**Perchlorate proposal notes**

**SUMMARY**

The EPA is proposing to set both the enforceable Maximum Contaminant Level (MCL) for the perchlorate regulation and the perchlorate MCLG at 0.056 mg/L (56 μg/L).

In addition to the proposed regulation, the EPA is requesting comment on three alternatives: 1) whether the MCL and MCLG for perchlorate should be set at 0.018 mg/L (18 μg/L), 2) whether the MCL and MCLG for perchlorate should be set at 0.090 mg/L (90 μg/L), or 3) whether instead of issuing a national primary drinking water regulation, the EPA should withdraw the Agency’s February 11, 2011, determination to regulate perchlorate in drinking water based on new information that indicates that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and there may not be a meaningful opportunity for health risk reduction through a drinking water regulation. Under this last 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 for perchlorate.

**GENERAL INFORMATION**

*What is the EPA proposing?*

The EPA is proposing an NPDWR for perchlorate in accordance with its February 11, 2011, (76 FR 7762) determination to regulate perchlorate under the SDWA. Based on the best available peer reviewed science at that time, the EPA found that perchlorate met the SDWA’s three criteria for regulating a contaminant: 1) the contaminant may have an adverse effect on the health of persons, 2) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern, and 3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Third, in light of new considerations that have come to the EPA’s attention since it issued its positive regulatory determination in 2011, including information on lower levels of occurrence of perchlorate than the EPA had previously believed to exist and new analysis of the concentration that represents a level of health concern, this action also discusses and requests comment on an alternative action under which the EPA would withdraw its 2011 determination to regulate perchlorate.

**ASSESSMENT AND MODELING OF THE HEALTH EFFECTS OF PERCHLORATE**

The mode of action of perchlorate toxicity has been proposed as follows: exposure to perchlorate is known to inhibit the uptake of iodide by the thyroid gland through the NIS (NRC, 2005; SAB for the U.S. EPA, 2013). A sufficient inhibition of iodide uptake results in iodide deficiency within the thyroid. Given that T3 and T4 require iodide for production, a decrease in intra-thyroidal iodide can result in decreased production of these hormones. This could in turn result in increased TSH, the hormone that acts on the thyroid gland to stimulate iodide uptake to increase thyroid hormone production (Blount, Pirkle, Osterloh, Valentin-Blasini, & Caldwell, 2006; National Research Council (NRC), 2005; Steinmaus, Miller, Cushing, Blount, & Smith, 2013; Steinmaus et al., 2016). For populations with developing brains (e.g., fetuses, neonates, and children), disruptions in homeostatic thyroid hormone function can result in adverse neurodevelopmental effects (Alexander et al., 2017; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; SAB for the U.S. EPA, 2013). Specifically, decreased maternal thyroid hormone levels during pregnancy, including in the hypothyroxinemic range2, have been linked to decrements in neurocognitive function in offspring (Alexander et al., 2017; Thompson et al., 2018; Wang et al., 2016). There is also limited evidence to suggest an association with other adverse neurodevelopmental outcomes including ADHD, expressive language delay, reduced school performance, autism, and delayed cognitive development (Alexander et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016, Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; van Mil et al., 2012).

The difficulty in estimating the likelihood and magnitude of the potential implications of perchlorate’s mode of action on expressed neurodevelopmental health effects in humans exposed to perchlorate during development is the lack of robust epidemiological studies, especially in sensitive populations. Therefore, based on the known mode of action of perchlorate the Agency estimated potential health risks using a novel approach suggested by the EPA’s Science Advisory Board (SAB for the U.S. EPA, 2013). The EPA’s approach to estimating perchlorate risks has evolved over time with improved research and modeling capabilities.

*Sensitive population for deriving MCLG*

The EPA is proposing an MCLG that is developed to protect the fetuses 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 an 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). The choice of this population is consistent with discussion by the NRC (2005), and the SAB (2013). The EPA believes that by protecting this population, the other sensitive populations (i.e., breast- and bottle-fed infants) will also be protected.

