



American Water Works
Association

The Authoritative Resource on Safe WaterSM

Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

Advocacy
Communications
Conferences
Education and Training
Science and Technology
Sections

July 10, 2012

Mr. Thomas Carpenter
U.S. Environmental Protection Agency
Science Advisory Board Perchlorate Panel DFO
(via email)

RE: Perchlorate Comments for Science Advisory Board (SAB) Perchlorate Panel

The American Water Works Association (AWWA) appreciates the opportunity to comment on the SAB's consideration of perchlorate as detailed in the May 30, 2012 *Federal Register* notice (77 FR 31847) and supporting materials. 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 50,000 plus 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 4,000 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 positions submitted by AWWA to the Agency in response to the October 10, 2008 *Federal Register* notice (73 FR 60262) and the August 3, 2009 *Federal Register* notice (74 FR 41883) in the context of the charge set forth for consideration by the SAB. In addition, AWWA is providing comment on the overall SAB process as it relates to the information and associated charges under review by the perchlorate panel.

Comments on SAB Review Process

AWWA values the purpose and objective of the SAB. However, as stated in prior comments (letter dated June 2, 2011), we remain concerned that the SAB review process is not fulfilling its intended mission. In the context of the SAB Perchlorate Panel, we believe that the charge set forth by the Agency should be fully reviewed and discussed by the Panel with the option to modify as appropriate to ensure full and appropriate consideration of the science under review. We believe that the charge questions as currently prepared are deficient in that they omit consideration of several key scientific principles that should be evaluated by the Panel. In terms of the SAB review process we have two principle comments with regard to 1) the SAB's

consideration of precedent being established with this regulatory action and 2) the associated transparency and openness issue with the process overall.

Precedent for Regulation Based on Non-Adverse Effect

The criteria for selecting a contaminant for potential drinking water regulation, as defined in the Safe Drinking Water Act (SDWA), requires a consideration of whether contamination is occurring at levels “of public health” concern and whether regulation of the contaminant would meaningfully reduce potential health risks. AWWA has previously acknowledged and complimented the National Research Council for the extensive assessment of risk that resulted in setting the perchlorate oral Reference Dose (RfD) at 7×10^{-4} mg/kg-day.¹ In consideration of the SDWA criteria, it should be emphasized that the RfD represents a No Observed Effect Level (NOEL) versus the traditional No Observed Adverse Effect Level (NOAEL). As discussed by Crawford-Brown et al. (2006)² and in the Agency’s 2008 preliminary determination, a NOAEL is by definition equal to or higher than a NOEL where the effect used to establish the NOEL is a precursor to the adverse effect of interest in establishing a NOAEL. The NRC’s use of a precursor to an adverse effect (iodine uptake inhibition) in establishing a threshold for exposure represents a “more conservative, health-protective approach”. The NRC’s stated intent was to assure that the RfD was protective of the most sensitive subpopulation (iodide-deficient pregnant women and their fetuses).

AWWA believes that it is imperative that the SAB consider the implications of shifting the regulatory construct to a point-of-departure representative of a non-adverse effect. This is unprecedented and has broad implications for the overall regulatory approach considering that all substances/compounds have some effect on the human body at low levels, but effects that are not adverse in the context of public health. This is an important consideration that is absent from the charge set forth by the Agency for the SAB and is essential in framing the necessity of the approaches outlined in the white paper.

In addition, the charge issues require further clarification since those on the official charge document differ from the questions posed in the white paper. The Panel should take time to identify the most critical scientific challenges at issue and to provide input on the state of the science and the soundness of the Agency’s approach to those issues.

