-drinking-water routes at an Average Daily Rate of Intake (ADRI) value roughly equivalent to that of the general population that is the target of regulatory determinations. This is supported by the FDA's Total Diet Study[10] and the NHANES assessments[11,12], which suggests a ubiquitous exposure to perchlorate from various food sources. If this is the case, application of an RSC would in effect "double count" the influence of the non-drinking-water exposures, because the NOEL from the Greer study already reflected these background exposures (absent these background exposures, the NOEL of 0.007 mg/Kg-day would be expected to be higher).

Since the RfD is based on a NOEL versus the traditional NOAEL, EPA is already building in extra levels of protection. The current request for comments recognizes that this is a departure from the traditional approach and that the NOEL which is based on "using a nonadverse effect that is upstream of the adverse effect is a more conservative and health protective approach". The NRC's use of a precursor to an adverse effect is represented in Figure 1. The RfD represents a point of departure (POD) that precedes the inhibition of iodine uptake by the thyroid.

Figure 2 provides a generic representation of the difference between the NOEL and NOAEL. Given the very conservative and precautionary nature of the RfD, further adjustment of the RfD as suggested by the Agency for purposes of recommending HRLs is unwarranted. This is further supported by the epidemiological studies that cover multiple life stages at perchlorate levels above and below the suggested HRLs and observed no adverse effects.

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8 USEPA. 2005. EPA Sets Reference Dose for Perchlorate. New release dated 02/18/2005. http://yosemite.epa.gov/opa/admpress.nsf/b1ab9f485b098972852562e7004dc686/c1a57d2077c4bfda85256fac005b8b32!OpenDocument

9 Crawford-Brown, D., Raucher, B., and M. Herrod 2006. Inter-Subject variability of risk from perchlorate in community water supplies. *Environmental Health Perspectives,* 114:7:975.

10 Murray, C.W III, S.K. Egan, H. Kim, N. Beru, P.M. Bolger. 2008. US Food and Drug Administration's Total Diet Study: Dietary Intake of Perchlorate and Iodine. *Journal of Exposure Science and Environmental Epidemiology* 18:571.

11 Blount, B.C., J.L. Pirkle, J.D. Osterloh, L. Valentín-Blasini, and K.L. Caldwell. 2006. Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States. *Environmental Health Perspectives*. 114:12:1865.

12 Blount, B.C., L. Valentín-Blasini, J.D. Osterloh, J.P. Mauldin, and J.L. Pirkle. 2007. Perchlorate Exposure of the US Population, 2001–2002. *Journal of Exposure Science and Environmental Epidemiology* 17:400.

