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RE: National Primary Drinking Water Regulations: Perchlorate; Docket ID No. EPA–HQ–OW–2018–0780

The American Water Works Association ("AWWA") appreciates the opportunity to comment on the request for comments regarding EPA's proposed National Primary Drinking Water Regulation for perchlorate published in the *Federal Register* on June 26, 2019.

AWWA is an international, nonprofit, scientific and educational society dedicated to providing solutions to ensure the effective management of water. Founded in 1881, AWWA is the largest organization of water supply professionals in the world. Our membership includes more than 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total members represent the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

Following extensive review of this issue for many years, EPA has rightly suggested that perchlorate does not exist in public water systems with a frequency and at levels of public health concern and that the regulation of perchlorate does not present a meaningful opportunity for health risk reduction.[1] EPA also rightly concluded that the benefits of any of its proposed perchlorate regulations would not justify the costs of such regulatory action.[2] If EPA proceeds, it will set a troubling precedent and undermine the scientific credibility of the Agency's regulatory process under the Safe Drinking Water Act. As such, EPA should withdraw the positive regulatory determination for perchlorate.

[1] EPA, National Primary Drinking Water Regulations: Perchlorate, 84 Fed. Reg. 30524, 30557 (June 26, 2019).
[2] EPA, Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation (June 26, 2019), *available at* https://www.regulations.gov/document?D=EPA-HQ-OW-2018-0780-0124.

AWWA firmly supports the efforts of the Agency to follow through on the recommendations of the Science Advisory Board and peer review panel identifying weaknesses regarding the innovative modeling efforts applied during this evaluation. AWWA appreciates the opportunity to share our concerns, which are aimed at ensuring that sound science guides EPA's regulatory actions. Our full comments are below. If you have any questions, please feel free to contact Kevin Morley or me in our Washington Office at 202-628-8303.

Best regards,

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AWWA Comments on Perchlorate NPDWR
Docket ID No. EPA–HQ–OW–2018–0780

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I. Introduction

The American Water Works Association ("AWWA") respectfully submits these comments on EPA's perchlorate proposal. AWWA represents the full spectrum of the water community. AWWA is an international, non-profit, scientific and educational society dedicated to protecting public health through the provision of safe drinking water.

On June 26, 2019, EPA proposed a maximum contaminant level goal ("MCLG") and a national primary drinking water regulation ("NPDWR") for perchlorate.[1] EPA specifically proposed setting a perchlorate MCLG at 56 µg/L.[2] But EPA also proposed several alternatives: set the MCLG at 18 µg/L, set the MCLG at 90 µg/L, or withdraw the 2011 determination to regulate perchlorate and decline to promulgate a MCLG or NPDWR for perchlorate.[3] AWWA supports the withdrawal alternative, which is the regulatory option that is consistent with EPA's finding that the benefits of any level of perchlorate regulation do not justify the costs. Absent withdrawal, AWWA requests that EPA adjust the monitoring requirements due to the significant burden the current requirements would impose on utilities and primacy agencies. Several critical issues stand out based on a review of the proposed rule and supporting materials:

- EPA's analysis does not establish that environmentally relevant doses of perchlorate result in *adverse* health effects;
- EPA's own analysis shows that the costs of any of the proposed MCLGs exceed the benefits;
- If EPA decides to promulgate a standard, it should provide an expedited approach for waivers, especially given the unfounded assumption that perchlorate would mirror the incidence of arsenic.

In summary, AWWA believes that 1) EPA is not required to promulgate a final MCLG and NPDWR for perchlorate; 2) it would, in fact, be arbitrary and capricious, an abuse of

[1] EPA, National Primary Drinking Water Regulations: Perchlorate, 84 Fed. Reg. 30524, 30557 (June 26, 2019).
[2] *Id.*
[3] *Id.* at 30525.

discretion, and contrary to law for EPA to promulgate a perchlorate MCLG and NPDWR; 3) there are significant flaws in the technical merits of EPA's analysis underlying the proposed MCLG; 4) if EPA withdraws the determination to regulate, it would be reasonable instead to work towards finalizing a health advisory level to provide guidance; and 5) if EPA nevertheless chooses to promulgate a final MCLG and NPDWR for perchlorate, EPA should adjust the monitoring requirements and barriers to water systems seeking waivers in order to bring the costs of the regulation more closely into balance with the benefits.

II. EPA Is Not Required to Promulgate a Final MCLG and NPDWR for Perchlorate

EPA's current proposal stems from over a decade of statutory and legal processes including prior regulatory actions and litigation. Neither EPA's prior regulatory actions nor the outcome of the prior litigation requires EPA to promulgate a final MCLG and NPDWR.

a. Explanation of the History of Perchlorate Regulation

On October 10, 2008, EPA published a preliminary determination not to regulate perchlorate under the Safe Drinking Water Act ("SDWA").[4] To regulate perchlorate under the SDWA, EPA must find:

i) perchlorate may have an adverse effect on the health of persons,

ii) perchlorate is known to occur or there is a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern, and

iii) in the sole judgment of the Administrator, regulation of perchlorate presents a meaningful opportunity for health risk reduction for persons served by public water systems.[5]

[4] EPA, Drinking Water: Preliminary Regulatory Determination on Perchlorate, 73 Fed. Reg. 60262 (Oct. 10, 2008).
[5] 42 U.S.C. § 300g-1(a).

In its October 2008 determination, EPA found that there was no meaningful opportunity for health risk reduction through regulating perchlorate under the SDWA.[6]

On February 11, 2011, EPA reversed its determination not to regulate perchlorate and published a determination to regulate perchlorate under the SDWA.[7] In its 2011 determination, EPA found that perchlorate meets all three of the SDWA's statutory requirements.[8] At that time, EPA did not publish a specific proposal to regulate perchlorate.

On February 18, 2016, the Natural Resources Defense Council ("NRDC") filed a complaint against EPA, alleging that the 2011 determination triggered a mandatory duty under the SDWA to propose and finalize a MCLG and a NPDWR for perchlorate.[9] NRDC and EPA entered into a consent decree on October 18, 2016 ("Consent Decree").[10] EPA proposed a MCLG and NPDWR for perchlorate on June 26, 2019.[11] EPA proposed setting the MCLG at 56 µg/L.[12] EPA also proposed several alternatives: set the MCLG at 18 µg/L, set the MCLG at 90 µg/L, or withdraw the 2011 determination to regulate perchlorate and decline to promulgate a MCLG or NPDWR for perchlorate.[13]

b. The Consent Decree Does Not Prevent EPA From Reconsidering and Withdrawing the 2011 Determination

The Consent Decree is premised on the fact that EPA's 2011 determination to regulate perchlorate triggered a mandatory duty for EPA to propose a MCLG and NPDWR.[14] EPA agreed

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[6] 73 Fed. Reg. at 60265, 60280.
[7] EPA, Drinking Water: Regulatory Determination on Perchlorate, 76 Fed. Reg. 7762 (Feb. 11, 2011).
[8] *Id.*
[9] Consent Decree, Case No. 16-cv-01251, ECF 38 at 2 (Oct. 18, 2016) ("Consent Decree") (citing 42 U.S.C. § 300h-1(b)(1)I).
[10] *Id.*
[11] 84 Fed. Reg. 30524.
[12] *Id.*
[13] *Id.* at 30525.
[14] Consent Decree at 2-3 ("Whereas, EPA's Determination To Regulate triggered a mandatory duty under SDWA section 1412, 42 U.S.C. § 300g-1(b)(1)(E) to propose a [MLCG] and [NPDWR] for perchlorate by February 11, 2013; . . . Whereas, NRDC alleges that EPA's Determination to Regulate triggered a mandatory duty under SDWA section 1412, 42 U.S.C. § 300g-1(b)(1)(E), to publish a final MCLG and promulgate a final NPDWR for perchlorate by August 11, 2014[.]").