*Epidemiological Literature*

The SAB recommended that the EPA integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies. There is substantial epidemiological evidence that early pregnancy hypothyroxinemia is a risk factor for a variety of adverse neurodevelopmental outcomes, including those related to both cognition and behavior (Costeira et al., 2011; Finken, van Eijsden, Loomans, Vrijkotte, & Rotteveel, 2013; Ghassabian et al., 2014; Gyllenberg et al., 2016; Henrichs et al., 2010; Júlvez et al., 2013; Kooistra, Crawford, van Baar, Brouwers, & Pop, 2006; Korevaar et al., 2016; Y. Li et al., 2010; Oostenbroek et al., 2017; Päkkilä et al., 2015; Pop et al., 2003, 1999; Roman et al., 2013; van Mil et al., 2012). These individual studies showing that maternal hypothyroxinemia is associated with offspring neurodevelopment are also supported by three meta-analyses (including one full systematic review), all of which conclude maternal hypothyroxinemia is associated with increased risk of cognitive delay, intellectual impairment, or lower scores on performance tests when considering the entire body of evidence on this topic (Fan & Wu, 2016; Thompson et al., 2018; Wang et al., 2016). Additionally, the American Thyroid Association concludes that “overall, available evidence appears to show an association between hypothyroxinemia and cognitive development of the offspring” (Alexander et al., 2017, p. 337).

The EPA did not conduct a full systematic review and weight of evidence evaluation between maternal thyroid hormones and neurodevelopmental outcomes given: 1) the body of scientific literature regarding this association, and 2) the SAB recommendation that the EPA “consider available data on potential adverse health effects (neurodevelopmental outcomes) due to thyroid hormone level perturbations regardless of the cause of those perturbations” (p. 25). Instead, the EPA conducted a “methodologic approach to reviewing the literature” to evaluate the body of literature on this topic. This approach assisted in extrapolating the relationship modeled by the BBDR model to neurodevelopmental outcomes by concentrating on studies that allowed for evaluation of incremental changes in fT4 as they relate to incremental changes in neurodevelopmental outcomes. More specifically, the EPA only used studies that had sufficient data to show a quantitative relationship between maternal fT4 and a neurodevelopmental outcome. The EPA acknowledges that by not giving any weight to the studies that did not show a quantitative relationship between fT4 and neurodevelopmental outcomes, the Agency may be overestimating the dose of perchlorate that may be associated with adverse neurodevelopmental outcomes. This is a health protective decision that adds to the margin of safety.

Ultimately, the EPA developed a dose-response function that estimates incremental changes in a neurodevelopmental endpoint based on a given change in thyroid hormone concentration (fT4), which could be linked to a given dose of perchlorate using the BBDR model.

*Identifying a Point of Departure for Developing the MCLG*

From the seven analyses presented in Table III-2 above, the EPA chose to use its independent analysis of the Korevaar et al., (2016) data (comprising of 3,600 useable mother/child data pairs) as the basis for calculating the point of departure (POD) for the MCLG. There are three reasons for this selection: 1) there is sufficient quantitative data to derive a health impact function for the sensitive population of interest; 2) the analysis adjusts for an appropriate set of confounders, and 3) the neurodevelopmental endpoint – intelligence quotient (IQ) – is more straightforward to interpret because there is more national and cross-national data available (more on the selection of this endpoint below). The other studies presented in Table III-2 do not provide one or more of these features (USEPA, 2018b).

There are a variety of neurodevelopmental endpoints used to examine behavior and cognition in children (e.g., intelligence quotient (IQ), motor skills, vocabulary and language development, stimulus responsiveness, etc.). The EPA selected IQ decrements because this was the endpoint evaluated in the Korevaar et al., (2016) study. The EPA determined that the Korevaar study was the most rigorous analysis that examined the relationship between decreased thyroid hormones and neurodevelopmental effects. As such, in the derivation of the MCLG, IQ is a surrogate for a suite of potential neurodevelopmental effects that might occur to the offspring of hypothyroxinemic and iodine deficient mothers.

For the specific context of setting an MCLG for perchlorate, 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). The EPA selected IQ as a surrogate for neurodevelopmental effects based upon its evaluation of the epidemiologic literature describe above. The need to utilize the best available peer reviewed data to inform scientific assumptions and policy choices to meet the statutory requirements associated with developing an MCLG under the SDWA highlights the challenges associated with regulating chemicals for which potential effects are indirect, and scientific data do not address all uncertainties. The Agency must make a policy decision informed by science, consistent with statutory requirements even in situations where the data do not provide clear choices. To develop the proposed MCLG for perchlorate, the EPA made a policy decision to use a 2 IQ point decrement in the population-distribution of IQ for the sensitive population. By selecting this approach, the EPA is not establishing a precedent for future Agency actions on other contaminants for which there is concern about potential thyroid effects, either under the SDWA or other statutory frameworks.

