This document is scheduled to be published in the
Federal Register on 06/26/2019 and available online at
**https://federalregister.gov/d/2019-12773**, and on **govinfo.gov**

**6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 141, and 142**

**[EPA-HQ-OW-2018-0780; FRL-9994-68-OW]**

**RIN 2040-AF28**

# National Primary Drinking Water Regulations: Perchlorate

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule, request for public comment.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing a drinking water regulation for perchlorate and a health-based Maximum Contaminant Level Goal (MCLG) in accordance with the Safe Drinking Water Act (SDWA). 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). The EPA is proposing requirements for water systems to conduct monitoring and reporting for perchlorate and to provide information about perchlorate to their consumers through public notification and consumer confidence reports. This proposal includes requirements for primacy agencies that implement the public water system supervision program under the SDWA. This proposal also includes a list of treatment technologies that would enable water systems to comply with the MCL, including affordable compliance technologies for small systems serving 10,000 persons or less.

**DATES**: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].** Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

**ADDRESSES**: Submit your comments, identified by Docket ID No. **EPA-HQ-OW-2018-0780**, at https://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

**FOR FURTHER INFORMATION CONTACT**: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M),

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**SUPPLEMENTARY INFORMATION**: 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. This proposed rule is organized as follows:

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## I. General Information

### *A. What is the EPA Proposing?*

This action contains a proposal and three alternatives for public comment. First, the EPA proposes to establish a Maximum Contaminant Level Goal (MCLG) and National Primary Drinking Water Regulation (NPDWR) for perchlorate in public water supplies. The EPA proposes an MCLG of 56 µg/L, and to regulate perchlorate in drinking water at an enforceable maximum contaminant level (MCL) of 56 µg/L.

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.

Second, as explained in more detail below, the EPA is soliciting comment on two alternative MCLG/MCL values of 18 µg/L and 90 µg/L respectively. 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. Under this alternative, there would be no MCLG or NPDWR for perchlorate.

*B. Does This Action Apply to Me?*

Entities that could potentially be affected include the following:

| **Category** | **Examples of potentially affected entities** |
|---|---|
| Public water systems | Community water systems<br>Non-transient, non-community water systems |
| State and tribal agencies | Agencies responsible for drinking water regulatory development and enforcement |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could be affected by this action. To determine whether your facility or activities could be affected by this action, you should carefully examine this proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the FOR FURTHER INFORMATION CONTACT section.

## II. Background

*A. What is Perchlorate?*

Perchlorate is a negatively charged inorganic ion that is comprised of one chlorine atom bound to four oxygen atoms ($ClO_4$-), which is highly stable and mobile in the aqueous environment. Perchlorate comes from both natural and manmade sources. It is formed naturally via atmospheric processes and can be found within mineral deposits in certain geographical areas. It is also produced in the United States, and the most common compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water.

*B. Statutory Authority*

Section 1412(b)(1)(A) of the SDWA requires the EPA to establish NPDWRs for contaminants that may have an adverse effect on the health of persons; that are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and where in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

*C. Statutory Framework and Regulatory History*

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish every five years a Contaminant Candidate List (CCL). The CCL is a list of drinking water contaminants that are

known or anticipated to occur in public water systems and are not currently subject to the EPA drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. Contaminants listed on the CCL may require future regulation under the SDWA. The EPA included perchlorate on the first, second, and third CCLs published in 1998, 2005, and 2009.

Once listed on the CCL, the Agency continues to collect data on CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in drinking water. Section 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after public comment, issue a determination whether or not to regulate at least five contaminants on the CCL. For any contaminant that the EPA determines meets the criteria for regulation, under Section 1412(b)(1)(E), the EPA must issue a proposed national primary drinking water regulation within two years and issue a final regulation 18 months after the proposal (which may be extended by 9 months).

As part of its responsibilities under the SDWA, the EPA implements section 1445(a)(2), "Monitoring Program for Unregulated Contaminants." This section requires that once every five years, the EPA issue a list of no more than 30 unregulated contaminants to be monitored by public water system. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems (CWS) and non-transient, non-community water systems (NTNCWS). The UCMR collects data from a census of large water systems (serving more than 10,000 people) and from a statistically representative

sample of small water systems. On September 17, 1999, the EPA published its first UCMR (64 FR 50556) which required all large systems and a representative sample of small systems to monitor for perchlorate and 25 other contaminants (USEPA, 1999, 2000b).

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure inhibits the transport of iodide[1] into the thyroid by a protein molecule knows as the sodium/iodide symporter (NIS), which may lead to decreases in two hormones, thyroxine (T3) and triiodothyronine (T4) and increases in thyroid-stimulating hormone (TSH) (National Research Council (NRC), 2005b). Additionally, the NRC concluded that the most sensitive population to perchlorate exposure are "the fetuses of pregnant women who might have hypothyroidism or iodide deficiency" (p. 178). The EPA established a reference dose (RfD) consistent with the recommended National Research Council RfD of 0.7 µg/kg/day for perchlorate. The reference dose is an estimate of a daily exposure to humans that is likely to be without an appreciable risk of adverse effects. This RfD was based on a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability (USEPA, 2005b).