that the 2011 determination to regulate triggered a duty for EPA to *propose* a MCLG and NPDWR.[15] However, under the express terms of the Consent Decree, and consistent with general principles of administrative law, EPA retains full discretion to revisit any of its prior judgements, including those that triggered its duty to propose regulations in the first place.[16]

Agencies may (and sometimes are required to) reconsider prior determinations based upon new information.[17] Moreover, the Consent Decree expressly contemplated that further study would occur before EPA decided how to proceed.[18] Thus, it was entirely plausible at the time of the Consent Decree that this process of further study would result in new information that would warrant EPA revisiting its prior determination to regulate. EPA's reconsideration of its prior determination to regulate is consistent with the discretion the statute provides to EPA and with general principles of administrative law. Therefore, there is no inconsistency with the Consent Decree if the EPA does not promulgate an MCLG and NPDWR.

c. EPA May Reverse the 2011 Determination if it Finds That Perchlorate Does Not Meet the Statutory Criteria for Regulation Under the SDWA

EPA has already reversed its decision on whether to regulate perchlorate once, and it may do so again. In 2008, EPA published a negative regulatory determination for perchlorate because it found that perchlorate did not meet the SDWA criteria for regulating a contaminant.[19] In 2011, EPA reversed its decision and published a determination to regulate because it found that perchlorate did meet the SDWA criteria.[20] In its Consent Decree with NRDC, EPA expressly

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[15] *See id.* at 2 ("Whereas, EPA's Determination To Regulate triggered a mandatory duty under SDWA section 1412, 42 U.S.C. § 300g-1(b)(1)(E) to *propose* a [MLCG] and [NPDWR] for perchlorate by February 11, 2013[.]") (emphasis added).
[16] *Id.* at 7 ("Nothing in this Consent Decree shall be construed to limit or modify any discretion accorded EPA by the SDWA or by general principles of administrative law.").
[17] *See, e.g., United States v. Akzo Coatings*, 949 F.2d 1409, 1429 (6th Cir. 1991) ("We must inquire, as the district court should have done, whether the information contained in the Hayes affidavit is of such significance that the agency must reconsider its decision [to enter into the Consent Decree] in light of the new information[.]").
[18] Consent Decree at 3-4 ("Whereas, EPA has begun a peer review process for its BBDR modeling approach[.]").
[19] 73 Fed. Reg. 60262.
[20] 76 Fed. Reg. 7762.

reserved all discretion under the SDWA and general principles of administrative law.[21] Both sources of law provide EPA the authority to withdraw the 2011 determination.

The SDWA provides EPA significant discretion to determine whether or not to regulate a contaminant. The SDWA provides that the "Administrator shall . . . publish a MCLG and promulgate a NPDWR . . . *if the Administrator determines that* . . . " the contaminant meets three criteria for regulation.[22] The Administrator has discretion to determine that perchlorate does not meet the criteria for regulation. Further, one of the statutory criteria for regulation under the SDWA is whether, "[i]n *the sole judgment of the Administrator*, regulation of such contaminant presents a meaningful opportunity for health risk reduction."[23] The Administrator has discretion to exercise his sole judgment to determine that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. Significant agency discretion is therefore built into the SDWA. Nothing in the SDWA prevents the agency from exercising its discretion to reverse a prior determination to regulate.

General principles of administrative law also support EPA's ability to reverse its prior determination. Agencies are permitted to change policy; rules are not "instantly carved in stone."[24] As the Supreme Court articulated in *FCC v. Fox*, there is no heightened standard of review when rescinding a rule; agencies must simply "display awareness" of the change and provide a "reasoned explanation."[25] A reasoned explanation exists if the new policy is permissible under the statute, and if the agency shows that there are "good reasons" supporting the new policy.[26] Where a new policy rests upon factual findings that contradict those which underlay a prior policy, the agency must explain why it disregarded the prior factual findings.[27] Agencies can explain why it disregarded prior factual findings by introducing new evidence or by reevaluating existing evidence.[28]

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[21] Consent Decree at 7.
[22] 42 U.S.C. § 300g-1(b) (emphasis added).
[23] *Id.* (emphasis added).
[24] *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837, 863 (1984).
[25] *FCC v. Fox*, 556 U.S. 502, 515 (2009) (internal citations omitted).
[26] *Id.*
[27] *Id.* at 515-16.
[28] *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1038 (D.C. Cir. 2012)

EPA can provide a reasoned explanation for revisiting its 2011 determination to regulate. As explained above, the SDWA permits EPA to determine not to regulate perchlorate if EPA finds that perchlorate does not meet the statutory criteria for regulation. Further, EPA can provide good reasons to support this change in position. It is plausible that the peer review process produced new information or uncovered issues with the modeling that supported the previous rule. Even if the agency does not rely on any new evidence, the agency can meet its burden by explaining why it reconsidered old facts; "this kind of reevaluation is well within an agency's discretion."[29]

III. It Would be Arbitrary and Capricious, an Abuse of Discretion, and Contrary to Law to Promulgate a MCLG and NPDWR for Perchlorate

The scientific record does not support regulating perchlorate. Additionally, the costs of implementing a NPDWR for perchlorate far outweigh any benefits.

a. The Current Record Does Not Support the Statutorily Required Findings Necessary to Regulate Perchlorate, and Promulgating a Regulation in the Absence of Such a Record Would be Arbitrary and Capricious, an Abuse of Discretion, and Contrary to Law

The SDWA directs EPA to promulgate a MCLG and NPDWR for a contaminant if the following three criteria are met:

i) the contaminant may have an adverse effect on the health of persons,

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

[29] *Id.* (citing *Fox*, 556 U.S. at 514-15).

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.[30]

EPA must use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" to evaluate whether the criteria for regulation under the SDWA are met.[31] The second two criteria are in question here.

First, the record does not demonstrate that there is a substantial likelihood that perchlorate occurs in public water systems at levels and frequencies that represent a public health concern. EPA's analysis contains numerous conservativisms (i.e., approaches that tend toward overstating the presence and risk of perchlorate) that ultimately undermine a finding that the presence of perchlorate is an actual public health concern. EPA has not demonstrated that an adverse effect is likely to result in public health concerns at any of the proposed MCLG levels: 18, 56 or 90 µg/L. Further, EPA's analysis is scientifically unsound. A detailed analysis of the technical aspects of the proposed rule is provided in section IV of these comments.

Second, the record does not reveal an opportunity for meaningful health risk reduction through perchlorate regulation. In its 2011 Determination to Regulate, EPA used a non-adverse effect to determine the reference dose for perchlorate, rather than the first adverse effect.[32] In the absence of a finding that the level of perchlorate present in public water systems triggers an adverse effect, it is not possible for EPA to make a sound determination that there is a meaningful opportunity for improvement—in the absence of having determined where an adverse effect occurs, one cannot determine whether adverse effects will be minimized or eliminated through additional regulation. Moreover, even assuming that setting the standard at 90, 56 or 18 could produce some marginal improvement in health outcomes, those improvements are not likely to be "meaningful." The states whose water systems contain the most perchlorate already regulate perchlorate; California and Massachusetts both have implemented perchlorate regulations. The record does not demonstrate that a federal NPDWR can provide any further meaningful health risk reduction.