**MAXIMUM CONTAMINANT LEVEL AND ALTERNATIVES**

The EPA determined that setting an MCL equal to the proposed MCLG of 56 μg/L is feasible given that the approved analytical method for perchlorate for UCMR 1 has a minimum reporting level (MRL) of 4 μg/L (USEPA 1999, 2000c) and that available treatment technologies can treat to concentrations well below 56 μg/L (USEPA, 2018c). Therefore, the EPA is proposing to set the MCL for perchlorate at 56 μg/L.

Because the EPA is taking comment on alternative MCLG values of 18 μg/L and 90 μg/L the Agency evaluated the feasibility of setting an MCL at these levels. The EPA determined that the proposed MCL of 56 μg/L is feasible, therefore a higher MCL alternative such as 90 μg/L is also feasible. The EPA has concluded that analytical methods are capable of measuring perchlorate at 18 μg/L and that treatment technologies have been demonstrated to achieve this level under field conditions (USEPA 2018a, 2019b). Therefore, the EPA is requesting comment on the feasibility of the proposed MCL of 56 μg/L as well as the feasibility of the alternative MCLs of 18 μg/L and 90 μg/L.

**OCCURRENCE**

The UCMR 1 is the primary source of occurrence data the EPA relied on to estimate the number of water systems (and associated population) expected to be exposed at levels of perchlorate which could potentially exceed the proposed and alternative MCL levels.

In summary, the perchlorate occurrence information suggests that at an MCL of 56 μg/L, two systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. One of these two systems would exceed the alternative MCL of 90 μg/L. In addition, at an MCL of 18 μg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold.

**MONITORING AND COMPLIANCE REQUIREMENTS**

The EPA is proposing to require CWS and NTNCWSs to monitor for perchlorate in accordance with the standardized monitoring framework set out in 40 CFR 141 Subpart C (Standardized Monitoring Framework). Public water systems must sample entry points to the distribution system consistent with requirements in 40 CFR 141.23(a).

The EPA is proposing that consistent with the standardized monitoring framework water systems would be initially required to monitor quarterly for perchlorate. The EPA is also proposing that based upon the monitoring results States would be able to reduce the monitoring frequency to annually, once every three years or once every nine years if the State concludes that the system is reliably and consistently below the MCL. If a water system exceeds the perchlorate MCL, the system is in violation and triggered into quarterly monitoring for that sampling point in the next quarter after the violation occurred (40 CFR 141.23(c)(7)). The state may allow the system to return to the reduced monitoring frequency when the state determines that the system is reliably and consistently below the MCL. However, the state cannot make a determination that the system is reliably and consistently below the MCL until a minimum of 2 consecutive ground water or 4 consecutive surface water samples below the MCL have been collected (40 CFR 141.23(c)(8)). All systems must comply with the sampling requirements, unless a waiver has been granted in writing by the state (40 CFR 141.23(c)(6)).

*When must systems complete initial monitoring?*

Pursuant to Section 1412(b)(10), this rule would be effective three years after promulgation. To satisfy initial monitoring requirements, CWS serving populations greater than 10,000 persons must collect 4 quarterly samples for perchlorate during the second compliance period of the fourth compliance cycle (January 1, 2023– December 31, 2025) of the Standardized Monitoring Framework.

**TREATMENT TECHNOLOGIES**

The Agency solicits public comment on the choice of available treatment technologies discussed in this section.

The Agency identifies the best available technologies (BAT) as those meeting the following criteria: (1) the capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large and metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all of the water in a system into compliance. The Agency is proposing the following technologies as BAT for removal of perchlorate from drinking water based its review of the treatment and cost literature (USEPA, 2018a):

* ion exchange;
* biological treatment; and
* centralized reverse osmosis.

There are also non-treatment options that might be used for compliance in lieu of installing and operating treatment technologies. These include blending existing water sources, replacing a perchlorate-contaminated source of drinking water with a new source (e.g., a new well), and purchasing compliant water from another system. Below are brief descriptions of each proposed BAT.

**HEALTH RISK REDUCTION COST ANALYSIS**

*Method for estimating costs*

The EPA estimated costs for CWS and NTNCWS to monitor and report perchlorate levels and also estimated the costs for a subset of public water systems with perchlorate levels greater than the proposed MCL to install and operate treatment. The EPA assumed that affected water systems would adopt ion exchange treatment because it is the most cost-effective treatment option and easy to operate on a ‘throw-away’ basis.

