American Water Works Association

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March 17, 2025

Dr. Jennifer McLain
Director
Office of Ground Water and Drinking Water
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

SUBMITTED ELECTRONICALLY

RE: Consultation and Coordination on forthcoming Proposed National Primary Drinking Water Regulations for Perchlorate

Dear Dr. McLain,

The American Water Works Association (AWWA) appreciates the opportunity to provide comments in response to the Executive Order 13132 Federalism / Unfunded Mandates Reform Act (UMRA) Consultation for the forthcoming proposed rule on Perchlorate held January 16, 2025. EPA must comply with D.C. Circuit decision that remanded the agency's July 2020 withdrawal of its determination to issue drinking water regulations for perchlorate by proposing National Primary Drinking Water Regulation (NPDWR) by November 21, 2025. Consequently, the attached comments respond to questions EPA presented during the recent federalism consultation and were drafted in manner that considers the statutory duties and the associated analyses required of the agency under the Safe Drinking Water Act (SDWA).

The attached comments address elements of the proposed perchlorate rulemaking discussed with EPA during the federalism consultation, including the following:

1. Monitoring and reporting requirements
2. Treatment and compliance options
3. Consumer Confidence Report
4. Public notification requirements
5. Additional Information Regarding the Use of Best Available Science

Thank you for the opportunity to inform the agency's deliberations as it develops a proposal for perchlorate. If you have any questions regarding this correspondence or if AWWA can be of assistance in some other way, please contact Kevin Morley at (202) 326-6124 or mailto:kmorley@awwa.org.

Best regards,

FOR THE AMERICAN WATER WORKS ASSOCIATION

G. Tracy Mehan, III
Executive Director – Government Affairs

cc: NPDWRperchlorate@epa.gov
Eric Burneson, EPA/OW/OGWDW
Anne Lausier, EPA/OW/OGWDW
Andrew Hanson, EPA/OIA

Attachments

Who is AWWA

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 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 membership represents 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.

Attachment 1

FORMAL COMMENTS ON THE FEDERALISM CONSULTATION AND COORDINATION ON PROPOSED NATIONAL PRIMARY DRINKING WATER REGULATIONS FOR PERCHLORATE

Prepared by:
American Water Works Association
1300 Eye Street, NW, Suite 701W
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March 17, 2025

FORMAL COMMENTS ON THE FEDERALISM CONSULTATION AND COORDINATION ON PROPOSED NATIONAL PRIMARY DRINKING WATER REGULATIONS FOR PERCHLORATE

INTRODUCTION

The American Water Works Association (AWWA) respectfully submits these comments in response to the January 16, 2025, Executive Order 13132 Federalism / Unfunded Mandates Reform Act (UMRA) Consultation for the forthcoming proposed rule on perchlorate. 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. EPA specifically proposed setting a perchlorate MCLG at 56 µg/L. The proposed rule also included 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. AWWA's comments[1] supported the withdrawal alternative, which represented the regulatory option that was consistent with EPA's finding that the benefits of any level of perchlorate regulation do not justify the costs. EPA withdrew the regulatory determination for perchlorate on July 21, 2020,[2] finding that it "was not found in drinking water with a frequency and at levels of public health concern to support a meaningful opportunity for health risk reduction through a national perchlorate drinking water regulation."

In March 2022, EPA announced the completion of its review of the July 2020 perchlorate action pursuant to the requirements of Executive Order 13990. The agency concluded then that the July 2020 action was supported by the best available peer reviewed science and that it was conducted in accordance with the Executive Order.[3]

In May 2023, the D.C. Circuit vacated and remanded EPA's July 2020 withdrawal of its determination to issue drinking water regulations for perchlorate.[4] The D.C. Circuit concluded that once the agency issues a final regulatory determination that it must then promulgate a final NPDWR. We believe that this conclusion is contrary to the stated Congressional intent in the SDWA that requires EPA to use the best available science to inform regulatory decisions throughout the process, and that making a regulatory determination is a "initiating step" in that process.