Transparency and Openness

EPA has restricted verbal public comment at the July 18-19 meeting to no more than 5 minutes. We believe that this is an inadequate amount of time to provide for proper communication of the scientific issues under consideration by the Perchlorate Panel. The Agency solicited comments on public involvement in EPA advisory activities (76 Federal Register 27315). In AWWA’s response letter dated June 2, 2011, it was noted that information provided by the public is often treated as less valuable than the information compiled by the Agency. The public notice and allotted time on the agenda includes little opportunity for substantive public comment. This actively discourages the exchange of information between SAB members and knowledgeable observers, through direct instruction to the committee members, informal pressure on committee members and the public, or both.

¹ National Research Council (2005). Health Implications of Perchlorate Ingestion, Committee to Assess the Health Implications of Perchlorate Ingestion. <http://dels.nas.edu/Report/Health-Implications-Perchlorate-Ingestion/11202>

² Crawford-Brown, D., Raucher, B. and Harrod, M. (2006). Inter-subject variability of risk from perchlorate in community water supplies. *Environmental Health Perspectives* 114:7:975.

Therefore, AWWA requests that the SAB and the Agency make consideration for additional time to provide for dialogue among experts on the panel and the public as the various charges are considered.

Comments on EPA Charge to the SAB Perchlorate Panel

Charge Issue I – Sensitive Life Stages

Since the RfD is based on a NOEL versus the traditional NOAEL, EPA’s determination is already premised on the providing of additional levels of protection. The background material for the SAB does not properly recognize that this is a departure from the traditional approach and that the NOEL, which is based on “using a non-adverse 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. In fact the NRC noted that the RfD is equivalent to an amount more than 20 times the reference dose originally proposed by EPA and should not threaten the health of even the most sensitive populations. The NRC defined sensitive subpopulations as people with thyroid disorders, pregnant women, fetuses, and infants.