The EPA estimated initial costs for all CWS and NTNCWS operators to read and understand the rule and provide training to their staff to implement the proposed rule. The EPA also estimated the recurring costs for all CWS and NTNCWS operators to conduct monitoring, report results, and apply for waivers. For the purpose of these estimates, the EPA assumed that both small and large systems would require the same amount of time to read the rule, apply for a waiver, and collect a water sample but that it would take large systems twice as long to provide initial training to their staff.

Systems will incur monitoring costs over the analysis period. The EPA estimated monitoring frequency based on the proposed initial monitoring requirements, the standard monitoring framework requirements for inorganic contaminants, and the proposed implementation schedule.

To estimate costs to CWSs and NTNCWSs associated with time spent on compliance monitoring and other administrative costs, the EPA generally uses the labor rate13 for full-time treatment plant operators in CWSs from USEPA (2011c), which vary based on the size of the system. The EPA calculated a weighted average fully loaded hourly wage rate for water systems of $34.71.

Additionally, the EPA assumed that systems will incur an average analytical cost of $64 per sample, which is the average cost per sample obtained from multiple laboratories for perchlorate quantitation using Method 314.0.

To estimate treatment cost, the EPA utilized the occurrence data described in Section VI to estimate the number of system entry points that exceed the proposed and alternative MCLs. The EPA estimated costs that those water systems would incur to install and maintain treatment using its work breakdown structure (WBS) cost estimating models. The EPA used the WBS models to generate total capital and O&M cost estimates for each technology and nontreatment option for up to 49 different system flow rates. The EPA generated separate estimates that correspond to different water sources (groundwater or surface water), three different cost levels (low, mid, and high), and different technology-specific scenarios (e.g., 105,000 or 170,000 bed volumes for ion exchange). The EPA used the mid-cost estimates for ion exchange to generate expected costs for all entry points requiring perchlorate removal. This technology cost-effectively removes perchlorate, but its ability to remove co-occurring contaminants depends on influent characteristics and process design. Therefore, the EPA did not assume that treatment might result in ancillary quantifiable or non-quantifiable benefits of removing co-occurring ions such as nitrate. Treatment costs include waste disposal for spent resin, but do not include post-treatment costs for corrosion control because blending rates at most entry points should not result in much chloride addition or changes in corrosivity.

For purposes of estimating the costs and benefits, the EPA assumed that CWSs and NTNCWSs in California and Massachusetts would not incur additional cost or realize benefits because these States currently regulate perchlorate at a more stringent level than the proposed MCL and alternative MCL.

Water systems typically recover costs through increased household rates, resulting in increased costs at the household level15. To calculate the magnitude of the cost increase for systems that exceed the proposed MCL or alternative MCL, the EPA first estimated the number of households that may incur costs as a result of the rule based on the population served by affected CWSs and NTNCWSs and the average household size (U.S. Census Bureau, 2017b). The EPA divided the total annual system-level costs by the number of households served by the system.

*Method for estimating benefits*

Currently available science has limited this quantitative benefits assessment to the relationship between perchlorate and IQ. Given that alterations in thyroid hormones have been associated with other adverse outcomes, including reproductive outcomes (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and effects on cardiovascular systems (Asvold et al., 2012; Sun et al., 2017) there are likely non- quantified benefits of risk reductions for other endpoints or reduced exposure to co-occurring contaminants, which are addressed below.

The population impacted by the rule for which benefits can be quantified is specific to live births from mothers who were served by a CWS or NTNCWS with perchlorate concentrations above the potential MCLs. To determine the nationwide population of children that will experience a quantifiable benefit of avoided IQ decrements from reducing maternal perchlorate exposure during pregnancy, the EPA first estimated the total population being served by systems above the MCL based on data from UCMR 1. The EPA then multiplied the total population served for each affected CWS and NTNCWS by the proportion of women of childbearing age (aged 15-44) in the US, which is 19.7 percent (U.S. Census Bureau, 2017a). The number of women of child-bearing age for each entry point was then multiplied by the annual number of live births in the US, or 62 births per 1,000 women (6.2 percent) (Martin, Hamilton, & Osterman, 2017).

Other potential benefits not quantified or monetized include additional avoided health effects which cannot currently be monetized, improved public perception of water quality, as well as a possible reduction of other co-occurring contaminants that target the thyroid, such as nitrate, as a result of water treatment for removal of perchlorate. For example, all of the treatment technologies evaluated for this rule (ion exchange, biological treatment, and reverse osmosis) can also remove co-occurring nitrate from drinking water. Section XIII provides additional discussion of uncertainties in this analysis.

