American Water Works Association

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April 5, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Dear Administrator McCarthy;

The American Water Works Association (AWWA) is writing in response to the National Resource Defense Council's (NRDC) lawsuit, filed February 17, 2016, in the matter of *NRDC v. EPA*, Case No. 16-cv-1251 (S.D. N.Y), in which the NRDC is seeking to compel the U.S. Environmental Protection Agency (EPA) to finalize a rule regulating perchlorate pursuant to the Safe Drinking Water Act (SDWA).

We are deeply concerned that this litigation will unnecessarily truncate the EPA's current peer-review process. Any consent order resulting from this litigation should allow for a full review of scientific body of knowledge that has been gathered by the Agency prior to any final decision.

Given the importance of maintaining the integrity of the SDWA rule-making process, and the underlying science, AWWA has provided substantial comment to EPA and EPA's Science Advisory Board over the last decade on the regulatory determination of perchlorate under SDWA.

> Feb. 2, 2005 - Letter urging EPA to use sound science and requesting the Agency "make perchlorate a top priority, and to regulate this contaminant as expeditiously as feasible consistent with the requirements of the Safe Drinking Water Act."
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> May 27, 2005 - Letter urging EPA use the framework of the Contaminant Candidate List (CCL) to make a regulatory determine for perchlorate. In addition, we encouraged the agency to identify knowledge gaps that needed to be filled and identify what EPA will do to close those gaps, if information prevented the agency from making such a determination.

Nov. 10, 2008 - Letter supporting EPA proposed negative regulatory determination for perchlorate based on the criteria established in the SDWA.

Sep. 18, 2009 - Letter restating AWWA's position that regulating perchlorate would not present "a meaningful opportunity for health risk reduction for persons served by public water systems." We also expressed concern regarding the appropriateness of using iodide deficiency to address the public health issue under SDWA and the omission of peer-reviewed studies that reflected inconsistencies in health impacts from exposure in drinking water in the subpopulations that were and continue to be the focus of the reassessment.

AWWA also offered substantive comments in four separate submissions to the EPA's SAB between July 2012 and March 2013 during the reassessment.

1. EPA's Decision-Making Under SDWA Must be Guided by Statutory Criteria, Not an Arbitrary Deadline Imposed by a Court

AWWA's interest in the NRDC litigation remains the same as it has been throughout this lengthy process, that is, to ensure that the integrity of the SDWA process is maintained, including the use of best available science to promulgate a national primary drinking water regulation for a contaminant found in drinking water. Toward this end, it is worth emphasizing the three broad criteria the agency must use in making a regulatory determination. SDWA requires the presence of all three of the following:

> (i) the contaminant may have an adverse effect on the health of persons;
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> (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
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> (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. 42 USC §300g-1-(a)

As is well documented, the regulatory determination process for perchlorate has a long and complicated history, beginning in 1998, when perchlorate was first placed on SDWA's contaminant candidate list (CCL). After extensive review by EPA from 2005 through 2008, including a report by the National Academy of Sciences, EPA proposed a preliminary negative regulatory determination, concluding that there was not a "meaningful opportunity for health risk reduction" through a national drinking water regulation.. Consistent with its statutory

mandate under the SDWA, EPA issued a health advisory concurrently with this negative regulatory determination. Notwithstanding, in 2011, under a new Administration, the EPA subsequently reversed its decision, making an off-cycle positive regulatory determination.

The question whether to regulate perchlorate under SDWA has a long and complicated history, and underscores the concerns and criticisms levied by some regarding the inconsistency and lack of transparency in the regulatory determination process.[1] As noted by a 2011 GAO report, in light of the statute's granting of such broad discretion to EPA, Agency decision-making has the potential to be influenced – or the perception of influence - by factors other than best available science, including changes in Agency leadership. Certainly, EPA's change in leadership in 2009 has raised questions as to the role of non-scientific factors that may have led to the Agency's 2011 reversal.[2] As such, the AWWA strongly supported the Agency's decision in 2012