Figure 1. Depiction of Point of Departure (POD) used to derive NOEL

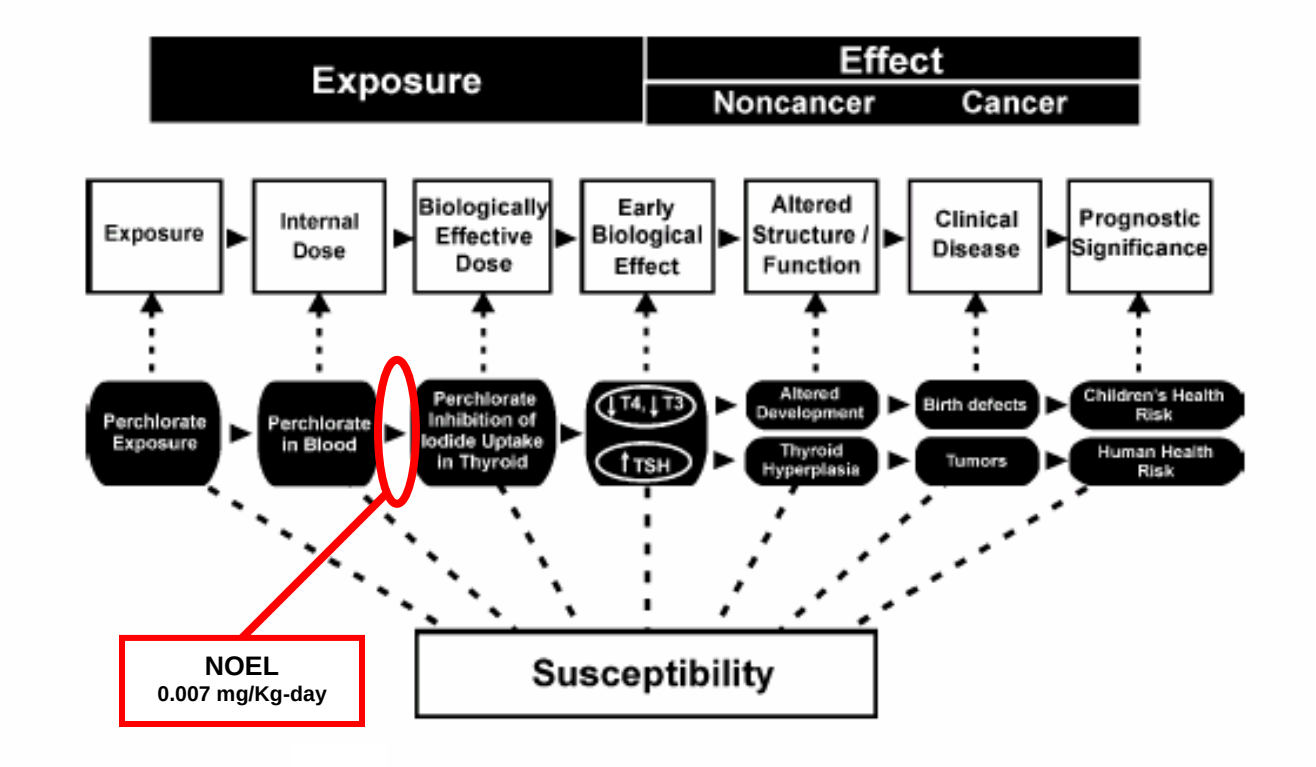
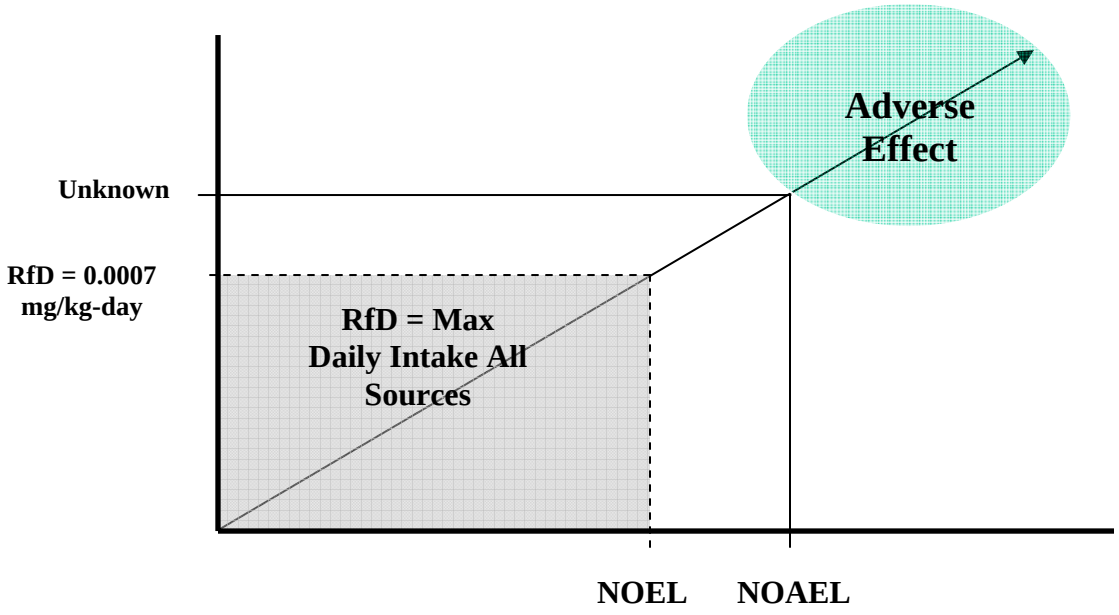