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[30] 42 U.S.C. § 300g-1(a).
[31] *Id.* § 300g-1(b)(3)(A).
[32] 76 Fed. Reg. at 7764.

The record therefore does not support the statutory findings required to promulgate a MCLG and NPWDR. Promulgating a rule in the absence of the statutorily required findings would be arbitrary and capricious, an abuse of discretion, and contrary to law.

b. Even if the Required Statutory Findings are Made, Promulgating a MCLG and NPDWR Would be Arbitrary and Capricious Because the Costs Outweigh the Benefits

EPA would be acting in an arbitrary and capricious manner if it finalized a perchlorate regulation because the costs of all three of the proposed MCLGs exceed the benefits. In *Michigan v. EPA*, the Supreme Court overturned a rule where "EPA refused to consider whether the costs of its decision outweighed the benefits."[33] In that case, "[t]he costs to power plants were . . . between 1,600 and 2,400 times as great as the quantifiable benefits from reduced emissions of hazardous air pollutants."[34] The relevant statute mandated EPA to regulate if "appropriate and necessary," and the Court found that cost must be considered in this determination because "[o]ne would not say that it is even rational, never mind 'appropriate,' to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits."[35]

Similarly, the SDWA directs EPA to regulate if, among other things, there is a "meaningful opportunity for health risk reduction."[36] There is no meaningful opportunity for health risk reduction where the costs of regulation far exceed the benefits. The SDWA explicitly directs EPA to analyze the costs and benefits of its proposals to set maximum contaminant levels.[37] EPA prepared this analysis and found that the costs of all three of its proposed perchlorate regulations exceed the benefits of those regulations.[38] It would be arbitrary and capricious for EPA to promulgate a perchlorate regulation when EPA's own analysis concludes that the costs of the regulation exceed the benefits.

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[33] 135 S.Ct. 2699, 2706 (2015).
[34] *Id.*
[35] *Id.* at 2707.
[36] 42 U.S.C. § 300g-1(a).
[37] *Id.* § 300g-1(b)(3)(C)(i).
[38] EPA, Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation at 6.3, *available at* https://www.regulations.gov/document?D=EPA-HQ-OW-2018-0780-0124.

IV. There are Significant Flaws in the Technical Merits of EPA's Analysis Underlying the Proposed MCLG

The proposed rule poses a series of questions reviewers are asked to consider and comment upon before any final determination is made. The comments provided here focus on several topics EPA presented in the proposed rule: 1) the adequacy of EPA's review and application of the epidemiologic literature; 2) the adequacy of EPA's methodology to derive the MCLG; 3) the three alternative MCLGs; 4) EPA's finding that the benefits of any proposed regulations do not justify the costs; 5) EPA's proposal to adopt the proposed rule even though the benefits do not justify the costs; and 6) the feasibility of treatment technologies and the disproportionate burden on small systems.

a. A Review of the Epidemiologic Literature Reveals Defects in EPA's Analysis

EPA's review focused on literature related to changes in one specific hormone rather than a broader consideration of epidemiological studies on perchlorate and various health endpoints. In the proposed rule, EPA outlines its approach as:

> [A] two-step dose-response model to estimate health benefits of a reduction in perchlorate exposure as a result of regulating perchlorate in drinking water not to exceed the proposed MCL of 56 µg/L and alternative MCLs of 18 µg/L and 90 µg/L. The first step relates changes in perchlorate to changes in maternal free-thyroxine ("fT4") during the first trimester of pregnancy using the EPA's BBDR model . . . The second step of the dose-response model subsequently relates the predicted changes in maternal fT4 from the BBDR model to changes in child IQ using the function estimated in the EPA independent analysis of the Korevaar et al., (2016) study data. Ultimately, the changes in IQ are estimated for each impacted iodine intake group, and all of the impacted iodine intake groups'

> IQ decrements are averaged together based on the proportion of individuals in each iodine intake category.[39]

As noted, EPA used data from Korevaar et al. However, EPA's literature review identified approximately 55 studies that might form a basis for analysis, narrowing these to 15 or 16 studies that might be relevant to the analysis.[40] The Agency further noted that:

> Not every paper the EPA located in its literature review found a statistically significant association between maternal fT4 as a continuous variable (i.e., the initially identified 16 studies identified as potentially useful to inform a dose-response function) and the neurodevelopmental outcome of interest. However, many studies…have concluded there is a relationship between maternal hypothyroxinemia and various neurodevelopmental outcomes. The relationship between maternal fT4 levels and neurodevelopmental outcomes appears strongest in the hypothyroxinemic range, and when looking at the entire range of fT4 as a continuous variable (as opposed to a categorical cut off), the significant relationship between the two variables may dissipate. Therefore, the EPA has concentrated on the neurodevelopmental impacts of changes in fT4 in the lower range of fT4 from the Korevaar et al., (2016) data.[41]

EPA focused on Korevaar et al, but did not directly use those results. The Agency instead reanalyzed the Korevaar et al data; this reanalysis forms the basis for EPA's dose-response function. Critically, EPA's reanalysis results in a reduction in the estimated sensitivity of individuals exposed to perchlorate by a factor of approximately 1.8. That result undermines any argument that the proposed rule could be cost beneficial—with a lower sensitivity to perchlorate, there must be fewer benefits to a NPDWR that seeks to reduce perchlorate exposure.

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[39] 84 Fed. Reg. at 30552.
[40] *Id.* at 30536.
[41] *Id.* at 30535-30536

Table III-2 in the proposed rule summarizes and compares the original Korevaar results, EPA's reanalysis of the Korevaar data, and other the studies that EPA considered adequate to incorporate into its analysis.

Table III-2. Estimated Dose of Perchlorate per 1, 2, and 3 Percent Decrease[a] in Neurodevelopment for the Population of Low-Iodine Intake Women of Reproductive Age Based on Upper Effect Estimates at the 10th Percentile fT4 Level[b]

Study	Endpoint	Dose-Response Function	β (95% CI)	ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a,b,c]			Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a,b,c]		
				1%	2%	3%	1%	2%	3%
Korevaar et al., (2016) Quadratic	IQ	$\Delta IQ = (\beta_1 \times lnfT4_2 + \beta_2 \times ln(fT4_2)^2) - (\beta_1 \times lnfT4_1 + \beta_2 \times ln(fT4_1)^2)$	β1 = 33.8 (9.8, 57.8) β2 = -6.2 (-10.6, -1.9)	-0.13 (1.9%)	-0.25 (3.8%)	-0.38 (5.7%)	1.9	3.9	6.1
Korevaar et al., (2016) EPA independent analysis	IQ	$\Delta IQ = (\beta_1 \times \ln(fT4_2)) - (\beta_1 \times \ln(fT4_1))$	17.26 (3.77, 30.75)	-0.21 (3.1%)	-0.41 (6.2%)	-0.61 (9.2%)	3.1	6.7	10.8
Pop et al., (2003)	MDI	$\Delta MDI = \beta \times \Delta fT4$	6.3 (1.92, 10.6)	-0.09 (1.0%)	-0.19 (2.8%)	-0.28 (4.2%)	1.3	2.8	4.3
Pop et al., (2003)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.4 (4.0, 12.8)	-0.08 (0.9%)	-0.16 (2.4%)	-0.23 (3.5%)	1.1	2.3	3.5
Pop et al., (1999)	PDI	$\Delta PDI = \beta \times \Delta fT4$	8.5 (0.01, 17.0)	-0.06 (0.6%)	-0.12 (1.8%)	-0.18 (2.6%)	0.8	1.7	2.6
Endendijk et al., (2017)	Anxiety/ depression score	$\Delta AD = \left(\frac{1}{\beta * fT4_2}\right) - \left(\frac{1}{\beta * fT4_1}\right)$	0.12 (0.11, 0.13)	-0.03 (0.45%)	-0.08 (1.2%)	-0.12 (1.9%)	0.4	1.1	1.8
Finken et al., (2013)	SD of reaction time	ΔSD Reaction Time (ms) = β × Δ fT4	-4.9 (-9.5, -0.2)	-0.28 (4.2%)	-0.57 (8.5%)	-0.85[d] (12.7%)	4.4	9.8	16.5[d]