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[1] *See* written Testimony of David Trimble, GAO Report dated July 12, 2011, titled Improvements in Implementation Are Needed to Better Assure the Public of Safe Drinking Water, which states:

> [C]onsistency and accountability are lacking in this important program because EPA has not developed guidance on the application of the broad statutory criteria, which are susceptible to varying interpretations. In its comments, EPA highlighted that, under these criteria, ultimately it is the Administrator's judgment as to whether regulation of a contaminant in drinking water presents a meaningful opportunity for health risk reduction, after considering the information presented by agency staff. As stated in our report, the statutory criteria are so broadly stated that they could potentially be interpreted so as to lead to regulating all the contaminants on the candidate list, some of them, or none of them. It is precisely for these reasons that we believe it is essential for the staff to have sufficient guidance on applying the broad criteria consistently and transparently so that the Administrator's judgment can be based on sound and consistent information. Without such guidance, the basis for EPA's determinations and the quality of the documentation the staff use to support them can fluctuate over time as a result of, among other reasons, changes in agency leadership and staff.

[2] In her January 14, 2009, confirmation hearing, then Ms. Lisa Jackson, the nominee for EPA Administrator, engaged in the following colloquy with Senator Boxer:

> Senator Boxer: *A number of questions which I think for the most part you could say yes or no to, unless you want to elaborate. I want to get these things on the record. The first one is about perchlorate. Perchlorate is used to make rocket fuel. When it gets into drinking water, this toxic chemical can interfere with the thyroid and affect hormone systems, which control the way the body develops. Infants and pregnant women are especially vulnerable to perchlorate. It has contaminated drinking water supplies across the Country. California, my State, has 290 water sources with at least 4 parts per billion of perchlorate. The GAO found in 2005 that nearly 400 sites in 35 States had perchlorate. In 2006, the CDC found widespread human exposure to perchlorate in the U.S. And they found that many women who were exposed to perchlorate in drinking water had significant changes in thyroid hormone levels. A 2008 FDA study found perchlorate in 74 percent of all foods tested, including baby food. Yet, EPA recently refused to regulate perchlorate. We had quite a to-do over here in that hearing. And they won't regulate it in drinking water, and they sent the issue back to the National Academy of Sciences. Now, again, delay, delay, delay. We have had years of it and we need action. Do you commit to us to immediately review this failure to establish a drinking water standard for perchlorate and act to address the threat to pregnant women and children caused by this dangerous toxin?*
> Ms. Jackson: *Yes, Madam Chair.*

to enlist the support of the SAB and the more recent decision earlier this year, based on SAB's recommendation, to embark upon a rigorous peer-review of the Agency's dose-response modeling.[3]

We firmly believe that the current peer-review process is critical to ensuring the fidelity of the regulatory process and the soundness of its scientific underpinning. As such, we remain deeply concerned that the NRDC litigation may seek to truncate that process by imposing an arbitrary and unrealistic deadline influenced largely by timing and political considerations. In such case, it is likely that sound science would not be used in establishing an MCL.

2. EPA's 2011 Regulatory Determination May Need to be Revisited Based on the Agency's Peer-Review and PBPK Modeling

As noted above, SDWA also provides the Administrator "sole" discretion on whether a national drinking water standard "presents a meaningful opportunity for health risk reduction." Given information regarding perchlorate's frequency of occurrence and the fact that the states of California and Massachusetts already established MCLs under state law, 6 micrograms per liter (ug/L) and 3 ug/L, respectively, a legitimate question remains whether a national MCL is appropriate or even lawful. However, this question cannot be answered until the peer-review process has followed its proper course.

Although SDWA's statutory obligation to finalize an MCL within 18 months of a positive regulatory determination is not in dispute, if the peer-review process casts serious doubt on the effectiveness of a national MCL, as a matter of law, the Agency must reconsider its prior negative regulatory determination. EPA must also properly consider the effectiveness and cost-benefits of finalizing an MCL on protecting public health.

Toward this end, and in the context of the NRDC litigation, we would strongly urge the EPA against rushing to finish the peer-review process or agreeing as part of any litigation settlement to any arbitrary timeframe that truncates the process.