[1] For the purposes of this FRN, "iodine" will be used to refer to dietary intake before entering the body. Once in the body, "iodide" will be used to refer to the ionic form.

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262). In that preliminary determination, the EPA tentatively concluded that perchlorate did not occur with a frequency and at levels of public health concern and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA derived and used a Health Reference Level (HRL) of 15 µg/L based on the RfD of 0.7 µg/kg/day in making this conclusion (USEPA, 2008a). Based primarily on the UCMR 1 occurrence data, the EPA estimated that less than 1% of drinking water systems (serving approximately 1 million people) had perchlorate levels above the HRL of 15 µg/L. Based on this information the Agency determined that perchlorate did not occur frequently at levels of health concern. The EPA also determined that there was not a meaningful opportunity for a NPDWR to reduce health risks.

In January 2009 the EPA published an interim health advisory for perchlorate of 15 µg/L, consistent with the HRL derivation for perchlorate of 15 µg/L described above. Health Advisories are non-enforceable and non-regulatory and provide technical information to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. Health Advisories provide the public, including the most sensitive populations, with a margin of protection from a lifetime of exposure. For perchlorate, the health advisory was developed for subchronic exposure (USEPA 2008d).

In August 2009, the EPA published a supplemental request for comment with a new analysis that derived potential alternative HRLs for 14 life stages, including infants and children. The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information (74 FR 41883; USEPA, 2009a). After careful consideration of public comments on the October 2008 and August 2009 notices, on February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011a). The Agency stated then that when considering the alternative HRL benchmarks described in the 2009 notice, the likelihood of perchlorate to occur at levels of concern had significantly increased in comparison to the levels described on the 2008 preliminary negative determination. The EPA concluded that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally described in the 2008 notice.

In its 2011 determination, the Agency found that perchlorate may have an adverse effect on the health of persons, that it is known to occur in public drinking water systems with a frequency and at levels that present a public health concern, and in the judgment of the Administrator, regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. As a result of the determination, and as required by Section 1412(b)(1)(E), the EPA initiated the process to develop an MCLG and NPDWR for perchlorate as described in this notice.

In September 2012, the U.S. Chamber of Commerce (the Chamber) submitted to the EPA a Request for Correction under the Information Quality Act regarding the EPA's regulatory

determination. In the request, the Chamber claimed that the UCMR 1 data did not comply with data quality guidelines and were not representative of current conditions. In response to this request, the EPA reassessed the data and removed certain source water samples that could be paired with appropriate follow-up samples located at the entry point to the distribution system. The EPA also updated the UCMR 1 data for systems in California and Massachusetts using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented.

In response to a lawsuit brought to enforce the deadlines in Section 1412(b)(1)(E), the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water no later than October 31, 2018, and finalize an NPDWR and MCLG for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose an NPDWR with a proposed MCLG for perchlorate in drinking water was later extended to May 28, 2019. The consent decree is available in the docket for today's proposed rule.

**III. Assessment and Modeling of the Health Effects of Perchlorate**

Perchlorate inhibits uptake of iodide into the thyroid gland by competitively binding to the NIS (ATSDR, 2008; Greer et al., 2002; NRC, 2005; SAB 2013; Taylor et al., 2013). Iodide is necessary for the synthesis of thyroid hormones and decreased iodide uptake into the thyroid can adversely affect thyroid hormone production (SAB for the U.S. EPA, 2013; Blount et al., 2006; Steinmaus et al., 2007, 2013, 2016, McMullen et al., 2017; Knight et al., 2018). These changes in

thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring (SAB for the U.S. EPA, 2013; Korevaar et al., 2016; Fan and Wu, 2016; Wang et al., 2016; Alexander et al., 2017; Thompson et al., 2018). In addition, alterations in thyroid homeostasis may impact other body systems including the reproductive (Alexander et al., 2017; Hou et al., 2016; Maraka et al., 2016) and cardiovascular systems (Asvold et al., 2012; Sun et al., 2017).

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 range[2], 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. The following sections describe information sources the EPA used in its assessment as well as the regulatory process followed by the Agency in its decision making.

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[2] Maternal hypothyroxinemia is defined as TSH in the reference range and fT4 in the lower percentiles. The SAB notes that hypothyroxinemia has been defined by a "variety of cutoffs…ranging from fT4 below the 10$^{th}$ or 5$^{th}$ percentiles to below the 2.5$^{th}$ percentile" (SAB, 2013, p.10) in the population.

*A. 2008 Preliminary Regulatory Determinations*

In 2005, at the request of the EPA and other federal agencies, the NRC evaluated the health implications of perchlorate ingestion. The NRC concluded that perchlorate exposure could inhibit the transport of iodide into the thyroid, leading to thyroid hormone deficiency (NRC, 2005). A significant inhibition of iodide uptake results in intra-thyroid iodide deficiency, decreased synthesis of T3 and T4, and increased TSH. The NRC also concluded that a prolonged decrease of thyroid hormones is potentially more likely to have adverse effects in sensitive populations (e.g., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency). Based on these findings, the NRC recommended a reference dose of 0.7 µg/kg/day.