We also recognize that the D.C. Circuit remanded the 2020 rule to EPA for reconsideration and that decisions by the U.S. District Court for the Southern District of New York established a set of deadlines for proposing a NPDWR by November 21, 2025, and promulgating a final rule by May 21, 2027. Therefore, as the agency proceeds with developing a new proposed rule, we are providing comments to inform EPA's process to ensure the best available science is properly considered and

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[1] AWWA Comments on National Primary Drinking Water Regulations: Perchlorate; Docket ID No. EPA–HQ–OW–2018–0780, , August 26, 2019, https://www.regulations.gov/comment/EPA-HQ-OW-2018-0780-0258

[2] EPA, Drinking Water: Final Action on Perchlorate, July 21, 2020, 85 FR 43990.

[3] https://www.epa.gov/newsreleases/epa-announces-plan-protect-public-perchlorate-drinking-water

[4] *NRDC v EPA* (Case # 20-1335) https://media.cadc.uscourts.gov/opinions/docs/2023/05/20-1335-1998466.pdf

to minimize unnecessarily burdensome requirements being imposed on water systems and states to the extent practicable.

AREAS FOR COMMENT PER FEDERALISM CONSULTATION

During the January 16, 2025, federal consultation, EPA specifically requested comment related to the following areas:

1. Monitoring and reporting requirements, including eligibility and criteria for reduced monitoring and waivers
2. Treatment and compliance options
3. Consumer Confidence Report
4. Public notification requirements

1. MONITORING AND REPORTING REQUIREMENTS

AWWA requests that EPA properly consider the annual burden a perchlorate rule would impose on water systems and primacy agencies. This should include an expedited approach for waivers, especially given the unfounded assumption in the 2019 proposed rule that perchlorate would mirror the incidence of arsenic. Previously EPA proposed that community water systems (CWS) and non-transient non-community water systems (NTNCWS) would be required to monitor for perchlorate in accordance with the Standardized Monitoring Framework (SMF).

Occurrence data previously collected by EPA under UCMR1 provides ample justification to support an expedited process for reduced monitoring. Based on a simple review of UMCR 1 data, it is reasonable to estimate that 99.93% of systems would likely be eligible for waivers under all previously proposed MCLGs. Even using a conservative estimate of 90 percent, Table 1 demonstrates that the number of systems expected to seek waivers under a traditional application of the SMF would generate an unnecessary burden on water systems and state primacy agencies. The burden analysis associated with the wavier process is based on data compiled by EPA in the Health Risk Reduction and Cost Analysis (HRRCA) [5] for the 2019 proposed rule. Therefore, we are recommending that the agency seek opportunities to adjust the monitoring requirements to minimize burden and cost using an alternative monitoring requirement designed for perchlorate.

[5] 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.

Table 1. Estimated Number of Monitoring Waivers and Associated Cost Burden

	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
Water system Application	16	55,868	893,894	$555	$31,006,962
Cumulative			**1,340,842**		**$53,633,664**

Alternative Monitoring Framework for Perchlorate

AWWA recommends that EPA consider an alternative approach than was proposed in 2019 for perchlorate. This approach recognizes that the traditional wavier process is overly burdensome on water systems and primacy agencies. Current practice demonstrates that waivers are not typically granted by states, consequently a more workable monitoring framework is needed.

The existing dataset demonstrates that perchlorate has a low occurrence rate nationally, therefore we believe the agency should adopt a monitoring approach that can address unnecessary administrative processes. For purposes of the perchlorate proposed rule, it is recommended that the agency consider the following monitoring protocol in Table 2, where reliably and consistently below the MCL is equal to one half the MCL. As an example, if the MCL was set at 18 ug/L, the lowest level proposed in 2019, then a sample at or below 9 ug/L would represent a sample that is reliably and consistently below the MCL purposes of this sampling protocol.