[a]. The analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI) are based on a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points), which equates to a 1, 2, or 3 point change, respectively. The analyses for anxiety/depression score and SD of reaction time are based on a 1%, 2%, or 3% change from the study mean of each measure, which for anxiety/depression is 0.01, 0.02, or 0.03 points, respectively, and for reaction time is 2.7, 5.4, and 8.1 milliseconds (study mean SD of reaction time = 270 ms), respectively.
[b]. This is based on the regression analysis for the range of fT4 data within each study using the upper beta estimates from the 95% CI. These results are for the low-iodide intake population of 75 µg/day. In all functions, fT4 is in units of pmol/L.
[c]. The BBDR model with a pTSH of 0.398 was used for these analyses.
[d]. The value which results in a 3% change in the standard deviation of reaction time falls between 16 and 17 µg/kg/day. Because data was not available on the changes of fT4 at doses between 16 and 17 µg/kg/day perchlorate, the EPA took the midpoint of the range of values for the change in fT4 at 16 and 17 µg/kg/day and assumed the dose of perchlorate associated with this change was the midpoint between 16 and 17 µg/kg/day.

In this table, EPA converted the results of the studies into both a change in fT4 and a dose of perchlorate that results in a 1, 2 and 3% change in the neurodevelopmental endpoint (which is the same as a 1, 2 and 3 point change in IQ for the Korevaar et al study). The table shows that EPA's reanalysis of the Korevaar et al data resulted in an increase in the required dose of perchlorate by approximately a factor of 1.8, as mentioned previously, meaning the reanalysis suggests the child is less sensitive than originally reported by Korevaar et al. Taking the 3% value for perchlorate dose as an example, the range of results is 1.8 to 16.5 µg/kg-day, with the Korevaar et al value at 6.1 and the reanalysis at 10.8, nearer the upper end of the values in the table (meaning the lower end of sensitivity as reflected in a risk coefficient).

EPA focused its analysis on effects in the fetus initiated by changes in maternal fT4. However, there is a broader context for considering epidemiological studies on perchlorate and various health endpoints. Crawford-Brown et al (2016) reviewed 28 epidemiological studies related to perchlorate exposure, with endpoints ranging from Iodide Uptake Inhibition ("IUI"), hormonal levels and clinical effects. While effects were seen for the first two endpoints, *there were no statistically significant elevations for clinical effects at environmentally relevant levels of exposure*.

Crawford-Brown is not necessarily inconsistent with the results of the epidemiological studies reviewed by EPA. The studies reviewed by EPA examined the relationship between fT4 and clinical effect, not between perchlorate dose and clinical effect. Taken together, however, Crawford-Brown and the studies reviewed by EPA suggest that compensatory mechanisms for changes in fT4 may cause the relationship between fT4 and clinical effect to be different than that between perchlorate dose and clinical effect. Specifically, such mechanisms might cause the IUI effect and/or the change in fT4 caused initially by perchlorate to be mitigated prior to appearance of any clinical effect, at least at environmentally relevant doses. Based on AWWA's review, this suggests a significant scientific and technical defect in EPA's BBDR model, because the BBDR overlooks such compensatory mechanisms. Therefore, the BBDR model would also likely overestimate changes in IQ or other neurodevelopmental effects, especially at low dose levels.

b. An Examination of the Methodology EPA Used to Derive the MCLG Reveals Flaws in the BBDR Model

As mentioned previously, EPA described its analysis as a two-step process. In reality, it is a three-step process, because it is necessary to first establish intake rates of perchlorate in food and water, then run the BBDR model, and then apply the risk coefficient relating fT4 and IQ decrement. Some context is required to comment on EPA's methodology. Therefore, this section will i) compare EPA's analysis to EPA's prior and more traditional regulatory analyses, ii) explain EPA's assumptions regarding perchlorate intake rates from food and water, and iii) explain issues with the BBDR model.

i. Comparison of New Approach and EPA's Traditional Approach

Until the time of the EPA's currently proposed rule, the primary basis for considering a MCLG or MCL for perchlorate was the direct application of data from a study by Greer et al (2002). Greer et al examined the relationship between perchlorate dose and IUI. The Greer analysis began with a no observed effect level ("NOEL") (not necessarily a NOAEL as the effect of IUI is not necessarily an adverse effect in and of itself) of 0.007 mg/kg-day. The National Research Council (2005) further recommended a total uncertainty factor of 10 for intra-species extrapolation (the data were from humans, although not from pregnant women and/or their fetus). The Reference Dose was therefore 0.007/10 = 0.0007 mg/kg-day or 0.7 µg/kg-day. As a result, the RfD would, for the case where populations are exposed solely to perchlorate as the goitrogen, yield a Reference Concentration or RfC of 18 µg/L, assuming 2 L/day consumption of water by a woman weighing 50 kg. This is the same lower bound on the MCLG EPA considered in its current proposed rule and corresponds to the estimated IQ decrement of 1 point or 1% at that level.

Nevertheless, the current MCLG approach in the proposed rule differs significantly from this more traditional regulatory assessment approach. EPA first establish a Point of Departure ("POD") using the combined BBDR and epidemiology results. EPA stated:

> Applying these response rates to the results from the reanalysis of Korevaar et al., (2016), results in a POD dose of 3.1 µg/kg/day for a 1 point decrease in the sensitive population's IQ, a POD dose of 6.7

> μg/kg/day for a 2 point decrease in the sensitive population's IQ, and a POD dose of 10.8 μg/kg/day for a 3 point decrease in the sensitive population's IQ. These PODs associated with a 1, 2, or 3 point decrease from the standardized mean IQ are calculated for the most sensitive population. Specifically, the POD is designed to provide an adequate margin of safety for the fetuses of mothers with fT4 at the 10th percentile of a population with iodine intake of 75 μg/day and a TSH feedback loop that is less than 60% as effective as individuals with median TSH feedback loop efficacy. That is, the analysis is designed to protect the population of fetuses of mothers with suboptimal thyroid functioning. For these reasons, and for the methodological reasons described previously, the EPA believes that the selection of these parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive population and allows for an adequate margin of safety.[42]

To contrast, the Greer et al data yields a POD of 0.007 mg/kg-day or 7 μg/kg-day, to which a factor of 10 UF was applied to extrapolate to the sensitive subpopulation in the absence of a model. When compared to the approach applied in the proposed rule, the Greer et al POD with 10 UF aligns with the POD for a 1-point IQ decrease.