Based on NRC's analysis, the EPA established a perchlorate reference dose (RfD) of 0.7 µg/kg/day in 2005 (USEPA, 2005). This value was based on a no observed effect level (NOEL) of 7 µg/kg/day identified from a study (Greer, Goodman, Pleus, & Greer, 2002) of perchlorate's inhibition of radioactive iodine uptake in healthy adults and the application of an uncertainty factor of 10 for intraspecies variability.

As discussed above, in 2008, the EPA derived an HRL of 15 µg/L using the RfD of 0.7 µg/kg/day, a default bodyweight of 70 kg, a default drinking water consumption rate of 2 L/day, and a perchlorate-specific relative source contribution (RSC) of 62 percent that was derived for a pregnant woman (USEPA, 2008a) (73 FR 60262). The RSC is the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate (i.e., food) have been considered. The EPA's HRL was calculated to offer a margin of protection against adverse

health effects to the subpopulation identified by the NAS as likely the most sensitive to the effects of perchlorate exposure, fetuses.

*B. 2009 Supplemental Request for Comment and 2011 Final Regulatory Determination*

The EPA received over 33,000 comments in response to its 2008 preliminary determination to not regulate perchlorate (USEPA, 2011a). After reviewing the comments, the EPA developed alternative HRLs for other sensitive populations in addition to fetuses of pregnant women. The EPA developed alternative HRLs for 14 life stages including infants and children. The EPA also evaluated the occurrence of perchlorate at levels above these alternative HRLs using the UCMR 1 occurrence data.

The analysis used the RfD of 0.7 µg/kg/day and life stage-specific bodyweight and exposure information (i.e., drinking water intake, RSC) for each of the 14 life stages evaluated. The resulting HRLs ranged from 1 µg/L to 47 µg/L. In August 2009, the EPA published a supplemental request for comment with the new analysis and HRLs (74 FR 41883; USEPA, 2009a). After careful consideration of public comments, on February 11, 2011, the EPA published its final determination to regulate perchlorate (76 FR 7762; USEPA, 2011a).

*C. Science Advisory Board Recommendations*

As required by Section 1412(d) of the SDWA, as part of the NPDWR development process, the EPA requested comments from the Science Advisory Board (SAB) in 2012, seeking guidance on how best to consider and interpret the life stage information, the epidemiologic and biomonitoring data since the NRC report, physiologically-based pharmacokinetic (PBPK)

analyses, and the totality of perchlorate health information to derive an MCLG for perchlorate. The SAB recommended the following:

- derive a perchlorate MCLG that addresses sensitive life stages through physiologically based pharmacokinetic/pharmacodynamic (PBPK/PD) modeling based upon perchlorate's mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters;
- expand the modeling approach to account for thyroid hormone perturbations and potential adverse neurodevelopmental outcomes from perchlorate exposure;
- utilize a mode-of-action 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 to neurodevelopmental impacts; and
- "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" (SAB for the U.S. EPA, 2013, p. 19).

This SAB-proposed framework would incorporate the previous endpoint of iodide uptake inhibition that was the basis for the RfD as part of a broader and more comprehensive framework that links perchlorate exposure to adverse neurodevelopmental outcomes. It also focuses on the smaller changes in thyroid hormones (specifically free T4 (fT4)) that are associated with

maternal hypothyroxinemia and subsequent adverse neurodevelopmental health effects rather than the significant changes in thyroid hormones (both fT4 and TSH) that are associated with hypothyroidism.

*D. Perchlorate Model Development and Peer Reviews*

To address the SAB recommendations, the EPA revised an existing PBPK/PD model that describes the dynamics of perchlorate, iodide, and thyroid hormones in a woman during the third trimester of pregnancy (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b). The EPA also created its own Biologically Based Dose Response (BBDR) models that included the additional sensitive life stages identified by the SAB, i.e., breast- and bottle-fed neonates and infants (SAB for the U.S. EPA, 2013, p. 19).

To determine whether the Agency had implemented the SAB recommendations for modeling thyroid hormone changes, the EPA convened an independent peer review panel to evaluate the BBDR models in January 2017 (External Peer Reviewers for USEPA, 2017). In addition to estimating effects on breast fed infants, several reviewers recommended that the EPA shift the primary focus of its analysis to modeling the exposure implications to the fetus during early pregnancy. This was based on the knowledge that fetuses lack a functioning thyroid gland until approximately 16 gestational weeks and the substantial epidemiological evidence linking early pregnancy low fT4 levels with adverse neurodevelopmental outcomes (Endendijk et al., 2017, Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004, Pop et al., 1999; Pop et al., 2003). Specifically, the SAB recommended that the EPA use specific sensitive

populations to develop the MCLG for perchlorate: "the fetuses of hypothyroxinemic pregnant women, and infants exposed to perchlorate through either water-based formula preparations or the breast milk of lactating women" (SAB for the U.S. EPA, 2013, p. 19).