A court enforcing a statutory obligation to perform a non-discretionary duty, as in the present case, "may exercise its equity power" to set enforceable deadlines to achieve an ultimate and intermediate nature. *See Appalachian Voices v. EPA*, Civil Action No. 12-0523, Consolidated Case Nos. 12-0585 and 12-069 (D.D.C., Oct. 29, 2013). According to the District Court in *Appalachian Voices*,

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Senator Boxer: *Thank you.*

[3] Request for Nominations for Peer Reviewers for EPA's Biologically Based Dose-Response (BBDR) Model for Perchlorate in Drinking Water, 81 Fed. Reg. 10,617 (Feb. 9, 2016).

> [A] court may afford an agency additional time for compliance "where it is convinced by the official involved that he has in good faith employed the utmost diligence in discharging his statutory responsibilities." Generally, courts reject agency arguments that amount to no more than a general desire to further study an issue before acting, but in determining appropriate relief, a court is also charged to "separate justifications grounded in the purpose of the Act from the footdragging efforts of a delinquent agency." (citations omitted)

Here, it is clear that the EPA continues to diligently follow the mandates of the SDWA through using a peer-review process. We are confident that a court, if faced with the legal and evidentiary considerations, will properly conclude that such delay is appropriate and anything other than agency foot-dragging.

3. The Precedential Effect of Regulating Perchlorate Cannot be Underestimated

Legal considerations notwithstanding, given the growing list of unregulated contaminants that are under consideration by the Agency, we believe that the integrity of the process, focusing on best available science, is in the public's best interest. This includes consideration of the following:

Meaningful Opportunity – The current actions counter to the Agency Inspector General's conclusion that regulatory action under the Safe Drinking Water Act is not an appropriate or effective way to address the overarching public health issue - iodide deficiency.[4] The National

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[4] Office of Inspector General Scientific Analysis of Perchlorate, Report No. 10-P-0101, April 19, 2010, which states:

> Against established EPA risk assessment procedures, EPA derived the perchlorate RfD from a nonadverse biological effect instead of an adverse effect. The perchlorate RfD protects against all human biological effects from exposure, which is a stricter public health criterion than limiting environmental exposure to protect against adverse effects in humans. This shift in risk management constitutes a significant change in environmental policy.
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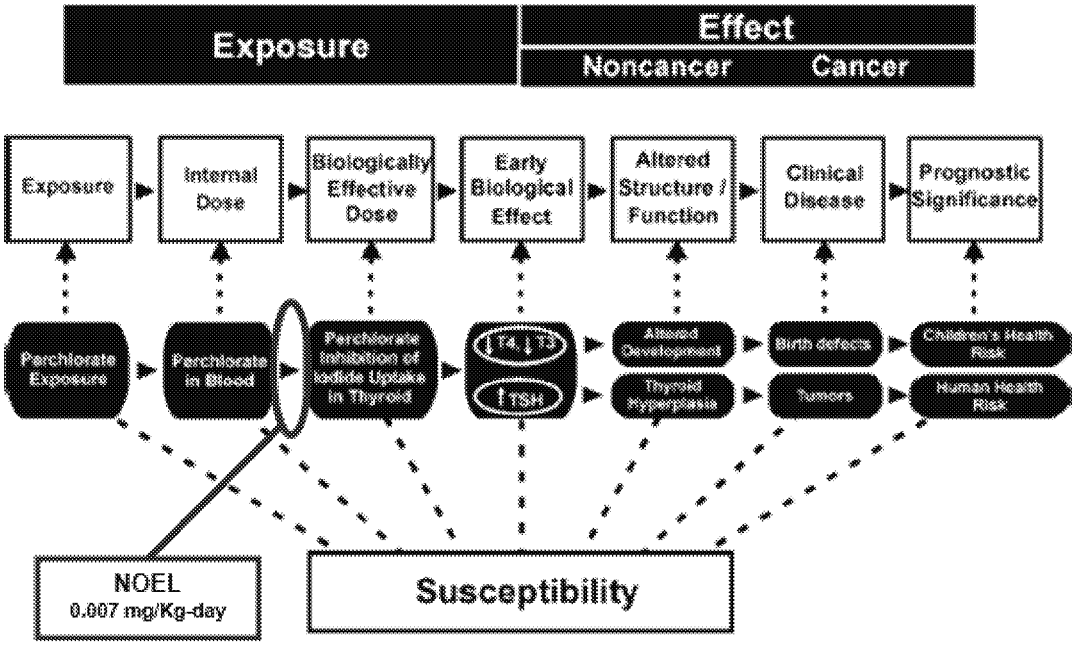
> Based on our scientific analysis, perchlorate is only one of several chemicals that stress the thyroid's ability to uptake iodide. The other sodium iodide symporter (NIS) stressors include thiocyanate, nitrate, and the lack of iodide. All four of these NIS stressors meet EPA's risk assessment guidance for conducting a cumulative risk assessment using the dose-addition method. Our analysis implemented a cumulative risk assessment that found the following: 1) the risk from each of the four NIS stressors is not equal; 2) EPA's perchlorate RfD is conservative and protective of human health, and further reducing the perchlorate exposure below the RfD does not effectively lower risk; 3) increasing maternal total iodide intake to healthy levels will reduce the frequency and severity of permanent mental deficits in children; and 4) correcting moderate and mild iodide deficiency occurring in about 29 percent of the U.S. pregnant and nursing population is the most effective approach for reducing risk.