Table 2. Alternative Monitoring Framework for Perchlorate

Monitoring Framework	Surface Water	Groundwater
Initial monitoring period (first year)	4 quarterly samples	2 samples per year
If initial monitoring is reliably and consistently (R&C) below MCL	1 sample every 3yrs	1 sample every 3 years
If R&C <MCL after 3 consecutive 3-year periods	1 sample every 9 years	1 sample every 9 years
If >MCL or not R&C <MCL	4 quarterly samples	2 samples per year

In terms of historical data, EPA should allow sampling data collected by a water system in the past 5 years as source to satisfy the initial monitoring period and expedite the transition to reduced monitoring. The practical quantitation levels (PQLs) for EPA Methods 314.1 and 314.2 are adequate to support this alternative monitoring framework. Given the known level of occurrence nationally, the agency could also propose having systems shift directly to a 9-year monitoring cycle after four consecutive quarters year of monitoring data that is reliable and consistently less than one-half the MCL. Such an approach might be particularly appropriate for groundwater supplies as such supplies typically have less variability in contaminant concentration than surface water supplies.

EPA should avoid creating a rule that is fundamentally a burdensome monitoring requirement. Consideration of an alternative approach is consistent with Congressional intent seeking to ensure that regulations do not impose unnecessary burdens that ultimately fall to customers. In developing the 1996 SDWA amendments it was recognized that "[c]ustomers will pay for safe drinking water . . . [b]ut are not willing to pay for complying with drinking water rules that provide only marginal increases in health protection at significant costs, particularly when there is so much uncertainty concerning both the occurrence and real threat to public health of many contaminants."[6] It was also noted that the statutory regime before the 1996 amendments "force[d] our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water," and could "impose large aggregate costs nationwide while producing only small gains in public health risk reduction."[7]

HRRCA Data Quality Issues

Based on our review of the 2019 HRRCA, we would like to highlight several data quality issues that should be addressed in the new proposed rule.

1. *Data Assumptions*
   In assessing the burdens of the 2019 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.[8] More specifically, the wavier ratio in the perchlorate proposed rule directly 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.[9]

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[6] H.R. Rep. No. 104-632 , https://www.congress.gov/congressional-report/104th-congress/house-report/632/1

[7] S. Rep. No. 104-169, https://www.congress.gov/congressional-report/104th-congress/senate-report/169/1

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

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

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 may be requested by water systems from primacy agencies for perchlorate. This assumption should not be carried forward in any new HRRCA being prepared for the new perchlorate proposed rule. EPA has occurrence dataset from UCMR 1 that provides a national profile, so the application of assumptions from the arsenic rule appears to be arbitrary absent further explanation and must be corrected in the 2025 proposed rule. Moreover, the experience of AWWA's members is that primacy agencies are not providing monitoring waivers. A more appropriate cost analysis would assume that waivers will not be available.

2. *Data Availability*
   In 2019, AWWA was unable to replicate the data in the HRRCA due to information that was excluded from the docket, specifically the "Perchlorate Benefit-Cost Analysis Spreadsheet." This omission frustrated our ability in 2019 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 the 2019 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 were 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).

   How the actual and estimated number of EPDS is distributed across systems by population size is not presented by EPA in the HRRCA. Therefore, the estimate of compliance monitoring samples in HRRCA Exhibit 5-5 could not be verified and the absence of this relationship prevented AWWA from providing an alternative analysis for consideration. EPA's failure to provide a replicable data set and model also demonstrates that the agency failed to establish a record supporting its estimate of how infrequently distribution systems would be waiver eligible. This omission must be corrected in support of the 2025 proposed rule if the analysis assumes primacy agencies grant waivers under the rule.