The EPA considered all recommendations from the 2017 peer review. The previously developed BBDR model describing perchlorate's effects in the third trimester (Lumen, Mattie, & Fisher, 2013; USEPA, 2009b) was calibrated only for that phase of pregnancy, not for the first trimester, and lacked a description of TSH signaling (feedback) that becomes significant as individuals become hypothyroxinemic or hypothyroid. In particular, this signaling was considered necessary to accurately predict responses of women with very low iodine intake, which was also part of the 2017 peer review recommendations. Therefore, the Lumen et al., (2009b) model needed to be revised to address these recommendations and the EPA implemented those changes needed to increase the scientific rigor of the model and modeling results. These modifications include:

- Extending the model to early pregnancy;
- Incorporating biological feedback control of hormone production via TSH signaling, such that the model can describe lower levels of iodide nutrition;
- Calibrating the model and evaluating its behavior for upper and lower percentiles of the population, as well as the population median; and
- Conducting an uncertainty analysis for key parameters.

The EPA convened a second independent peer review panel in January 2018 to evaluate these updates to the BBDR model. The EPA also presented several approaches in the draft *Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water* (MCLG Approaches Report) to link the thyroid hormone changes in a pregnant mother predicted by the BBDR model to neurodevelopmental effects using evidence from the epidemiological literature (External Peer Review for U.S. EPA, 2018). The 2018 peer review identified a variety of strengths and limitations of the modeling (to be discussed in more detail later in this notice). The peer review panel was largely supportive of the efforts described in the MCLG Approaches Report, as evidenced by the following from the peer review final report:

> *Overall, the panel 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 [in the peer-reviewed report], the current models are fit-for-purpose to determine an MCLG (External Peer Reviewers for U.S. EPA, 2018, p. 2).*

The EPA also presented an alternative, population-based approach evaluating the shift in the proportion of the population that would fall below a hypothyroxinemic cut point, given exposure to perchlorate (Section 7 of the MCLG Approaches Report). This

approach does not directly connect the BBDR output to a neurodevelopmental endpoint. However, for pregnant women in early pregnancy, this shift could be related to avoiding an increase in the population of offspring's risk of adverse neurodevelopmental impacts. The 2018 peer review identified strengths associated with this approach, including

> *1) the central premise, that hypothyroxinemia is associated with adverse neurodevelopmental effects is supported by a large number of studies, including categorical studies; 2) this approach encompasses a variety of adverse neurodevelopmental outcomes, as indicated by these studies, rather than focusing on one or a limited number of adverse outcomes, as with the two-stage approach; and 3) this approach avoids all of the uncertainties associated with determining a quantitative relationship between a specific maternal fT4 level and the magnitude an adverse neurodevelopmental effect.* (*External Peer Reviewers for U.S. EPA, 2018, p. 7)*

The peer reviewers expressed concern about hypothyroxinemia being a precursor effect, rather than an adverse health outcome, which they argued may create difficulties in explaining the basis for an MCLG based on this approach to some audiences. However, the EPA has used precursor effects as the basis for setting regulatory and non-regulatory limits previously. The peer-review panel also expressed concern that a standard definition of hypothyroxinemia has not yet been established, as clinicians use varying fT4 thresholds to define their own working

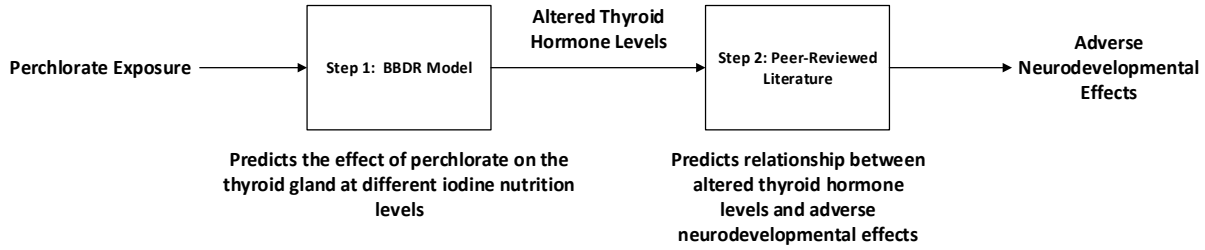
definition of the condition. This also could lead to difficulties communicating the population at risk for developing this precursor effect as a result of perchlorate exposure.

Ultimately, the EPA chose to develop the MCLG using dose-response functions from the epidemiological literature to estimate neurodevelopmental impacts in the offspring of pregnant women exposed to perchlorate. The EPA selected this proposed approach because it is consistent with the SDWA's definition of an MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. The EPA is requesting public comment in Section XIV on the adequacies and uncertainties of the methodology to derive the MCLG including the decision not to pursue this population-based approach for setting the MCLG.

Based on the comments of the peer reviewers, the EPA's final analysis informing the derivation of the MCLG and benefits of avoided perchlorate exposure is based upon a 2-step approach to modeling the neurodevelopmental effects on offspring of pregnant women exposed to perchlorate in drinking water (see Figure 1). In summary, because of the known mode of action, the lack of epidemiological studies particularly in the sensitive populations and the direction of the SAB to use a "data-driven approach [which] represents a more rigorous way to address differences in biology and exposure between adults and sensitive life stages" (p. 2, SAB 2013 for U.S. EPA), the EPA uses a combination of the BBDR model that simulates perchlorate potential impacts on maternal thyroid hormones during pregnancy and the epidemiology literature that relates incremental changes in maternal thyroid hormones to neurodevelopmental

outcomes in children. The following sections describe the approach in greater detail, highlighting each step in which decisions and assumptions were made.