Figure 2. Perchlorate RfD represents a conservative point of departure (POD) for hazard assessment



The study by Mendez et.al.[13] further supports findings that the NOEL based RfD is sufficiently conservative and health protective of sensitive subpopulations. This study finds that the total dietary exposure (food and drinking water) of reproductive age women in the U.S. is approximately one-third of the RfD for perchlorate at the 95th percentile, which is complementary to the findings of the joint assessment prepared by EPA-CDC. Given this evidence related to limited exposure potentials and estimated intakes well below the RfD, it is clear that there is limited potential for perchlorate to present a significant adverse affect on the nation's health, including sensitive subpopulations.

Occurrence Analysis

The Agency requested comments on the appropriateness of using a Bayesian model to estimate perchlorate occurrence in public water systems and populations served by such systems. This estimate would use UCMR1 data that had a laboratory detection level of 4 µg/L and project national occurrence at levels below 4 µg/L. While AWWA recognizes the validity of Bayesian modeling, we believe that the study as proposed is not necessary to support the Agency's regulatory decision making for perchlorate. The weight of evidence as discussed in our comments does not support the need for further analysis of occurrence since regulation of perchlorate would not present a meaningful opportunity for health risk reduction for persons served by public water systems.

Multiple studies have presented data demonstrating that perchlorate is widely found at low levels and may originate from anthropogenic and/or natural sources; it even occurs in some dietary supplements[14] and groundwater more than 28,000 years old[15]. Since the major route of exposure is food and not water, estimating low level concentrations of perchlorate in the minor source will not provide any additional useful information. The only reason to determine perchlorate concentrations in water is to estimate human exposure. Given the previous discussion and the Agency's assessments, there clearly is sufficient data from human studies that have been completed to sufficiently characterize exposure. These studies (e.g. NHANES, FDA Total Diet Study) examined urine, saliva, and breast milk and in all cases the study subjects had perchlorate. There were no studied individuals who did not have perchlorate. So we know that in the U.S., exposure to perchlorate is very close to universal. Further, examination[16] of the existing UMCR dataset provides no general indicator of a causal relationship between occurrence and known locations of perchlorate releases with exception of locations at extremely high levels that were typically adjacent to industrial and military users of perchlorate. In the vast majority of UCMR occurrences, an obvious source could not be easily identified. Studies[17,18,19,20] of natural

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[13] Mendez, W., Dederick, E., and J. Cohen. 2009. Drinking water contribution to aggregate perchlorate intake of reproductive-age women in the United States estimated by dietary intake simulation and analysis of urinary excretion data. *Journal of Exposure Science and Environmental Epidemiology* advance online publication 16 September 2009.

[14] Snyder, S., Pleus, R., Vanderford, B., J. Holady. 2006. Perchlorate and chlorate in dietary supplements and flavor enhancing ingredients. *Analytica Chimica Acta,* 567:1:26.

[15] Plummer, L. N.; Bohlke, J. K.; Doughten, M. W. 2006. Perchlorate in pleistocene and holocene groundwater in North-Central New Mexico. *Environ. Sci. Technol.* 40:1757.

[16] Brandbuber , P, Clark, S. and K. Morley. (publication pending) The Occurrence of Perchlorate in Public Drinking Water Systems, *Journal AWWA.*

[17] Jackson, W., Rainwater, K., Anderson, T., Lehman, T., Tock, R., Rajagopalan, S., and M. Ridley. 2004. Distribution And Potential Sources Of Perchlorate In The High Plains Region Of Texas Final Report. Submitted to the Texas Commission on Environmental Quality.