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

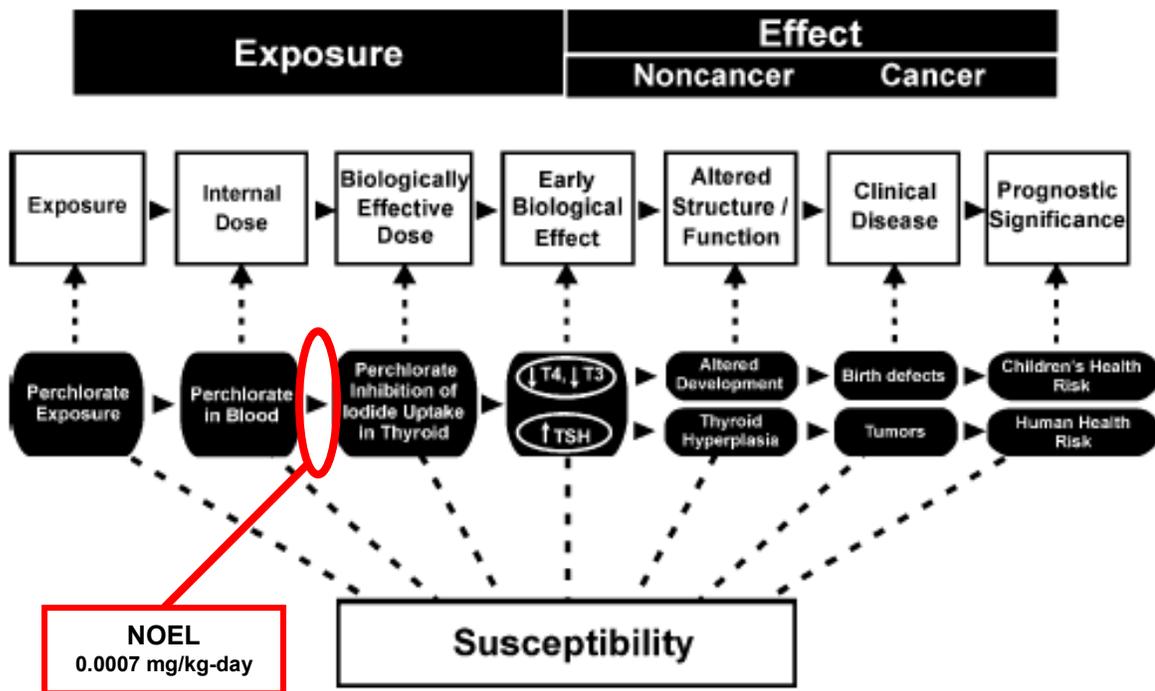
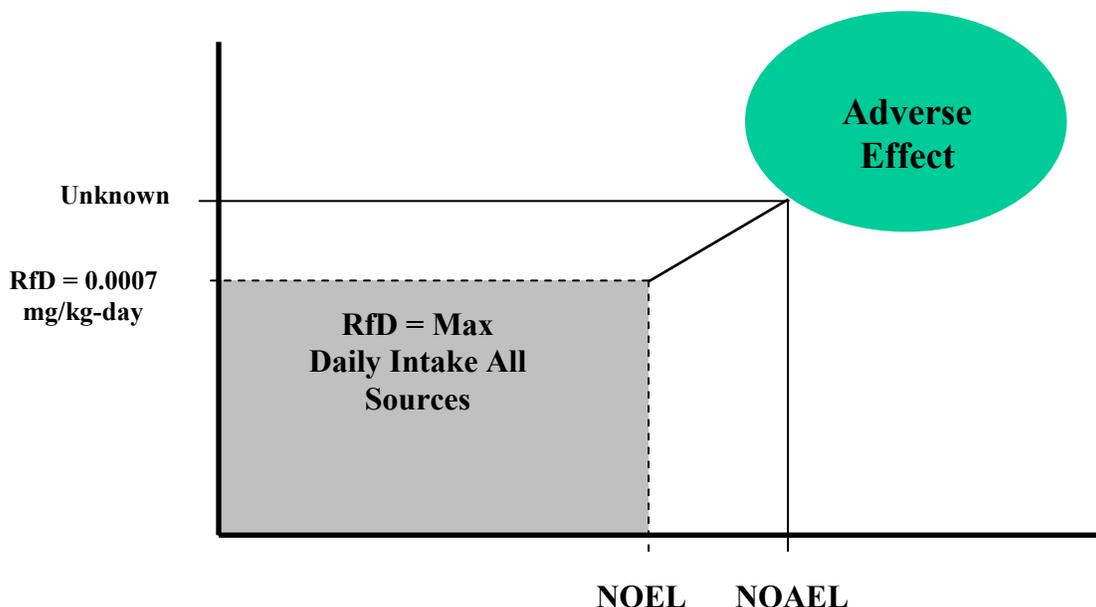


Figure 2 provides a generic representation of the difference between the NOEL and NOAEL. As will be discussed further in these comments, the adverse effect occurs at a point well beyond the

NOEL when, and if, perchlorate exposure overwhelms the thyroid's ability to uptake of iodide. In more simple terms perchlorate must out-compete iodide, which means iodide exposure is also a critical factor to consider. Given the very conservative and precautionary nature of the RfD, further adjustment of the RfD as proposed by the Agency for purposes of recommending Health Reference Levels (HRLs) for multiple life stages 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 effect. These studies are discussed further relative to Charge Issue III.

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



In the white paper discussion of life-stage MCLGs, the Agency describes dietary ingestion pathways for perchlorate exposure. The key study cited is the Total Dietary Study (TDS) conducted by the Food and Drug Administration (FDA) as reported in Murray et al. (2008). The level of perchlorate exposure is an important factor relative to the amount of iodine ingestion. The NRC indicated that “iodide uptake would most likely have to be reduced by at least 75% for months or longer” to trigger an adverse effect. Therefore, it is important for the SAB to consider the levels of both iodine and perchlorate. This is especially critical since the major conclusion of the NRC report is that the real public health issue is iodide deficiency and not perchlorate exposure.