**Figure 1. Two-Step Modeling Approach to Link Maternal Perchlorate Exposure to Measurable Adverse Neurodevelopmental Impacts in Offspring**




Note: Process figure does not imply the strength of scientific evidence.

*E. Sensitive Population for Deriving MCLG*

SDWA 1412(b)(4)(A) requires MCLGs to be set at a concentration in water "at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." SDWA 1412(b)(3)(C)(V) further requires that the EPA "consider the effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population." The EPA has interpreted these requirements to establish MCLGs that avoid adverse effects within the portions of the population that are at greater risk of adverse effects from exposure to the contaminant. 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. This conclusion is based on the EPA's analysis of predictions of the impact of perchlorate on fT4 levels from the original EPA BBDR model (which was peer reviewed in January of 2017) and an analysis of the literature on the connection between altered thyroid hormones in these life stages, and neurodevelopmental outcomes.

The EPA's original BBDR model demonstrated that perchlorate had minimal impact on the thyroid hormone levels for 30-, 60-, and 90-day formula-fed infants, even at doses as high as 20 µg/kg/day. Specifically, the model demonstrated that "the range of iodine levels in formula is sufficient to almost entirely offset the effects of perchlorate exposure at 30, 60 and 90 days" (USEPA, 2017; p. 73). As a result of these findings the EPA concluded that any MCLG based on the fetus of the first trimester hypothyroxinemic pregnant mother would also protect the formula-fed infant.

To determine if the same would be true for the breast-fed infant, the EPA compared the predicted percent change in fT4 experienced at given doses of perchlorate for both the breast-fed

infant and the first trimester pregnant mother at varying doses of iodine intake[3] (50 to 100 µg/day). Assuming 2 or 4 µg/kg/day of perchlorate, the first trimester hypothyroxinemic pregnant mother has a greater percent change in fT4 compared to the 30 and 60 day breast-fed infant at all maternal iodine intake levels evaluated, except for the 30 day breast-fed infant of a mother consuming only 50 µg/day iodine. However, given that the original BBDR model did not have a TSH feedback loop, T4, fT4, T3 and fT3 predictions for lactating mothers with less than 75 µg/day iodine intake were considered highly uncertain because the thyroid hormone levels had fallen into the hypothyroid range.

The Agency found that there are reports in the scientific literature suggesting that minor perturbations in thyroid hormone levels in the first trimester mother may adversely impact her offspring's neurodevelopment. Specifically, some studies show that children exposed gestationally to maternal hypothyroxinemia (without hypothyroidism) have a higher risk of reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Kooistra, Crawford, van Baar, Brouwers, & Pop, 2006; Man, Brown, & Serunian, 1991; Pop et al., 2003; Pop et al., 1999). Notably these effects are correlated with both degree (Henrichs et al., 2010; Pop et al., 1999) and duration (Pop et al., 2003) of maternal hypothyroxinemia (SAB for the U.S. EPA, 2013, p. 10).

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[3]Given that the current version of the BBDR model contains a TSH feedback loop and the infant models previously developed did not contain this feedback loop, this comparison is done with the feedback loop turned off.

The EPA did not find analogous evidence linking minor perturbations in thyroid hormones during infancy to adverse neurodevelopmental outcomes in infants. This finding is consistent with conclusions by the California Environmental Protection Agency (CalEPA) in their assessment of a public health goal for perchlorate (California Environmental Protection Agency, 2011, p. 90).

Specifically, two studies evaluated both the impact of maternal hypothyroxinemia and infant fT4 levels on subsequent neurodevelopmental outcomes. Costeira et al., (2011) found that children born to mothers with low fT4 in the first trimester had increased odds of mild-to-severe delays in psychomotor development compared to children born to mothers with normal fT4 levels. However, the authors found that neonatal thyroid status (measured on day 3 after birth) did not influence development. Additionally, Henrichs et al., (2010) found in their evaluation that although maternal hypothyroxinemia was associated with language delay and nonverbal cognitive delay, the neonatal thyroid status (thyroid hormones measured in cord blood) did not explain the relationship between maternal hypothyroxinemia, early pregnancy, and children's cognitive impairment.

The SAB pointed to two lines of evidence supporting their suggestion of the infant as a potentially sensitive population to perchlorate: preterm infants that experience transient hypothyroxinemia of prematurity (THOP) and infants that experience congenital hypothyroidism (SAB for the U.S. EPA, 2013). Thus, sufficient thyroid hormone levels in infancy are necessary for the infant brain to develop properly. However, the best evidence linking perturbations in

thyroid hormone levels to disrupted neurodevelopment for infants are in individuals with significant thyroid deficiencies manifesting as clinical conditions (e.g., THOP and congenital hypothyroidism). It is unclear and unknown if minor perturbations in thyroid hormones in infants, such as those that could be caused by environmental levels of perchlorate, would result in adverse neurodevelopmental outcomes similar to those seen in the literature for the offspring of first trimester pregnant mothers with hypothyroxinemia. Given the lack of evidence demonstrating minor perturbations in infant fT4 levels as being associated with neurodevelopmental outcomes, the EPA has concluded that it is appropriate to derive the perchlorate MCLG to protect the first trimester fetus of a pregnant mother with low-iodine intake. The EPA concludes that an MCLG calculated to offer a margin of protection against adverse health effects to these fetuses targets the most sensitive lifestage and will be protective of other potentially sensitive life stages as well.