In reanalyzing Korevaar, however, EPA:

> Opted to apply a UF of 3 to the POD, which adds an adequate margin of safety to the MCLG derivation. Section 4.4.5.3 of *A Review of the RfD & RfC Processes* recommends reducing the intraspecies UF from a default of 10 'only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s).' The EPA selected a UF of 3 instead of the full 10 because the modeled groups within the population that are identified as likely to be at greater risk to perchlorate in drinking

[42] *Id.* at 30536-37.

> water (i.e., the fetus of the iodide deficient pregnant mother) and has selected model parameters to account for the most sensitive individuals in that group (i.e., muted TSH feedback, low fT4 values, low-iodine intake).[43]

EPA applied a UF of 1 for all other factors. Therefore, the primary numerical difference between the more traditional regulatory risk approach noted above based on the Greer et al data, and EPA's approach in the proposed rule, is the application of 3 UF rather than 10 UF. If a factor of 3 had been applied to the RfD/RfC calculation based on the Greer et al data, the result would be an estimated MCL/MCLG of 54 µg/L, almost precisely equivalent to the central value considered by the EPA in the proposed rule of 56 µg/L. The BBDR modeling prepared by EPA supports using a factor of 3 UF rather than the 10 UF, applied to a POD that is approximately 3.3 times the value of the NOEL of 0.007 mg/kg-day based on the Greer et al study. As will be explained below, the lower UF value partially compensates for flaws in the BBDR model but does not solve the problems of scientific validity.

ii. Calculation of MCLG Based on New Approach

In calculating the MCLG, EPA made various assumptions, including details about the individual, the contribution of various sources to an individual's total perchlorate intake, and consumption. First, EPA:

> Selected an iodine intake level of 75 µg/day to simulate an individual with low-iodine intake. This value represents an intake between the 15th and 20th percentile of the women of child bearing age population distribution of estimated iodine intake from the National Health and Nutrition Examination Survey ("NHANES")."[44]

For those individuals, EPA's Relative Source Contribution ("RSC") values are contained in Table III-5 of the proposed rule:

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[43] *Id.* at 30537.
[44] *Id.* at 30530.

Table III-5. Estimates for RSC and MCLG by RfD

RfD[a] (µg/kg/day)	RSC_W[b] (percent)	DWI (L/kg/day)	MCLG[c] (µg/L)
1.0	56%	0.032	18
2.2	80%	0.032	56
3.6	80%[d]	0.032	90

a. The RfD values corresponding to protecting the fetus of a first trimester pregnant mother with low-iodine intake levels (i.e., 75 µg/kg/day), low fT4 levels (i.e., 10th percentile of a fT4 distribution for individuals with 75 µg/day iodine intake), and weak TSH feedback strength (i.e., TSH feedback is reduced to be approximately 60 percent less effective than for the median individual) from either a 1-point IQ loss, 2-point IQ loss, or a 3-point IQ loss, respectively.

b. The EPA calculated RSC values based on the following equation given a Food intake of 0.45 µg/kg/day:

$$RSC = \frac{RfD - Food}{RfD} \times 100\%$$

c. The EPA calculated the MCLG values based on the following equation given the respective RfD and RSC values and the DWI:

$$W\left(\frac{\mu g}{L}\right) = \frac{RfD}{DWI} \times RSC_w$$

d. The calculated RSC value using the equation in footnote b is 88 percent. However, the EPA has opted to follow previously established recommendations which employs a ceiling of 80 percent for the RSC value (USEPA 2000d).

EPA's RSC for the MCLG of 56 µg/L is 80%, allocating the remaining 20% to food as the other primary route of exposure. Notably, there is a difference in the values represented in Table III-5 of the proposed rule and the *Technical Support Document for Deriving the MCLG*. The actual RfD values in the support document are the basis of the published MCLG values, the RfD values in Table III-5 of the proposed rule would result in slightly lower MCLGs. EPA's assumed food intakes are given in Table III-4 of the proposed rule.

Table III-4. Perchlorate Dose from Food (µg/kg/day) in U.S. Women Ages 20-44 using the mean and 95th Percentile TDS Results[1]

Level of Bodyweight Adjusted Perchlorate Consumption from Population Distribution	Perchlorate Dose from Food (µg/kg/day)	
	Based on Mean Concentrations of Perchlorate in Food	Based on 95th Percentile Concentrations of Perchlorate in Food
Mean	0.09 – 0.12	0.23 – 0.24
50th Percentile	0.08 – 0.10	0.17 – 0.19
90th Percentile	0.18 – 0.21	**0.45**
99th Percentile	0.33 – 0.38	1.16 – 1.17

[1] Ranges are due to various approaches for handling values <level of detection. If no range is presented all approaches resulted in the same value.
Bolded value represents the selected value

EPA explained that to calculate the MCLGs, it:

> [S]elected the 90th percentile dose of perchlorate from food, assuming a scenario where the food contained the 95th percentile perchlorate concentration. This corresponds to a perchlorate dose for food of 0.45 μg/kg/day. The EPA chose to use the 90th percentile bodyweight-adjusted perchlorate consumption from food using the 95th percentile TDS results to estimate the perchlorate RSC from drinking water. The EPA believes this is the most appropriate value for perchlorate consumption from food to ensure the protection of potentially highly exposed individuals.[45]

The EPA approach for consumption of perchlorate through food is based on the NHANES data. EPA notes that:

> The NHANES data provided individual food consumption profiles for female participants age 20-44 (the women of childbearing age range used for the BBDR model). The EPA matched TDS perchlorate concentrations with each food consumed by a participant and calculated each participant's daily perchlorate dose (μg/kg/day) from food using the participant's body weight. The EPA estimated each participant's perchlorate dose using both mean and 95th percentile perchlorate concentrations in food . . . Specifically, the EPA calculated both the mean and the 95th percentile of the perchlorate levels in each food based on the 20 samples included in the TDS data. In order to estimate the 95th percentile from the 20 samples, the EPA used the second-highest test result for each food to represent the 95th percentile concentration.[46]

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[45] *Id.* at 30538.
[46] *Id.* at 30539.

As a point of comparison, had EPA chosen to use either the 50th percentile or mean bodyweight for food intake, the calculated RSCs would be higher than the standard threshold of 80% in nearly all instances. The effect would be higher calculated MCLGs as follows:

		Calculated RSC			Calculated MCLG		
RfD	**DWI**	**90th**	**Mean**	**50th**	**@ 90th RSC**	**@ Mean RSC**	**@ 50th RSC**
1.03	0.032	**56.3%**	77.2%	82.0%	18.1	24.8	25.6
2.23	0.032	**79.8%**	89.5%	91.8%	55.6	62.3	63.1
3.6	*0.032*	*87.5%*	*93.5%*	*95.0%*	*98.4*	*105.2*	*106.9*
3.6	0.032	**80.0%**			90.0		

iii. Concerns Regarding the BBDR Model

As mentioned previously, use of the BBDR model does not produce a result largely different from that based solely on use of the RfD values obtained using the Greer et al study. The BBDR model is the means by which EPA's Science Advisory Board sought to link perchlorate exposures to "biologically plausible" neurodevelopment effects based on epidemiological studies.[47] While we acknowledge this goal, minor changes to the BBDR structure or parameter values are unlikely to have a significant impact on regulatory risk management considerations relative to the more traditional approach of an RfD based on uncertainty factors to account for intra-species extrapolation. Again, this is demonstrated by the BBDR results which are quite close to those obtained using the approach based on the data of Greer et al and application of an uncertainty factor of 10.

