National Primary Drinking Water Regulation for Perchlorate: Proposed Rule

December 5, 2019

EPA

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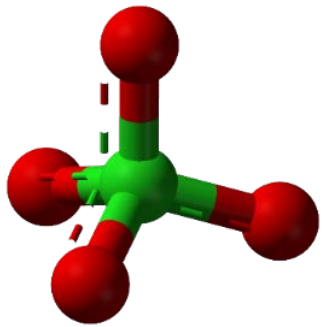
What is Perchlorate?

- Perchlorate is an inorganic ion, ClO_4^-
- Occurs primarily as a salt
- Variety of industrial uses, it is primarily used in the form of ammonium perchlorate as an oxidizer in solid fuels to power rockets, missiles, and fireworks
- Perchlorate also occurs naturally:
  - Soils in arid or semiarid regions (e.g., the High Plains of Western U.S.A.)
  - Atmospheric processes
- Trace amounts could occur as a result of improper handling of hypochlorite solutions (disinfectant)
- Highly soluble, dissociates completely



Regulatory History

- EPA included perchlorate on the 1st, 2nd, and 3rd Contaminant Candidate Lists (CCL); published 1998, 2005 and 2009.
- EPA included perchlorate in the 1st Unregulated Contaminant Monitoring Rule (UCMR1); data submitted 2001-2005.
  - 4.1% of water systems reported measurements greater than 4 µg/L (the minimum reporting level)
- 2008 preliminary Regulatory Determination.
  - Health Reference Level (HRL) of 15 µg/L based on reference dose of 0.7 µg/kg/day (NAS)
  - Decision to not regulate based on low occurrence at 15 µg/L
- 2009 supplemental request for comment on new analysis of derived alternative HRLs for 14 life stages.
  - Life-stage dependent HRLs ranging from 1 to 47 µg/L
- 2011 final Regulatory Determination
  - Decision to regulate based on meaningful opportunity to improve public health protection for 5 -16 million people served water containing perchlorate
  - SDWA required EPA to promulgate a proposed drinking water regulation by February 11, 2013, and a final rule by August 11, 2014.
- 2019 EPA issues proposed regulation for perchlorate
  - Request for public comment on proposed and alternative MCLG & MCL values, as well as comment on whether regulatory determination should be withdrawn.

Perchlorate Health Effects

- At sufficient levels, perchlorate interferes with the thyroid gland by inhibiting iodide uptake.
- Reduced iodide uptake by the thyroid impacts the amount of thyroid hormones produced.
- Thyroid hormones are critical for normal growth and development.
- Poor iodide uptake and subsequent impairment of thyroid function in pregnant women are linked to delayed development and decreased learning capability in their infants and children.

EPA Science Advisory Board Recommendations

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- In 2012, EPA sought recommendations from the EPA Science Advisory Board (SAB) on how to use the RfD and a proposed approach to derive an MCLG. The May 2013 SAB report recommended the following:
  - "derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling (PBPK);"
  - "expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;"
  - "utilize an MOA framework for developing the MCLG that links the steps in the proposed mechanism leading from perchlorate exposure through iodide uptake inhibition to thyroid hormone changes and finally neurodevelopmental impacts;"
  - "extend the [BBDR] model expeditiously to…provide a key tool for linking early events with subsequent events as reported in the scientific and clinical literature on iodide deficiency, changes in thyroid hormone levels, and their relationship to neurodevelopmental outcomes during sensitive early life stages."
- To address the SAB recommendations, EPA and FDA scientists worked collaboratively to develop models to predict the effects perchlorate exposure has on thyroid function in pregnant women and their children.