2. TREATMENT AND COMPLIANCE OPTIONS

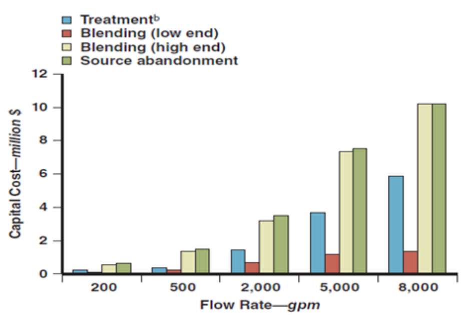
AWWA has examined treatment and associated compliance costs for perchlorate.[10] This analysis considered multiple compliance strategies as options a system could implement to reduce perchlorate concentrations prior to distribution. These compliance strategies include:

[10] Russell, C.G., Morley, K.M (2017). Estimating the National Costs of Regulating Perchlorate in Drinking Water. Journal - American Water Works Association, 109(2), E25-36. https://doi.org/10.5942/jawwa.2017.109.0009

- single-pass ion exchange,
- regenerable ion exchange,
- reverse osmosis,
- biological treatment;
- blending; and
- source abandonment.

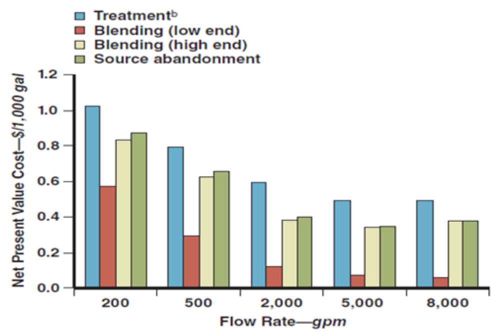
The analysis provided several approaches for considering the cost of compliance strategies based on system size and estimated net present value as presented in Figure 5 and Figure 6 from Russell & Morley (2017).

FIGURE 5 Conceptual capital costs[a] for perchlorate treatment, blending, or source abandonment



[a]Based on 2013 dollars data from the *Engineering News Record* 20-city construction cost indexes
[b]Single-pass ion-exchange treatment

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

The analysis also indicated that the treatment option of choice is single-pass ion exchange, followed by blending, followed by drilling a new source and source abandonment. The 2019 proposed rule and federalism consultation includes biological treatment and centralized reverse osmosis, which was not observe as a common compliance approach.

There are technologies and methods available to water systems for treatment and management of perchlorate levels. The costs and logistics of sustainably operating these technologies may favor source abandonment or blending. EPA did not consider abandonment or blending in the 2019 proposed rule, but these options were included in the cost tables provided for the current federalism consultation. 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.

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

3. CONSUMER CONFIDENCE REPORT

AWWA recommends that EPA adhere to standard Consumer Confidence Report (CCR) requirements for perchlorate in keeping with typical practice for other inorganic MCLs. AWWA advises against including additional perchlorate-specific information beyond the standard CCR requirements. The CCR is already lengthy, and adding more content would dilute its effectiveness while increasing the burden on both water systems and the states responsible for preparing these reports.

4. PUBLIC NOTIFICATION REQUIREMENTS

AWWA recommends that EPA adhere to standard Tier 2 Public Notification (PN) requirements for perchlorate in keeping with practice for MCLs with health consequences due to lifetime exposures. Requiring additional PN beyond what is typically mandated for similar contaminants would place an unnecessary burden on both states and water systems.

5. ADDITIONAL INFORMATION REGARDING THE USE OF BEST AVAILABLE SCIENCE

In comments filed by AWWA related to the 2019 proposed rule, we highlighted multiple issues related to EPA's approach to developing a MCLG for perchlorate. This includes EPA's use of "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.[11] It has been noted multiple times that EPA departed from standard practice when it adopted a reference dose for perchlorate that the National Academies of Science described as "a conservative, health-protective approach" to "protect the health of even the most sensitive populations."[12] This departure was described by the EPA Inspector General as follows:

> Against established EPA risk assessment procedures, EPA derived the perchlorate [reference dose] from a nonadverse biological effect instead of an adverse effect. The perchlorate [reference dose] 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.[13]

The IG report stated that "EPA's perchlorate [reference dose] is conservative and protective of human health, and further reducing the perchlorate exposure below the [reference dose] does not effectively lower risk" and highlighted that addressing moderate and mild iodide deficiency was a more effective way to address the risk to the pregnant and nursing population.