[18] Duncan, P.B, Morris, R.D., and E. Vavricka. 2005. Forensic identification of anthropogenic and naturally occurring source of perchlorate. *Environmental Forensics,* 6:205-215.

occurrence also do not provide a sound basis for predicting occurrence of perchlorate, unlike other inorganic substances that may associate with specific geological formations such as radionuclides and arsenic.

The Agency has proposed a statistical Bayesian procedure to estimate the distribution of censored perchlorate data. There are several different such procedures (Maximum Likelihood Estimate, Kaplan-Meier Non-Parametric techniques, Regression on Order Statistics) however that all make assumptions about the nature of the distribution, whether normal, log-normal, or non-normal. The Agency has not explained why this particular model would be used versus one of the other approaches noted here. Nor does the Agency explain what population distribution is being assumed. Without this information, it is impossible to comment on the validity of the proposed procedures for this or potentially future applications of this approach. Regardless, all such procedures must assume that a single population of results is being estimated. However there appear to be multiple populations of results, those resulting from natural sources, munitions, Chilean fertilizers, etc. There may, of course, be more than one natural source as cited in the studies previously noted. Given the fact that the occurrence data is mostly poly-modal due to multiple sources in areas such as California and Massachusetts, the use of any statistical procedure that is based on a mono-modal distribution will have little likelihood of producing useful results.

Consideration of Studies Published since EPA adopted the NAS RfD for perchlorate

In addition to the noted epidemiological, exposure assessment, and occurrence studies, AWWA would like to direct the Agency's attention to other references that should bear on the decision making process following this comment period.

- **AWWA and Water Research Foundation. 2009. Hypochlorite – An Assessment of Factors That Influence the Formation of Perchlorate and Other Contaminants.**

  Considering that perchlorate has been under review for Federal regulation and is currently regulated in California and Massachusetts (proposed in New Jersey), this study was commissioned to quantify potential perchlorate contributions from hypochlorite sources. Sodium hypochlorite is a commonly used form of chlorine in drinking water and water reuse applications for its ability to disinfect and maintain a residual level of disinfectant throughout the distribution system. Approximately 1/3 of all drinking water treatment plants (DWTPs) in the United States use bulk hypochlorite for disinfection.[21] Though the majority of liquid hypochlorite use is in the form of bulk hypochlorite delivered from regional manufacturers and/or distributors, and some use on-site hypochlorite generators (OSG).

  The data set for this study was limited to 12 OSG sites, 6 bulk hypochlorite sites, and 1 calcium hypochlorite site. This sample set suggested no difference between bulk sodium

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[19] Dasgupta, P., Martinelango, P., Jackson, W., Anderson, T., Tian, K., and R. Tock. 2005. The Origin of Naturally Occurring Perchlorate: The Role of Atmospheric Processes *Environ. Sci. Technol.*, 39:6:1569 -1575.

[20] Balaji Rao, Todd A. Anderson, Greta J. Orris, Ken A. Rainwater,† Srinath Rajagopalan, Renee M. Sandvig, Bridget R. Scanlon, David A. Stonestrom, Michelle A. Walvoord, and W. Andrew Jackson (2007) Widespread Natural Perchlorate in Unsaturated Zones of the Southwest United States *Environ. Sci. Technol*, 41:4522–4528.

[21] AWWA Disinfection Committee. 2008. Committee Report: Disinfection Survey Part 2 – Alternatives, experience and future plans. *Journal AWWA.* 100:11.

hypochlorite solutions, OSG solutions, and calcium hypochlorite solutions with respect to chlorate and perchlorate ion concentration, with the exception being bromate formation. The analysis did demonstrate the potential to exceed some existing state standards and HRLs proposed by the Agency. Therefore, as more pressure is placed on utilities using gaseous chlorine to move towards alternative disinfection practices for security related reasons, the sector requires more detailed information to fully characterize potential differences (in terms of contaminant formation/dosing) between the available options to avoid unintended future water quality consequences and proper consideration of the risk-risk tradeoffs.