However, Clewell et al (2019) exhaustively analyzed the scientific basis and performance of the BBDR model, assessing the clarity of the description of the model (and hence the transparency), the internal logic of the model, and the performance of the model against reference data. Their review builds on the experience of Clewell et al (2007), which is one of the primary Physiologically-Based Pharmacokinetic ("PBPK") models for perchlorate used in past

[47] Science Advisory Board (SAB) for the U.S. EPA. SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate. EPA-SAB-13-004. 2013.

assessments. Clewell et al (2019) compared the original PBPK results against the BBDR results. Based Clewell et al's 2019 analysis of the BBDR model, AWWA has many concerns, which are broken up into two categories. The first group of concerns focuses on the model's structure and parameter assumptions; the second group of concerns focuses on the performance of the model against published data.

1. BBDR Model's Structure and Parameter Assumptions

- The BBDR model is more of a scientific research tool than a regulatory risk tool, and it should be treated as a work in progress.
- Documentation of the model, including justification of parameters selected, is inadequate to a large degree. Users are unable to reproduce model results without making assumptions that are unstated in the documentation. Therefore, one cannot be certain those assumptions are the same as those employed by the EPA staff, or executed in the same way within the model. This greatly reduces transparency of the model and its justification.
- The BBDR model scripts needed to link the model to allow changes in parameter values (which would be needed for a full sensitivity and uncertainty analysis, neither of which have been performed adequately by the EPA) are cumbersome and poorly documented, leaving users uncertain as to whether they are being executed properly.
- The model greatly oversimplifies the human Chorionic Gonadotropin ("hCG") dynamics, leading the model to 'decouple' the parameters HCGREG and VCHNG, which govern two hormonal control processes that have the same underlying biology and hence should rise or fall together in parallel with gestational age. As Clewell et al (2019) demonstrate, the BBDR model used two different and unconnected equations for these two parameters despite the obvious linkages in biology. The EPA justifies this by referring to the NHANES data that appear to show no clear linkages. But as Clewell et al point out, this conclusion would be valid only if the NHANES data provided correlated hormonal samples for each individual, which they do not, showing instead population-level characteristics of each. This is likely to explain why the two metrics appear to be uncorrelated in the NHANES data. This aspect of the BBDR model therefore is not justified scientifically.

- The BBDR model uses a rate constant for binding of perchlorate to the NIS that is a factor of 3 lower than previously published values, without justification in the documentation. This in turn required the EPA analysts to provide "revisions to the Vmax (VmaxNISF_thy_P) and urinary excretion parameters (CLFUP)" when using the BBDR model. *The effect is to significantly increase the sensitivity of the individual to effects of binding reduction by perchlorate.*
- The epidemiological data used by the EPA is drawn entirely from non-U.S. populations. EPA justifies this choice by claiming that there is no reason to suspect significant differences in the effects of perchlorate in different populations. As pointed out by Clewell et al, however, the "American Thyroid Association (Alexander et al., 2017) suggests variability in the distribution of thyroid hormone levels across populations and even within ethnicities within a single population." *In fact, this measured variability between individuals and subpopulations is larger than the small perturbations in fT4 and clinical effects considered in the EPA analysis.*
- The BBDR model displays a strong relationship between fT4 and iodine intake, related to assumed iodine storage. This is especially true at lower levels of iodine intake representative of the environmental levels of exposure the EPA is considering. However, the NHANES data EPA cites shows no such relationship, and no such correlation, calling into question how storage is being treated within the BBDR model. Incorrect storage estimation will result in errors in the effect of changes in IUI due to perchlorate intake.

2. <u>BBDR Model Performance</u>

The prior points largely focus on the structure of the BBDR and the underlying parameter assumptions. These points focus on the performance of the model against published data. Clewell et al provide a comparison of the model results against several empirical studies.

- Steinmaus et al (2016) shows that the BBDR predicts significantly different changes in fT4 associated with any level of perchlorate intake by a factor of 3 to 10 when looking at the lower and central beta coefficient values from the data. The difference is much smaller when considering the lower value of beta from Steinmaus at high levels of perchlorate dose relative to the baseline (the difference is still a factor of more than 3 at low levels of perchlorate intake more typical of environmental exposures).

- Similar comparisons against the data by Greer et al (2002), Braverman et al (2006, with a focus on T3) and Téllez Téllez et al (2005) also show significant differences between the BBDR model's predictions and the data regarding hormonal effects of perchlorate.
- Previous models in the literature did not display these large differences between data and model results, suggesting that the BBDR requires significantly greater scientific review and justification.
- EPA's BBDR model under-predicts the 50th percentile fT4 levels by about 33% of the baseline value (meaning the value obtained with zero perchlorate exposure through water). *This is a massive difference given the small perturbations in fT4 being considered in the EPA's analysis of effects.* EPA does not provide an explain of this difference and any associated impact on the analysis.
- Data on measured fT4 levels in pregnant women, or even women of child bearing ages, are not well established and show significant variability between individuals, by approximately 25%. Therefore, it is not possible at present to make comparisons of model results against data for this hormone other than to confirm that estimates from the model fall within this wide range of variability. The width of the range of variability casts doubt on the application of the model in the subsequent EPA analysis that examines small changes in hormonal levels.

Although the BBDR model makes some improvements in hormonal dynamics, it has several flaws: documentation of the model is poor, the ability to perform a sensitivity and uncertainty analysis parameter-by-parameter is low due to unnecessarily complex script requirements, the unjustified uncoupling of two key parameters that are in fact biologically coupled introduces significant errors, and the model fails several key tests against published data that were dealt with adequately by previous models. As a result, there is a significant reduction in the estimated POD. This reduction is only partly offset by the fact that use of the BBDR model applied to the sensitive subpopulation allowed the EPA to use a UF value of 3 rather than 10 for intra-species variability and extrapolation. However, this compensating effect does not remove the problems of scientific validity noted in using the model results to establish the POD; the compensating effect simply mitigates part of that problem through a fortuitous application of compensating errors.

c. The Three Proposed MCLG and MCLs of 18, 56, and 90 μg/L are Based on Policy Choices, Not Scientific Choices

A critical flaw in EPA's analysis is that it focuses on any neurodevelopmental effect rather than an *adverse* effect. The three candidate MCLGs have been selected based on a 1%, 2% and 3% decline in IQ (or a 1, 2 and 3 point decline). No evidence is given however for the claim that either a 1, 2 or 3 point decline in IQ has clinical significance. IQ testing data has a standard deviation of 15 points. A difference of 4 points is within natural background variability. The estimated 1, 2, or 3 point changes are well within the expected statistical variance of the population, including sensitive subpopulations, on a day to day basis. Therefore, the data do not show a demonstrably adverse effect. Without an adverse effect, there is no meaningful opportunity to provide health risk reduction through regulation.