*F. BBDR Model Specification for the Sensitive Population*

The BBDR model used to develop the proposed MCLG has two main components:

- A pharmacokinetic model for perchlorate and iodide, which describes chemical absorption, distribution, metabolism, and excretion of perchlorate and iodide; and
- A pharmacodynamic model, which describes the joint effect of varying perchlorate and iodide blood concentrations on thyroidal uptake of iodide and subsequent production of thyroid hormones, including fT4.

The pharmacokinetic model component contains a physiological description of a human mother and fetus during pregnancy (e.g., organ volumes, blood flows) and chemical-specific information (e.g., partition coefficients, volume of distribution, rate constants for transport, metabolism, and elimination) that enable a prediction of perchlorate and iodide internal concentration at the critical target (i.e., thyroidal sodium-iodide symporter of the mother) in association with a particular exposure scenario (route of exposure, age, dose level). This component of the model is similar to many other PBPK models. Because perchlorate does not undergo metabolism in vivo (Clewell et al., 2007), potential uncertainty from this factor of the model is avoided since it does not need to be described.

The pharmacodynamic component of the model uses this internal concentration to simulate how the chemical will act within a known mechanism of action to perturb host systems and lead to a toxic effect.

Thus, the BBDR model estimates serum thyroid hormone levels in the mother at specific gestational weeks, given specific levels of iodine intake, the TSH feedback loop strength, and perchlorate doses. As noted above, to be health protective the EPA chose to model a sensitive individual (an adult woman with low iodine through the first trimester of pregnancy) to derive an MCLG, thereby protecting both this target sensitive population with an adequate margin of safety and those who are less sensitive with an even larger margin of safety.

The BBDR model simulates perchlorate's impact on thyroid hormones at each gestational week from conception to week 16. To derive the MCLG, the EPA selected outputs for

gestational week 13 to correspond with the thyroid hormone data reported in Korevaar et al., (2016), which is the basis for the Agency's quantitative relationship between maternal thyroid hormone levels and neurodevelopmental impacts.

Individuals with low iodine intake have increased sensitivity to perchlorate's impact on thyroid hormone levels because the functional iodide reserve of the hypothalamic-pituitary-thyroid (HPT) system is limited ( Blount et al., 2006, Steinmaus et al., 2007; Leung, Pearce, & Braverman, 2010). The 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 15$^{th}$ and 20$^{th}$ percentile of the women of child bearing age population distribution of estimated iodine intake from the National Health and Nutrition Examination Survey (NHANES). The EPA considered using a lower iodine intake level of 50 µg/day, which represents approximately the 5$^{th}$ percentile of the NHANES distribution. At 50 µg/day of iodine intake, however, the BBDR model predicts TSH levels that would be elevated to within the clinically hypothyroid range before exposure to any perchlorate[4] (TSH ranges between 4.51 and 5.41 milli-international units per liter (mIU/L) at

[4] For the purposes of this analysis, the EPA evaluated the American Thyroid Association's (ATA's) 2017 recommendations for defining hypothyroidism (Alexander et al., 2017). Specifically the ATA recommends "in the pregnancy setting, maternal hypothyroidism is defined as a TSH concentration elevated beyond the upper limit of the pregnancy-specific reference range" (Alexander et al., 2017, p. 332). ATA goes on to state, in the absence of population- and trimester-specific reference ranges defined by a provider's institute or laboratory, that the TSH reference ranges should be obtained from similar patient populations. From their recommended studies with trimester-specific data on a U.S. population, Lambert-Meserlian et al. (2008) is the largest U.S.-based population with a reference range upper bound of 3.37 mIU/L for the first trimester (and 3.35 mIU/L for the second trimester). Therefore, these values were used to compare to BBDR output TSH values in the first trimester (or second trimester in cases of gestational weeks 15 and 16) to determine the presence of hypothyroidism.

zero dose of perchlorate when evaluating gestational weeks 12 or 13). In contrast, at 75 µg/day iodine, the BBDR modeled concentrations of serum fT4 and TSH are significantly reduced from the population median but are still within the euthyroid range. Thus, the intake of 75 µg/day is a better approximation of the sensitive population – the offspring of pregnant women who have low fT4.