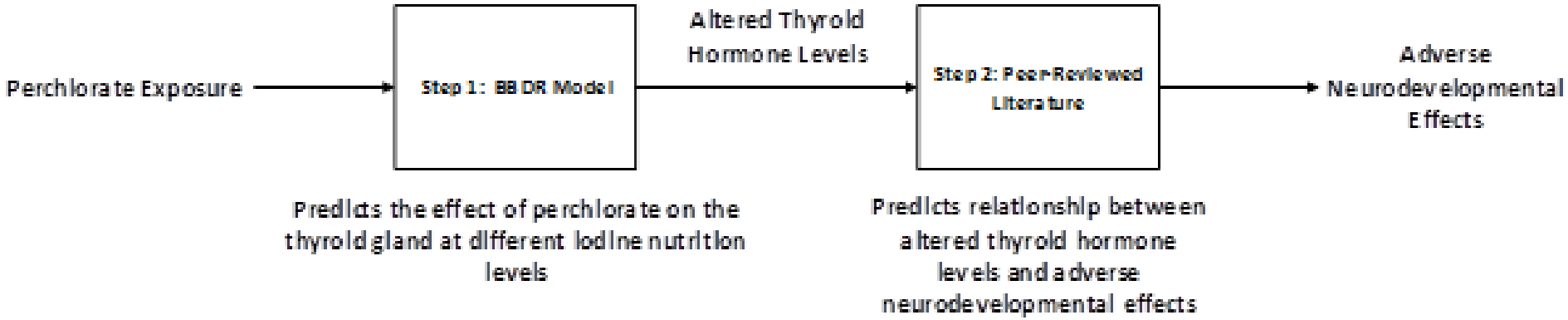
MCLG Development

Two Step Analysis and Peer Review:

2017: EPA (with support of FDA) prepared and peer reviewed a biologically-based dose response (BBDR) model that predicts thyroid hormone changes that result from iodine nutrition and perchlorate exposure.

2018: EPA prepared and peer reviewed a revised BBDR model and a analysis of epidemiologic studies examining thyroid hormones changes in pregnant women to neurodevelopment effects.

> *"Overall, the committee agreed that the EPA and its collaborators have prepared a highly innovative state-of-the-science set of quantitative tools to evaluate neurodevelopmental effects that could arise from drinking water exposure to perchlorate. While there is always room for improvement of the models, with limited additional work to address the committee's comments below, the current models are fit-for-purpose to determine an MCLG."*



MCLG Development (cont.)

Step 1: Convert point of departure to Reference dose (RfD): $RfD = \frac{POD}{UF}$

Step 2: Adjust RfD to remove relative source contribution from food (RSC): $RfD_{water\ only} = RfD\ - RSC$

Step 3: Convert RfD_{water} to concentration in µg/L based on weight-adjusted drinking water intake (DWI): $MCLG = \frac{RfD_{water}}{DWI}$

Proposed MCLG/MCL & Alternatives

Maximum Contaminant Level Goal (MCLG)

- MCLGs are non-enforceable public health goals.
- MCLGs consider only public health and not the limits of detection and treatment technology effectiveness.

Maximum Contaminant Level (MCL)

- MCLs are the maximum level allowed of a contaminant in water which is delivered to any user of a public water system.
- MCLs are set as close as feasible to the MCLG taking cost into consideration.

➢ Proposed MCLG/MCL = 56 µg/L (Prevents more than a 2 IQ point decrement in the most sensitive population).

➢ Alternative MCLG/MCLs = 18 µg/L & 90 µg/L (Prevents more than a 1 or 3 IQ point decrement in the most sensitive population, respectively).

Feasibility Evaluation - Alternative MCLs

- Determined that setting an MCL equal to an MCLG of 56 µg/L, 18 µg/L, or 90 µg/L is feasible:
  - the approved analytical method for perchlorate for UCMR 1 has a minimum reporting level (MRL) of 4 µg/L, and
  - available treatment technologies can treat to concentrations well below 18, 56, or 90 µg/L.
- EPA did not evaluate alternative MCL values greater than the corresponding MCLG values.
  - Infrequent occurrence above potential MCLGs,
  - Majority of the costs are for administrative and initial monitoring activities, and will not be significantly affected by MCL values greater than corresponding MCLG values

Implementation

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Applicability

- Community Water System (CWS): a public water system that serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.
- Non-Transient Non-Community Water System (NTNCWS): a public water system that is not a community water system and that regularly serves at least 25 of the same persons over six months per year.
- Primacy Agencies: agencies responsible for drinking water regulatory development and enforcement (states and tribes).