In more recent dietary assessments³ the FDA determined that it was unnecessary to recommend “that consumers of any age alter their diet or eating habits to reduce perchlorate exposure. If one eats a healthy diet that is consistent with the Dietary Guidelines for Americans, taking iodine supplements is not necessary for protection against the health effects associated with perchlorate at the levels present in water and food.” This assessment calls into question the probability that the public, any age category, will be exposed to enough perchlorate at levels exceeding the RfD from any source to overcome the body's compensation mechanisms for a sufficient period of time to cause a 75 percent inhibition.

³ Trumbo, P.R. (2010) Perchlorate consumption, iodine status, and thyroid function. *Nutrition Reviews* 68:1:62–66. doi:10.1111/j.1753-4887.2009.00260.x

AWWA questioned the effectiveness of regulating perchlorate in overcoming iodide deficiency in concurrence with the Agency's own Inspector General's conclusion. Furthermore, in the Agency's response to this comment⁴, the following statement was offered.

EPA based its final regulatory determination on a number of different factors including the careful consideration of public comments. Regarding correcting iodine deficiencies, the Food and Drug Administration and Centers for Disease Control generally conclude that there is sufficient iodine in the diet. Below are findings from FDA's Total Diet Study (2003-2004) that estimates the dietary intake of iodide for 14 age-sex groups (Murray et al., 2008) and CDC's National Health and Nutrition Examination Survey that measured perchlorate in the urine of study participants in (2003- 2004, no data on < age 6).

FDA's Total Diet Study findings:

- Infants, 6-11 months, exceeded their Adequate Intake
- Children and adult age/sex groups exceed their relevant Estimated Average Requirement

CDC's National Health and Nutrition Examination Survey:

- This finding confirms the stability of the U.S. iodine intake and continued adequate iodine nutrition for the country in general.
- On the basis of median urinary iodine concentrations, iodine intake of women of childbearing age appears adequate.

Based on this information, the SAB should seriously question the potential for perchlorate exposure to out-compete iodide in the thyroid for a sustained period of time such that it could potentially induce an adverse effect. This information when considered in the context of the most recent epidemiological evidence (see Table 1) suggests that the Agency's decision rational and methods are flawed and therefore unsubstantiated.

Charge Issue II - Physiologically-Based Pharmacokinetic (PBPK) Evidence

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 NRC 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.

⁴ USEPA. 2011. Comment Response Document for the Final Regulatory Determination on Perchlorate (Categorized Public Comments) [EPA 815-R-10-005]. EPA Comment ID: 28842.

AWWA recognizes the potential regulatory importance of these 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. All models need to be appropriately validated. 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 HRLs 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 RfD, as well as to other goitrogens. These studies also address the need expressed by the NRC to "explore the relative sensitivity of various life stages".

Charge Issue III – Epidemiological Evidence

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, as summarized in Table 1, which provide a significant weight of evidence finding that there is no adverse impact from exposure to perchlorate in drinking water in the subpopulations as defined by the NRC and included in the Agency's life stage analysis that is based on *inferred effects* versus actual *observed effects*. This omission represents a significant deficiency that countermands the Agency's stated commitment⁵ and obligations under Executive Order 13563⁶ and the SDWA to use the *best available peer reviewed science* for supporting sound and technical regulatory determinations.

Charge Issue IV – Information Integration

AWWA believes that the Agency's decision to regulate perchlorate is not supported by the criteria established in the SDWA. A precautionary approach is not justified by the available public health data, which provides no indication of epidemic cretinism, goiter, or hypothyroidism that might be expected if there was indeed a causal relationship to perchlorate exposure. For instance, the many years that some 20 million people were exposed to perchlorate levels in the teens and twenties of micrograms from Colorado River water, there is certainly no evidence of significant cretinism in Nevada, Arizona or California during these years. The absence of a public health effect is even more amplified when considering the loading from other goitrogens that far exceed potential contribution from perchlorate from any source.