TSH increases in response to decreases in T4 have been captured in numerous studies that document the relationship between these hormones (Blount et al., 2006; Steinmaus et al., 2013, 2016). The EPA designed the BBDR model to depict this feedback regulation by adjusting a set of three parameters: the number of sodium-iodide symporter sites, the T4 synthesis rate, and the T3 synthesis rate. The BBDR model allows for variability in the strength of the TSH feedback by varying these parameters with a variable called "pTSH." For the MCLG analysis, the EPA used a pTSH value of 0.398, which is the ratio of a median value for TSH from NHANES (non-pregnant women) to the 97.5 percentile value from NHANES (non-pregnant women). This value represents an assumption that sensitive individuals with high TSH and average fT4 levels exist, and this is because the stimulus strength of TSH is proportionally weaker. The EPA chose to use a low TSH feedback coefficient to ensure the MCLG is protective of the sensitive population.

Example output from the BBDR model for gestational week 13 and a low TSH feedback coefficient is presented in Table III-1.

**Table III-1. Summary of BBDR Model Results for fT4 Levels: Pregnant Women at Gestational Week 13, Assuming Low (75 µg/day) Iodine Intake and with Muted TSH feedback strength[a]**

| Perchlorate Dose (µg/kg/day) | Percentile fT4 (pmol/L)[b] (% decrease from 0 dose) | | | |
|---|---|---|---|---|
| | 2.5th | 5th | 10th | 50th |
| 0 | 5.57 | 6.09 | 6.70 | 8.84 |
| 1 | 5.50 (-1.26%) | 6.02 (-1.15%) | 6.63 (-1.04%) | 8.77 (-0.79%) |
| 2 | 5.43 (-2.45%) | 5.96 (-2.24%) | 6.56 (-2.04%) | 8.71 (-1.54%) |
| 3 | 5.37 (-3.59%) | 5.96 (-3.28%) | 6.50 (-2.98%) | 8.64 (-2.26%) |
| 4 | 5.31 (-4.68%) | 5.83 (-4.28%) | 6.44 (-3.89%) | 8.58 (-2.95%) |
| 5 | 5.25 (-5.73%) | 5.77 (-5.23%) | 6.38 (-4.76%) | 8.52 (-3.60%) |
| 6 | 5.19 (-6.73%) | 5.72 (-6.14%) | 6.33 (-5.59%) | 8.47 (-4.23%) |
| 7 | 5.14 (-7.69%) | 5.66 (-7.02%) | 6.27 (-6.39%) | 8.41 (-4.84%) |

[a] pTSH = 0.398; see USEPA, (2018b) for additional information on pTSH.
[b] The 50th percentile is direct output from the BBDR model, and additional percentiles are estimated by assuming a normal distribution with a SD of 1.67. All of the examined study data demonstrated a positive skew, and overall the lognormal function demonstrated a better fit than a normal distribution. Despite this, the available study data only accounted for variation due to gestation week and did not account for variation in perchlorate and iodine intake in the measured populations. Because perchlorate and iodine can affect fT4 levels, and this relationship produced the estimated median BBDR values, the distribution around values estimated by the model from perchlorate and iodine intake should account for a small reduction in variation due to the effect of perchlorate and iodine intake. Additionally, as iodine has a demonstrated lognormal distribution with strong right skew (e.g. Blount et al., 2007) and is predicted to have a stronger effect on fT4 than perchlorate (see Section 3). The EPA assumed the error around predicted fT4 would likely be closer to normal than lognormal after accounting for perchlorate and iodine intake.

When modeling changes in fT4, the baseline level of fT4 affects the magnitude of changes seen as a result of perchlorate exposure. Therefore, to predict the impact of perchlorate exposure on the population distribution of fT4 for the identified sensitive population, the EPA estimated a distribution for fT4 plasma concentrations around the median modeled values based on fT4 data from studies that were used to calibrate the BBDR model (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA assumed the variation around predicted fT4 concentrations for women with low fT4 of childbearing age would likely be close to normal after accounting for perchlorate and iodine intake, and thus estimated a combined standard deviation (SD) using the distributional information from each of the studies (C. Li et al., 2014; Männistö et al., 2011; Zhang et al., 2016). The EPA then used the estimated combined SD to predict a distribution of fT4 around the median fT4 estimated by the BBDR model. To protect the most sensitive population from adverse effects, the EPA chose to use the 10th percentile from this distribution of baseline fT4 to conduct its analyses to account for variability in thyroid hormones in the population[5].

*G. 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

[5] For a discussion on the details of the BBDR model, including uncertainties associated with the model the reader is directed to section 3.5 of the MCLG Approaches Report.

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.

The specifics of this "methodologic approach to reviewing the literature" follow. First, the EPA identified and screened the available 71 epidemiological studies, which potentially pertained to altered maternal thyroid hormone levels and offspring neurodevelopment to identify candidates based on the following criteria:

- Compatible with the sensitive life stages identified by the NRC and SAB;
- Continuous measure of thyroid hormone values (versus categorical values);
- Low risk of bias based on analysis using the National Toxicology Program's Office of Health Assessment and Translation (OHAT) Risk of Bias (ROB) tool score; and

- Access to underlying data.