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[11] *Id.* § 300g-1(b)(3)(A).

[12] National Research Council. Health implications of perchlorate exposure. National Research Council. Washington DC: National Academy Press. 2005.

[13] EPA, Office of Inspector General Scientific Analysis of Perchlorate, Report No. 10-P-0101, April 19, 2010.

The 2011 regulatory determination to reverse the 2008 preliminary determination to not regulate used a non-adverse effect to determine the reference dose for perchlorate, rather than the first adverse effect.[14] 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 as proposed in 2019 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.

For this reason, AWWA stands by our prior comments that the record does not support the statutory findings required to promulgate a MCLG and NPWDR. Promulgating a rule in the absence of the statutorily required findings is arbitrary and capricious, an abuse of discretion, and contrary to law. However, given the agency has been directed to proceed in proposing a NPDWR for perchlorate, we are providing additional technical comments that address concerns with EPA's use and application of the best available science.

A. Significant Flaws in the Technical Merits of EPA's Analysis Underlying the Proposed MCLG

The 2019 proposed rule posed a series of questions reviewers were asked to consider and comment upon before any final determination is made. The comments provided here focus on several topics EPA presented in the 2019 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; and 5) EPA's proposal to adopt the proposed rule even though the benefits do not justify the costs.

1. 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

[14] 76 Fed. Reg. at 7764.

iodine intake groups' IQ decrements are averaged together based on the proportion of individuals in each iodine intake category." [15]

As noted, EPA used data from Korevaar et al.[16] 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.[17] 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."[18]

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.

Table III-2 from the 2019 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. 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

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[15] 84 Fed. Reg. at 30552.

[16] Korevaar, T. I. M., Muetzel, R., Medici, M., Chaker, L., Jaddoe, V. W. V., de Rijke, Y. B., ... Peeters, R. P. Association of maternal thyroid function during early pregnancy with offspring IQ and brain morphology in childhood: a population-based prospective cohort study. The Lancet Diabetes & Endocrinology, 4, 1, 2016.

[17] *Id.* at 30536.

[18] *Id.* at 30535-30536.

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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	End-point	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/ depress-sion 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) = $\beta \times \Delta$ 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.

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.[19] 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's conclusion is not 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.

2. Examination of 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 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).[20] Greer et al examined the relationship between perchlorate dose and IUI. The Greer analysis began with a no

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[19] Crawford-Brown, D. and Crawford-Brown, S. Implications of the reanalysis and weight of evidence determination of human health studies for exposure to perchlorates under cumulative and aggregate risk assessment, *Journal of Environmental Protection*, 7, 12, 2016.

[20] Greer, M., Goodman, G., Pleus, R. and Greer, S. Health effects assessment for environmental per-chlorate contamination: the dose-response for inhibition of thyroidal radioiodine uptake in humans. Environmental Health Perspectives. 110, 2002. Erratum in: Environmental Health Perspectives, 113, 2005.

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 the 2019 proposed rule and corresponds to the estimated IQ decrement of 1 point or 1% at that level.

Nevertheless, the MCLG approach in the 2019 proposed rule differs significantly from this more traditional regulatory assessment approach. EPA first established 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."[21]

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 2019 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

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

modeled groups within the population that are identified as likely to be at greater risk to perchlorate in drinking 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)."[22]

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 2019 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 2019 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 in the 2019 proposed rule, 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)."[23]

For those individuals, EPA's Relative Source Contribution (RSC) values are contained in Table III-5 of the 2019 proposed rule:

[22] *Id*. at 30537.
[23] *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 2019 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."[24]

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."[25]

As a point of comparison, had EPA chosen to use either the 50th percentile or mean bodyweight for food intake in the 2019 proposed rule, 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 in the following table.