- **Russell, C., Roberson, A., Chowdhury, Z., and M. McGuire. 2009. National Cost Implications of a Perchlorate Regulation. *Journal AWWA*. 101:3:54.**

  Recognizing a lack of available information on projected national costs associated with perchlorate treatment, a study was conducted to estimate the national cost implications of setting a federal maximum contaminant level (MCL) for perchlorate at different levels between 4 and 24 μg/L. At the most stringent potential MCL evaluated (4 μg/L), the national compliance cost was estimated to be between $76 and $140 million per year at a 3% discount rate. The relatively low national compliance cost for perchlorate reflects the small number of public water systems (PWSs) expected to be affected (3.4% at a perchlorate MCL of 4 μg/L based on 90^{th} percentile perchlorate concentrations). However, the cost impacts to an individual system installing perchlorate treatment would likely be significant. With operations and maintenance (O&M) costs for perchlorate treatment over a 20-year period comparable to the capital costs for construction and with these O&M costs continuing in perpetuity, ratepayers could face a significant increase.

Current National Exposure to Drinking Water Perchlorate

AWWA believes that the population exposed to perchlorate that was indicated by EPA's UCMR1 data is no longer valid. In an informal survey conducted by AWWA, we found that many sources that had detected perchlorate from UCMR1 monitoring are either no longer being used or are being treated per the requirements of maximum contaminant levels (MCL's) established in California and Massachusetts. Additionally, successful treatment of the perchlorate source to Colorado River contamination has lowered concentrations to below 4 μg/L. AWWA believes that EPA would be well served to work with state primacy agencies to evaluate the 160 water systems with perchlorate detections from UCMR1 to determine the actual national population currently exposed to perchlorate above 4 μg/L. AWWA believes this information will further help inform EPA as to whether there is a meaningful opportunity for health risk reduction by regulating perchlorate.

Conclusion

AWWA believes that the Agency's originally proposed decision not to regulate perchlorate is supported by the criteria established in the SDWA. The primary public health issue - as stated by the NRC and others including the Agency's Inspector General[22] - is iodine deficiency. The SDWA is not an effective means or "tool" to manage a public health issue dominated by dietary issues. The public's exposure to all sources of goitrogens due to extensive contributions from other sources as demonstrated by the FDA food market assessment support the findings that regulation of drinking water would not have a meaningful impact on changing the nation's level of iodine deficiency. A precautionary approach is not justified by the available public health data that provides no indication of epidemic cretinism, goiter, or hypothyroidism, even given the loading of other goitrogens that far exceed potential contribution from perchlorate from all sources. A risk management approach that seeks to extract 100 percent of the risk reduction value from the smallest possible source is not only ineffective, but is a disservice to the mission of seeking the greatest protection of public health. The Agency should use the findings of this assessment to support a collaborative effort with the Department of Health and Human Services and Department of Agriculture to develop outreach materials that communicate the importance of proper dietary levels of iodine, specifically targeting sensitive subpopulations. Attempts have been made in the past to ensure the public received appropriate iodine levels.[23] AWWA believes that remains a better approach for addressing the problem of iodine deficiency, instead of using the Safe Drinking Water Act to address this issue

AWWA appreciates the opportunity to comment on these important drinking water issues. If you have any questions about these comments, please feel to call Kevin Morley or me in our Washington Office at 202-628-8303.

Sincerely,

Tom Curtis
Deputy Executive Director–Government Affairs

cc: Peter Silva, OW
Cynthia Doughtery, OGWDW
Eric Burneson, OGWDW

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[22] Wilson, M. 2008. *Scientific Analysis of Perchlorate*. US Environmental Protection Agency, Office of Inspector General:Washington DC. Available at http://www.epa.gov/oigearth/reports/2009/20081230-2008-0010.pdf

[23] Medicine: Pass the iodized salt, in Time 1949, 19 September. Available at http://www.time.com/time/magazine/article/0,9171,800702,00.html