Attempts have been made in the past to ensure the public receives appropriate iodine levels⁷ and studies have examined the cost effectiveness as a public health intervention.⁸ AWWA believes that such solution remains a better approach for addressing the problem of iodine deficiency, instead of using the SDWA to address this issue. We advise the SAB to fully consider the broad implications of this regulatory action relative to lack of data supporting an objective conclusion

⁵ 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>

⁶ Executive Order 13563: Improving Regulation and Regulatory Review, Signed by President Barack H. Obama January 18, 2011

⁷ Medicine: Pass the iodized salt, in *Time* 1949, 19 September. Available at <http://www.time.com/time/magazine/article/0,9171,800702,00.html>

⁸ Alderman, H. 2010. The economic cost of a poor start to life. *Journal of Developmental Origins of Health and Disease* 1:1:19–25.

that such action represents a meaningful opportunity to protect public health as required by the SDWA.

Table 1. Studies Assessing Effect of Perchlorate Exposure on Sensitive Subpopulations

Study	Findings
Leung et al. 2011 ⁹	U.S. vegetarians are iodine sufficient. U.S. vegans may be at risk for low iodine intake, and vegan women of child-bearing age should supplement with 150 µg iodine daily. Environmental perchlorate and thiocyanate exposures are not associated with thyroid dysfunction in these groups.
Pearce et al., 2011 ¹⁰	Low-level perchlorate exposure is ubiquitous, but is not associated with altered thyroid function among women in the first trimester of pregnancy.
Pearce et al., 2010 ¹¹	Low-level perchlorate exposure is ubiquitous but did not affect thyroid function in this cohort of iodine-deficient pregnant women.
Mendez et al. 2009 ¹²	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 assessment prepared by Huber et al., 2010.
Huber et al, 2010 ¹³	Calculated that an average 66 kg pregnant woman consuming a 90th percentile food dose (0.198 mg/kg/day) could also drink the 90th percentile of community water for pregnant women (0.033 l/kg/day) containing 15 µg/l perchlorate without exceeding the 0.7 mg/kg/day reference dose.
Amitai et al., 2007 ¹⁴	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.
Tellez et al., 2005 ¹⁵	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.
Crump et al., 2000 ¹⁶	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.

⁹ Leung, A.M., et al. 2011. Iodine Status and Thyroid Function of Boston-Area Vegetarians and Vegans. *J Clin Endocrinol Metab.* 96(8):E0000–E0000.

¹⁰ Pearce, E.N., et al. 2011. Effect of environmental perchlorate on thyroid function in pregnant women from Cordoba, Argentina, and Los Angeles, California. *Endocr. Pract.* 17(3):412-417.

¹¹ Pearce, E.N., et al. 2010. Perchlorate and thiocyanate exposure and thyroid function in first-trimester pregnant women. *J. Clin. Endocrinol. Metab.* 95(7):3207-3215.

¹² Mendez, W., E. Dederick, and J. Cohen. 2010. 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. *J. Expo. Sci. Environ. Epidemiol.* 20(3):288-297.

¹³ Huber, D.R., et al. 2010. Estimating perchlorate exposure from food and tap water based on U.S. biomonitoring and occurrence data. *J. Expo. Sci. Environ. Epidemiol.* 21(4):395-407.

¹⁴ Amitai, Y., et al. 2007. Gestational exposure to high perchlorate concentrations in drinking water and neonatal thyroxine levels. *Thyroid* .17(9):843-850.

¹⁵ Téllez, R., et al. 2005. Long-term environmental exposure to perchlorate through drinking water and thyroid during pregnancy and the neonatal period. *Thyroid.* 15:9:963.

¹⁶ Crump, C., et al. 2000. Does perchlorate in drinking water affect thyroid function in newborns or school-age children? *Journal of Occupational and Environmental Medicine.* 42:6:603.

AWWA appreciates the opportunity to comment on these important drinking water issues. If the SAB Perchlorate Panel has 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: Pamela Barr, OGWDW
Eric Burneson, OGWDW