Compliance Date

- Water systems must begin complying with the perchlorate regulation three years after promulgation.

The Standardized Monitoring Framework

FOURTH CYCLE									FIFTH CYCLE								
1st Period			2nd Period			3rd Period			1st Period			2nd Period			3rd Period		
2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037

Initial Monitoring: 4 quarterly samples at entry points to the distribution system

Large CWSs (serving greater than 10,000 persons)

- 2nd Period of the Fourth Cycle; January 2023 – December 2025

Small CWSs and NTNCWSs

- 3rd Period of the Fourth Cycle; January 2026 – December 2028

Grandfathered Data

Can be used to satisfy initial monitoring requirements if:

- Large CWSs use data collected during the 1st Period of the Fourth Cycle; January 2020 – December 2023
- Small CWSs and NTNCWSs use data collected during the 2nd Period of the Fourth Cycle; January 2023 – December 2025

The Standardized Monitoring Framework (cont)

FOURTH CYCLE									FIFTH CYCLE								
1st Period			2nd Period			3rd Period			1st Period			2nd Period			3rd Period		
2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037

Reduced Monitoring & Waivers

If initial monitoring does not exceed that MCL:

- Surface water systems can reduce to annual monitoring and may apply for a 9 year monitoring waiver after three rounds of annual monitoring with results less than the MCL.
- Groundwater systems can reduce to triennial monitoring and may apply for a 9 year monitoring waiver after three rounds of monitoring with results less than the MCL.
- One sample must be collected during the nine-year compliance cycle that the waiver is effective, and the waiver must be renewed every nine years.

Analytical Methods

EPA has approved the following analytical methods for perchlorate:

- EPA 314.0 Determination of Perchlorate in Drinking Water by Ion Chromatography
- EPA 314.1 Determination of Perchlorate in Drinking Water Using Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection
- EPA 314.2 Determination of Perchlorate in Drinking Water Using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection
- EPA 331.0 Determination of Perchlorate in Drinking Water by Liquid Chromatography Electrospray Ionization Mass Spectrometry
- EPA 332.0 Determination of Perchlorate in Drinking Water by Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry
- All of the proposed EPA analytical methods provide performance data to demonstrate their capability to reliably and consistently measure perchlorate in drinking water at the proposed and alternate MCLs.

Compliance Determination

- Compliance with the MCL is determined based on one sample if the level is at or below the MCL.
- If the level of perchlorate exceeds the MCL at any entry point in the initial sample, a confirmation sample is required within two weeks.
- Compliance would be determined based on the average of the initial and confirmation samples.

Consumer Notifications

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Consumer Confidence Report (CCR)

- Community Water Systems deliver a CCR, also known as an annual drinking water quality report, to their customers.
- These reports provide Americans information about their local drinking water quality.
- For CWSs allowed to monitor less frequently than once per year (i.e., waivers) report the date and result of its most recent monitoring – no data older than 5 years need be included.
- CWSs would report the highest detected level or average and the range of detected levels or averages for perchlorate.

Public Notification (PN)

- PN ensures that consumers will know if there is a problem with their drinking water.
- Violation of the perchlorate MCL would require Tier 2 PN; within 30 days of notification of violation.
- Failure to collect a sample or report perchlorate results would require Tier 3 PN; within one year.

Best Available Technologies (BATs)

EPA is proposing the following technologies as BAT for removal of perchlorate from drinking water:

- **Ion Exchange** - a physical and chemical separation process that can achieve high perchlorate removal rates.
- **Biological Treatment** - uses bacteria to reduce perchlorate to chlorate, chlorite, chloride, and oxygen.
- **Centralized Reverse Osmosis** - a membrane filtration process that physically removes perchlorate ions from drinking water.