Benefits analyses for IQ change typically uses lifetime earnings per IQ point as a way to characterize the economic significance of an IQ change, but those 'economic slope factors' result from higher IQ differences than are considered here at environmental levels of exposure to perchlorate. At present, the choice to focus on 1, 2 or 3 points of IQ is a policy choice rather than a scientific and clinical choice. EPA acknowledges this was a policy choice rather than a scientific choice by stating that "the EPA made a policy decision to evaluate the level of perchlorate in water associated with a 1 percent decrease, a 2 percent decrease, and a 3 percent decrease in the mean population IQ (i.e., 1, 2 and 3 IQ points)."[48] And as a policy choice, EPA has notably failed to ground these levels in the policy considerations that the statute directs the EPA to be guided by. Without such a grounding, the policy choice itself is indefensible, even allowing that the Agency may enjoy some policy discretion.

[48] 84 Fed. Reg. at 30536.

d. The Benefits of the Proposed MCLs for Perchlorate Do Not Justify the Costs

AWWA agrees with EPAs finding that the benefits of the proposed 56 µg/L MCL for perchlorate do not justify the costs. EPA's benefit and cost assessment results are reproduced in Table XII-14 of the proposed rule.

As shown in Table XII-14, the results of the cost-benefit analysis are qualitatively the same for an MCLG of either 18 µg/L or 90 µg/L. EPA's *Health Risk Reduction and Cost Analysis* ("HRRCA") results indicate clearly that the costs are larger—and in many cases much larger—than the benefits for both discount rates, all candidate MCLGs and occurrence distributions. The cost-benefit ratio varies from 3 to more than 20 across these combinations.

Table XII-14: Comparison of Annual Costs and Benefits by MCL (Millions; 2017$)

MCL Value	Cost 3% Discount	Benefit 3% Discount	Cost 7% Discount	Benefit 7% Discount
UCMR 1				
90 µg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 µg/L	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 µg/L	$15.95	$0.80 - $6.50	$16.88	$0.13 - $1.10
Incremental (from 90 µg/L to 56 µg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 µg/L to 18 µg/L)	$6.28	$0.36 - $2.93	$6.60	$0.06 - $0.50
National				
90 µg/L	$9.51	$0.40 - $3.26	$10.10	$0.07 - $0.55
56 µg/L[1]	$9.67	$0.44 - $3.57	$10.28	$0.07 - $0.60
18 µg/L	$16.95	$0.80 - $6.56	$17.96	$0.14 - $1.11
Incremental (from 90 µg/L to 56 µg/L)	$0.16	$0.04 - $0.31	$0.18	$0.0 – 0.05
Incremental (from 56 µg/L to 18 µg/L)	$7.28	$0.36 - $2.99	$7.69	$0.07 - $0.51

Source: (USEPA, 2019a). Detail may not sum to total because of independent rounding.
1. For the proposed MCL of 56 µg/L and the alternative MCL of 90 µg/L, the national estimates are the same as the estimates based on UCMR 1 data because there were no small system sample results to extrapolate to national small system estimates. At an MCL of 18 µg/L, national estimates include extrapolation for one small system entry point to national estimates based on sampling weights described above.

AWWA sought to reproduce the EPA's cost/benefit calculations based on the three candidate MCLG values coupled with the occurrence and population data reported by the EPA. Our review confirmed the EPA analysis of the benefits of the rule to within approximately 10%, which may reflect differences in rounding or the treatment of the percentile intervals in the occurrence. EPA correctly acknowledges that the current state of the science precludes including

unquantified benefits in the calculation. Our review also indicated that EPA underestimated the costs of promulgating an MCLG. As described more fully in section VI below, EPA underestimated the number of water systems that would be eligible for waivers. Therefore, EPA underestimated the administrative burden in processing those waivers.

Even without considering errors in EPA's estimation of the costs, EPA's analysis is clear that for all proposed MCLGs, the costs are far larger than the benefits. Strict cost-benefit principles suggest that a policy action is warranted only when the benefits outweigh the costs, or where marginal incremental benefits outweigh marginal incremental costs. The significant magnitude of the cost-benefit ratio does not support a finding that regulatory action is justified.

e. It is Problematic to Adopt an MCLG Notwithstanding the Determination That the Benefits Do Not Justify the Costs

As discussed in section III.b below, it is questionable whether an agency can ever justifiably exercise its discretion to adopt a regulatory requirement or standard where the agency's own analysis shows the proposed regulation is not justified. In this case, proceeding to promulgate an MCLG in light of the cost-benefit results would call into question the utility of devoting limited scientific resources to prepare the materials necessary to support a cost-benefit analysis in the first place. If the MCLG will be put in place regardless of the scientific findings, there is little reason to have expended the scientific resources. At a minimum, EPA should provide a more through justification for any decision to proceed given the negative cost-benefit assessment, as such an approach would have significant implications for future regulatory actions and will establish a precedent for ignoring the findings of those assessments that are required by SDWA Section 1412(b)(4)(C).

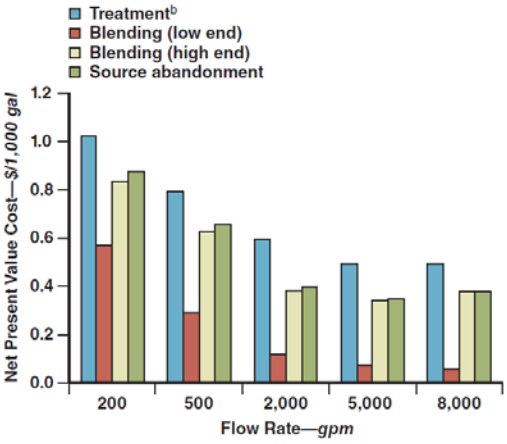
f. Concerns Regarding Treatment Technology Feasibility and the Disproportionate Burden on Small Systems

To comment on the feasibility of the proposed MCLGs and about implementation challenges for small systems, AWWA reviewed approaches implemented by utilities in multiple

states, including California and Massachusetts. AWWA's review indicates that the treatment option of choice is single-pass ion exchange, followed by blending, followed by drilling a new source and source abandonment. The proposed rule also considered biological treatment and centralized reverse osmosis, which AWWA did not observe as common approaches. That aside, there are technologies and methods available to utilities for treatment and management of perchlorate levels. However, at certain scale of operations, the costs of technologies may necessitate source abandonment, which EPA did not consider. In addition, for very large systems, the cost associated with technologies such as ion exchange may create significant operational capacity challenges due to the footprint of associated treatment platforms when scaled to typical daily production requirements.

In addition, due to economies of scale, small systems will be disproportionately burdened if a proposed MCL were exceeded and required action. Estimates of these costs by Russell and Morley (2017), demonstrates that for smaller systems (200-500 gallons per minute; see excerpt of Figure 6) the cost of all options is significantly higher.

FIGURE 6 Net present value conceptual costs for perchlorate compliance strategies[a]



[a]Based on 20-year life-of-service and 3% interest rate
[b]Single-pass ion-exchange treatment

V. EPA Can Reasonably Finalize a Health Advisory Level to Provide Guidance if the Regulatory Determination is Withdrawn

AWWA supports the Agency's withdraw of the regulatory determination for perchlorate based on analysis that a NPDWR would not provide a meaningful opportunity for risk reduction. Given that finding, there is merit in the Agency reviewing the interim health advisory level of 15 µg/L. Based on prior assessments and the proposed rule, it would be reasonable for EPA to finalize a health advisory level to provide guidance for addressing site specific conditions, which may inform existing or future cleanup operations. As the Agency proceeds with this process, it must avoid "regulation through guidance." Health advisories, particularly those that include recommendations for action should be classified as "Economically Significant Guidance Documents" and their development should meet the expectations of relevant Office of Management and Budget circulars including adhering to transparency and public engagement requirements; AWWA anticipates EPA being able to rely on the analysis performed for the proposed rulemaking to support this aspect.