		Calculated RSC			**Calculated MCLG**		
RfD	**DWI**	**90th Percentile**	**Mean**	**50th Percentile**	**RSC @ 90th Percentile**	**RSC @ Mean**	**RSC @ 50th Percentile**
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. <u>Concerns Regarding the BBDR Model</u>

As mentioned previously, use of the BBDR model does not produce a result very 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

[24] *Id.* at 30538.
[25] *Id.* at 30539.

“biologically plausible” neurodevelopment effects based on epidemiological studies.[26] 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.[27] 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 assessments.[28] 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.

a) <u>BBDR Model’s Structure and Parameter Assumptions</u>

- 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

[26] 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.

[27] Clewell III, H., Gentry, P.R., Hack, C.E., Greene, T. and Clewell, R.D. An evaluation of the USEPA Proposed Approaches for applying a biologically based dose-response model in a risk assessment for perchlorate in drinking water. *Regulatory Toxicology and Pharmacology*, 103, 2019.

[28] Clewell, R.A., Merrill, E.A., Gearhart, J.M., Robinson, P.J., Sterner, T.R., Mattie, D.R., Clewell III, H.J., 2007. Perchlorate and radioiodide across life stages in the human: using PBPK models to predict dosimetry and thyroid inhibition and sensitive subpopulations based on developmental stage. *J. Toxicol. Environ. Health*, Part A 70,408, 2007.

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."[29] *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.

b) <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 (2019) 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. [30] The difference is much smaller when considering the lower value of beta from Steinmaus at high levels of perchlorate dose

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[29] Alexander, E. K., Pearce, E. N., Brent, G. A., Brown, R. S., Chen, H., Dosiou, C., & Sullivan, S. 2017 guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and the postpartum. Thyroid. 27, 3, 2017.

[30] Steinmaus, C.M. Perchlorate in Water Supplies: Sources, Exposures, and Health Effects. *Curr Envir Health Rpt* 3, 136–143, 2016.

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)[31] and Téllez et al (2005)[32] 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 additional 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.

3. *The 2019 Proposed MCLG and MCLs of 18, 56, and 90 μg/L are Based on Policy Choices, Not Scientific Choices*

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[31] Braverman, L., Pearce, E.N., He, X., Pino, S., Seeley, M., Beck, B., Magnani, B., Bleunt, B.C., Firek, A.,. Effects of six months of daily low-dose perchlorate exposure on thyroid function in healthy volunteers. Journal of Clinical Endocrinology and Metabolism. 91, 7, 2006.

[32] Téllez Téllez, R., Michaud Chacon, P., Reyes Abarca, C., Blount, B. C., Van Landingham C. B., Crump, K. S., & Gibbs, J. P. Long-term environmental exposure to perchlorate through drinking water and thyroid function during pregnancy and the neonatal period. Thyroid, 15, 9, 963-975, 2005.

EPA's analysis focused on any neurodevelopmental effect rather than an *adverse effect*. The three candidate MCLGs selected in 2019 are 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)."[33] 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.

4. The Benefits of the 2019 Proposed MCLs for Perchlorate Do Not Justify the Costs

AWWA agrees with EPA's 2019 finding that the benefits of the proposed 56 μg/L MCL for perchlorate does not justify the costs. EPA's benefit and cost assessment results are reproduced in Table XII-14 of the 2019 proposed rule.

As shown in Table XII-14, the results of the benefit-cost 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 benefit-cost ratio varies from 3 to more than 20 across these combinations

AWWA sought to reproduce the EPA's benefit-cost 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 acknowledged in 2019 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 previously, EPA underestimated the cost of monitoring that would be necessary for all systems to comply with the rule as proposed in 2019.

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[33] 84 Fed. Reg. at 30536.

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.

Even without considering errors in EPA's estimation of the costs, EPA's 2019 analysis clearly found that for all proposed MCLGs, the costs are far greater than the benefits. Strict benefit-cost 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 benefit-cost ratio does not support a finding that regulatory action is justified.