EPA is proposing the following Small System Compliance Technologies for removal of perchlorate from drinking water:

- All of the above, and
- Point of Use Reverse Osmosis

Perchlorate Occurrence

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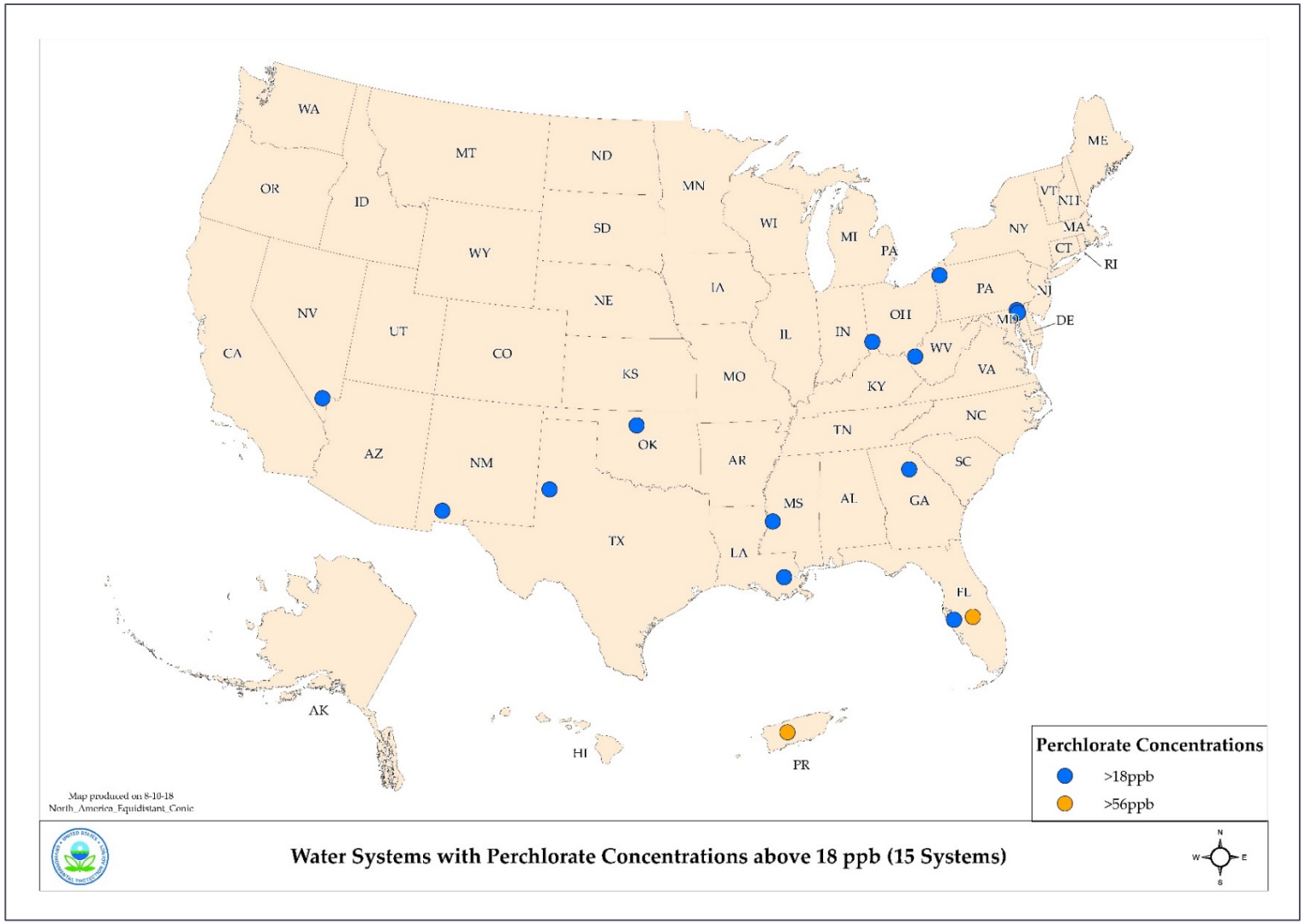