As the Agency distributes educational material in the absence of a rulemaking, there is the opportunity to learn from and incorporate key benefits from the normal rulemaking process, including:

a) Actively involving expert stakeholders to obtain insights into what information is needed, practical constraints that should be reflected, and insights into how to most clearly convey useful information.
b) Effectively engage the nongovernmental organization/association community throughout the development of educational materials. The association/NGO community provides an important informal vehicle for assuring that key stakeholder communities like state primacy agencies and water systems are ready when the Agency releases a final product and have informed and prepared their leadership and public(s).
c) Careful vetting of response strategies with actual practitioners. Educational materials that link thresholds for public health concern to response strategies (e.g., analytical methods, data collection strategies, treatment options, public notification) can be more effective than releasing one without the other, but consideration of input from actual

practitioners is critical. Where water system practice is an element of the response strategy, AWWA would be pleased to be of assistance in providing this review.

d) Demonstrate analytical method and treatment performance. Standardized analytical methods with verified performance at concentrations of interest, as well as demonstrated treatment options, are essential to the credibility of educational materials. AWWA anticipates EPA being able to rely on the analysis performed for the proposed rulemaking to support this aspect.

While the above represent key steps in the health advisory process, it is essential that the Agency's tenor and the substance of associated communication materials clearly and accurately reflect the role and purpose of health advisory.

VI. If EPA Chooses to Promulgate a MCLG and NPDWR, it Should Reconsider the Monitoring Requirements and Barriers to Utilities Seeking Waivers to Bring Costs More Closely Into Balance With Benefits

The EPA is proposing to require community water systems ("CWS") and non-transient non-community water systems ("NTNCWS") to monitor for perchlorate in accordance with the Standardized Monitoring Framework. To satisfy initial monitoring requirements, CWS serving populations greater than 10,000 persons would collect 4 quarterly samples for perchlorate during the second compliance period of the fourth compliance cycle (January 1, 2023 through December 31, 2025) of the Standardized Monitoring Framework. NTNCWS and CWS serving 10,000 persons or less would collect 4 quarterly samples during the third compliance period of the fourth compliance cycle (January 1, 2026 through December 31, 2028) of the Standardized Monitoring Framework.

If EPA proceeds with promulgating an MCLG and MCL for perchlorate, the existing occurrence data provides ample justification to support an expedited process for reduced monitoring. The occurrence data available to the Agency from UCMR 1 at the lowest proposed MCLG of 18 ug/L is estimated to affect 15 systems out of the 62,076 that EPA indicates would be mandated to monitor under a NPDWR for perchlorate. That represents 0.02% of the total number of systems EPA states would be covered by this proposed rule.

Given the known level of occurrence nationally, we recommend that the Agency transition systems to the 9-year monitoring cycle after one year of monitoring data below the MCL. EPA's implementation of SDWIS NexGen provides for an automated process to assess monitoring data and track utilities' status. SDWIS NextGen allows for an automated adjustment under the Standard Monitoring Framework that supplements the wavier application process. This approach would significantly reduce the burden on water systems and states. After all, given the occurrence data available, it is reasonable to expect that as proposed, states would be expected to process in excess of 62,000 waivers within 3 years of rule implementation. This is not an effective use of limited public resources and budgets.

In assessing the burdens of the proposed rule, EPA estimated that 60% of surface water systems and 10% of ground water systems would not be granted waivers, and the remaining 40 and 90 percent respectively would seek waivers from the primacy agency. This distribution is based on analysis prepared by EPA (2008) for its cost assessment associated with the Information Collection Request ("ICR") for the Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rule.[49] More specifically, the wavier ratio in the perchlorate proposed rule corresponds to the following in that ICR:

> Percentage of systems receiving a waiver is based on occurrence estimates in *Arsenic Occurrence in Public Water Supplies* and is carried over from the 2000 Arsenic Rule ICR. Twenty states (40 percent) are known to have adequate historical data to grant waivers. Therefore, EPA assumed that 40 percent of [surface water] systems with levels below 50 percent of the MCL will qualify for a waiver.[50]

It is inappropriate for EPA to apply assumptions associated with the arsenic rule, since there is no documented relationship for co-occurrence. As a result, EPA significantly underestimated the burden associated with the expected waivers that would be requested by utilities from primacy agencies. Further, EPA has an occurrence dataset from UCMR 1 that

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[49] USEPA. 2008. June. Draft Information Collection Request for the Disinfectants/Disinfection Byproducts, Chemical, and Radionuclides Rule.

[50] USEPA. 2008. June. Appendix A – Federal Register Notices Soliciting Comment on Information Collection Requests, from Exhibit 3 – Arsenic Monitoring Burden and Costs – CWSs.

provides a national profile, so the application of assumptions from the arsenic rule appears to be arbitrary absent further explanation. A simple review of UMCR 1 data indicates that it is reasonable to estimate that at minimum 90% of all systems would reliably and consistently have monitoring results below all proposed MCLGs.

Considered another way, in UCMR1 there were a total of 24,112 samples of which 17 had detections at or above 18 µg/L or 0.07%. Extrapolating that data to the universe of systems expected to comply with the propose rule, indicates that 99.93% of systems are likely to be eligible for waivers. Using a conservative estimate of 90 percent, the chart below provides an indication of the number of systems estimated to seek waivers and the burden associated with processing waivers by the primacy agency and utility community.

	Hr/Waiver	Estimated # of Systems seeking Waivers (90%)	Total Hrs	Cost/Waiver	Total Cost
State Review	8	55,868	446,947	$405	$22,626,702
Utility Application	16	55,868	893,894	$555	$31,006,962
Cumulative			1,340,842		$53,633,664

The analysis prepared by EPA for estimating compliance monitoring is addressed in the HRRCA.[51] However, we were unable to replicate the data published by EPA due to information that was not included in the docket, specifically the "Perchlorate Benefit-Cost Analysis Spreadsheet." This omission frustrated our ability to conduct a timely review and analysis of the assumptions and provide a more in-depth assessment. EPA did include a distribution of the number of systems by population size for purposes of calculating wage rates in public water systems in Appendix C of the HRRCA (Exhibit C-2). In its HRRCA analysis, EPA used a combination of UCMR 1 occurrence data and assumptions to estimate the number of entry points to the distribution system ("EPDS") for purposes of calculating compliance burden. For systems that are not included in the occurrence data, EPA assigned the number of entry points based on the population size classification of the system, calculated from the occurrence data (Exhibit 3-14).

[51] EPA, Health Risk Reduction and Cost Analysis of the Proposed Perchlorate National Primary Drinking Water Regulation at 6.3, available at https://www.regulations.gov/document?D=EPA-HQ-OW-2018-0780-0124.

How the actual and estimated number of EPDS is distributed across systems by population size is not presented in the HRRCA. Therefore, the estimate of compliance monitoring samples in Exhibit 5-5 could not be verified and the absence of this relationship prevents us from providing an alternative analysis for consideration. On the other hand, EPA's failure to provide a replicable data set and model also demonstrates that the Agency has failed to establish a record supporting its estimate of how infrequently distribution systems would be waiver-eligible.

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