*Comparison of Costs and Benefits*

Table XII-14 provides a comparison of benefits and costs for three MCL values. First, the table shows the total annual costs and total annual benefits for each MCL. In all cases, the total costs are substantially higher than the potential range of quantifiable benefits. The table also shows the incremental impact on costs and benefits between an MCL of 56 μg/L and an MCL of 18 μg/L and between an MCL of 90 μg/L and 56 μg/L.

Section 1412(b)(4)(C) of the SDWA requires that when proposing a national primary drinking water regulation, “the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs.” The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the States. Based on a comparison of costs and benefits estimated at the proposed MCL of 56 μg/L using the best available science and data, the EPA Administrator has determined based upon the available information that the benefits of establishing an NPDWR for perchlorate do not justify the associated costs.

Under these circumstances, Section 1412(b)(6)(A) of the SDWA provides, with exceptions not relevant here, that “the Administrator *may*, after notice and opportunity for public comment promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits.” The EPA has evaluated the benefits and costs of alternative MCL values of 18 μg/L and 90 μg/L. However, based upon the available information the Administrator also finds that the benefits of an NPDWR at the alternative MCL values would not justify the resulting rule costs. The alternative MCLs would not increase net benefits, while compliance costs associated mainly with nationwide CWS monitoring requirements would remain relatively similar. Consistent with the discretion afforded the Agency by SDWA Section 1412(b)(6)(A) to decide whether or not to adjust an MCL to a level where the benefits justify the costs, the EPA is however proposing, and may finalize, the MCL of 56 μg/L notwithstanding the Agency’s determination that benefits would not justify the costs.

**REQUEST FOR COMMENT ON PROPOSED RULE**

* The proposed MCLG and MCL of 56 μg/L as well as the alternative MCLG and MCL values of 18 μg/L and of 90 μg/L.
* The feasibility of the proposed MCL of 56 μg/L as well as the feasibility of the alternative MCLs of 18 μg/L and 90 μg/L.
* The costs and availability of Treatment Technologies (Section X).
* The adequacy of the underlying estimates, assumptions and analysis used to estimate costs and describe unquantified costs including the estimates of monitoring frequency, likelihood of systems receiving a monitoring waiver, the administrative labor rate and the operator labor rate. (Section XII and the Health Risk Reduction Cost Analysis).
* Potential implementation challenges associated with the proposed perchlorate regulation that the EPA should consider, specifically for small systems.
* The Administrator’s finding in accordance with Section 1412(b)(4)(C) of the SDWA that the benefits of the proposed 56 μg/L MCL for perchlorate do not justify the costs, and the information that supports that determination as described in Section XII of this notice.
* The Administrator’s proposal to, consistent with the discretion afforded him by SDWA Section 1412(b)(6)(A), adopt an MCL of 56 μg/L notwithstanding the Agency’s SDWA Section 1412(b)(4)(C) determination that the benefits of the MCL would not justify its costs.
* The Agency’s conclusion that no alternative MCL, including the alternative MCL values of 18 μg/L and 90 μg/L discussed above, would “maximize health risk reduction benefits at a cost that is justified by the benefits” and the information and analytical approaches used to arrive at that conclusion. The EPA is especially interested in comments suggesting other approaches to deriving an MCL for which the benefits justify the costs.

**REQUEST FOR COMMENT ON POTENTIAL REGULATORY DETERMINATION WITHDRAWAL**

First, the findings, described in the occurrence section (section VI) and in the updated health effects assessment (Section III), suggest that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and suggest that the regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems.

Specifically, perchlorate occurrence information suggests that at an MCL of 56 μg/L only 2 systems (0.004% of all water systems in the U.S.) would exceed the regulatory threshold. Even at an MCL of 18 μg/L, there would only be 15 systems (0.03% of all water systems in the U.S.) that would exceed the regulatory threshold. Only one system would exceed the alternative MCL of 90 μg/L.

SDWA Section 1412(b)(1)(A)(iii) states that the determination regarding the meaningful opportunity is “in the sole judgement of the Administrator” and therefore there may be other factors that contribute to this determination for any given contaminant.

If, after consideration of public comment, the EPA withdraws the perchlorate regulatory determination, there will be no NPDWR for perchlorate, although the EPA can re-list perchlorate on the CCL and proceed to regulation in the future if the occurrence or risk information changes.