Occurrence and Exposure Estimates

- SDWIS/FED 2018 inventory: 62,076 systems could be affected (excluding CA and MA systems)
- UCMR1 data provide basis for occurrence and exposure estimates

Affected Entity	Small Systems	Large Systems	Total Systems
MCLG = MCL 56 µg/L			
Entry points (population)	0 (0)	2 (32,432)	2 (32,432)
Water systems (population)	0 (0)	2 (64,733)	2 (64,733)
Alternative MCLG = MCL 18 µg/L			
Entry points (population)	1 (2,155)	16 (618,406)	17 (620,561)
Water systems (population)	1 (4,309)	14 (696,871)	15 (701,180)
Alternative MCLG = MCL 90 µg/L			
Entry points (population)	0 (0)	1 (25,972)	1 (25,972)
Water systems (population)	0 (0)	1 (25,972)	1 (25,972)

Cost Estimates

- Treatment costs for CWSs that need to reduce perchlorate
  - Assumed affected systems will use perchlorate selective ion exchange (IX) process (most cost-effective technology)
  - Estimated capital and operating & maintenance (O&M) costs for IX for the affected systems using a peer reviewed cost model
  - Treatment costs account for 10% of total costs at MCL of 56 µg/L (8% to 50% for 90 and 18 µg/L, respectively)
- Administrative costs apply to all primacy agencies and the universe of 62,076 CWSs and NTNCWSs
  - Initial and long-term monitoring costs incurred by CWSs and NTNCWSs under the standardized monitoring framework
  - State review of monitoring data, waiver requests and federal reporting costs
  - State primacy implementation activities
- National Cost Estimate
  - Treatment and administrative costs are aggregated to national level using a bottom-up approach
  - Annualized costs reflect staggered monitoring, reporting, monitoring waiver request schedules, and treatment capital and O&M costs.

Benefit Estimates

- Estimate annual number of live births given entry point population:

Demographic Category	MCL = 56 ug/L	MCL = 18 ug/L*	MCL = 90 ug/L
Total population served at entry points that exceed an MCL	32,432	659,547	25,972
Women aged 15-44 (19.7%)	6,839	129,843	5,116
Annual live births (62 per 1,000 women aged 15 -44)	396	8,050	317
Percent born to women with iodine intake < 75 ug/day	13.52%	13.52%	13.52%
Live births	54	1088	43

*Small system sample results extrapolated to national estimates

- Estimate potential IQ decrements from exposure to current entry point perchlorate levels (accounting for varying iodine intake levels)
- Estimate avoided IQ decrements for entry points that reduce perchlorate to below MCL levels
- Multiply avoided IQ decrements with $/IQ value

Benefit-Cost Analysis Summary

Comparison of Annual Costs and Benefits of the Proposed and Alternative MCLs (Million 2017$)

Item	National	
	3% Discount	7% Discount
MCL = 56 µg/L		
Total annual costs	$9.67	$10.28
Total annual quantified benefits	$2.00	$0.34
Alternative MCL = 18 µg/L		
Total annual costs	$16.95	$17.96
Total annual quantified benefits	$3.68	$0.62
Alternative MCL = 90 µg/L		
Total annual costs	$9.51	$10.10
Total annual quantified benefits	$1.83	$0.31

Proposed Rule and Alternatives

- Proposed perchlorate rule:
  - 56 µg/L as the MCLG and enforceable MCL
- Request for comment on alternative MCLGs & MCLs:
  - 18 µg/L as the MCLG and enforceable MCL
  - 90 µg/L as the MCLG and enforceable MCL
- Request comment on withdrawal of the 2011 Regulatory Determination:
  - Due to the low occurrence of perchlorate at levels of concern
  - Under this alternative the final action would be a withdrawal of the determination to regulate and there would be no MCLG or national primary drinking water regulation

Next Steps

- EPA is evaluating the almost 1,500 comments received on the proposal.
- Final action by June 19, 2020