Academy of Sciences (NAS) assessment of perchlorate also recognized iodide deficiency as the larger public health issue of concern.

Research findings[5] indicate that the total dietary exposure (food and drinking water) of reproductive age women in the U.S. is approximately one-third of the NRC reference dose 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 questionable that perchlorate presents a significant adverse effect on the nation's health, including sensitive subpopulations.

Health Effects – The NAS RfD represents a point of departure (POD) that precedes the inhibition of iodine uptake by the thyroid. This is a departure from the Agency's traditional approach of using a No Observed Adverse Effects Level (NOAEL) for regulatory actions. The NAS's use of a No Observed Effect Level (NOEL) is based on "using a nonadverse effect that is upstream of the adverse effect [which] is a more conservative and health protective approach". The NRC's use of a precursor POD is represented in Figure 1.

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



[5] Mendez, W., Dederick, E., 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. *Journal of Exposure Science and Environmental Epidemiology,* 20, 288–297; doi:10.1038/jes.2009.50.

More recently, the Science Advisory Board's (SAB) assessment provides a sufficient level of doubt with regard to the potential for perchlorate to trigger *inferred adverse effects*. This led the SAB to recommends that the Agency use a physiologically based pharmacokinetic (PBPK) modeling approach; however the SAB noted that *the model is not capable of predicting an actual adverse effect*. In addition, the SAB review included no considerations of perchlorate dose-response levels required to trigger the onset of hypothyroxinemia, or any other adverse health endpoint, to support the SAB's recommendation. The current peer review process will help verify that such modeling limitations have been address appropriately and can determine if any causality can be established with an adverse effect, rather than inferred.

Sensitive Subpopulation - The SAB redefined the sensitive subpopulation as "hypothyroxinemic pregnant and lactating women and infants exposed to perchlorate through water-based preparations of formula or breast milk". Further peer review will help determine if there is sufficient scientific evidence available to justify altering the NRC's definition of sensitive subpopulation, i.e. the fetuses, particularly those of pregnant women who have hypothyroidism or iodide deficiency.

We do not wish to prejudge the conclusions of the current peer-review process, but note the multiple precedential issues that will benefit from a through review given the implications for future rulemakings.

AWWA appreciates the opportunity to comment on these important drinking water issues. If you have any questions, please feel to call Kevin Morley or me in our Washington Office at **Ex. 6** **Ex. 6**

Yours Sincerely,

G. Tracy Mehan, III
Executive Director – Government Affiars

cc: Joel Beauvais – EPA, OW
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