Second, using these screening steps, the EPA categorized all 71 studies into three groups. One group consisted of studies that were not compatible[6] with extending the BBDR model (40 studies). Another group consisted of papers that were relevant to the pertinent life stages but did not have data from which a dose-response analysis could be conducted (15 studies). This includes studies that compared differences between groups, for example studies of offspring of mothers with hypothyroxinemia versus offspring of mothers without hypothyroxinemia. Consequently, these studies may have provided insight into the maternal thyroid hormone and offspring neurodevelopment relationship but did not have enough information to develop a continuous dose-response function. The last group of papers had data that may inform a dose-response function (16 studies). This last group of papers included publications that may have had categorical analyses but also presented data that assessed fT4 as a continuous variable and the outcome of interest. In most instances, the continuous fT4 variable encompassed the full range for fT4 and not just the hypothyroxinemic range. After excluding one paper due to a high risk of

[6] For example, if the study evaluated the impact of only neonatal thyroid hormones (i.e., at a potentially sensitive life stage), it cannot be used because the BBDR model is specific to early pregnancy. Further, if the study evaluates a population with an existing disease (i.e., hypothyroidism) that may have a different response to perchlorate compared to the euthyroid population, it was not considered compatible with BBDR model results. Additionally, if the study does not include information on T4 or fT4, it does not assist in understanding the implications of the BBDR modeling results. Another reason for exclusion at this stage include that the study does not have a population with an exposure window (i.e., when the thyroid hormone measurements are taken) that overlaps with the outputs for the BBDR model. Specifically, the study should evaluate thyroid hormone levels in pregnant mothers between conception and gestational week 16. The neurodevelopmental outcomes could be measured at any life stage.

bias (Kastakina et al., 2006) 15 papers remained that potentially had dose-response data between a continuous measure of fT4 and various neurodevelopmental outcomes describing cognition, behavior and other outcomes. The EPA notes that by selecting the papers that potentially had dose response data the Agency is deviating from the systematic weight of evidence review approach to identify those studies that the SAB recommended we examine to derive the MCLG.

Third, from these 15 papers five were selected for dose response assessment - four related to cognition (Finken et al., 2013; Korevaar et al., 2016; Pop et al., 2003, 1999) and one related to behavior (Endendijk, Wijnen, Pop, & van Baar, 2017). The other ten papers were excluded for a variety of reasons including updated analyses being presented in a different paper for which dose-response analysis was being conducted, lack of all the data needed to complete a dose-response assessment (e.g., dose-response results were presented as "per standard deviation of fT4" but the standard deviation needed to fully interpret the results for a continuous function was not presented in the paper, statistical methods presented in the paper were insufficient to allow for the derivation of a concentration response function ), or a lack of a relationship between maternal fT4 as a continuous variable and the outcome of interest evaluated in the paper. For example, Noten et al., (2015) found a relationship between maternal hypothyroxinemia and offspring arithmetic test performance. However, maternal fT4 as a continuous variable across the entire fT4 range was not associated with arithmetic test performance. Given this null finding, as well as the lack of published literature evaluating maternal fT4 as a continuous variable and

arithmetic test performance, it would be difficult for the Agency to justify setting an MCLG based on changes in this endpoint.

As laid out for the peer reviewers, for each study that met the criteria identified above for dose-response modeling, a relationship between maternal thyroid hormone levels (specifically fT4) and offspring neurodevelopment was derived (see USEPA, 2018b). These relationships were either presented in the original published paper or derived by the EPA through either the digitization of figures or through re-analysis of data provided by the study authors. The EPA used the upper effect estimate (the upper bound of the 95$^{th}$ percent confidence interval) from each study to assure consideration of the populations likely to be at greater risk from the dose of perchlorate associated with a given change in fT4.

Table III-2 provides a summary of the changes in fT4 predicted to produce a 1, 2, and 3 percent decrease in any given neurodevelopmental effect and corresponding perchlorate doses. The choice of 1, 2, and 3% is based on the analyses for IQ, Mental Development Index (MDI), and Psychomotor Development Index (PDI). Specifically, a 1%, 2%, or 3% change from the standardized mean for each test (i.e., 100 points) 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 (Endendijk et al., 2017; Finken et al., 2013).

These results provide the potential impacts of perchlorate on maternal fT4 (as predicted by the BBDR model) and subsequent neurodevelopmental impacts (derived from the epidemiologic literature[7]).

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

| Study | Endpoint | Dose-Response Function | β (95% CI) | ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a,b,c] | | | Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a,b,c] | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 1% | 2% | 3% | 1% | 2% | 3% |
| Korevaar et al., (2016) Quadratic | IQ | $\Delta IQ = (\beta_1 \times lnfT4_2 + \beta_2 \times ln(fT4_2)^2) - (\beta_1 \times lnfT4_1 + \beta_2 \times ln(fT4_1)^2)$ | β1 = 33.8 (9.8, 57.8) β2 = -6.2 (-10.6, -1.9) | -0.13 (1.9%) | -0.25 (3.8%) | -0.38 (5.7%) | 1.9 | 3.9 | 6.1 |
| Korevaar et al., (2016) EPA independent | 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 |

[7] For a more complete description of all the studies evaluated the reader is directed to Sections 5 and 6 of the MCLG Approaches Report. For a discussion on the uncertainties related to the approach the reader is directed specifically to section 6.5.

| Study | Endpoint | Dose-Response Function | β (95% CI) | ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a,b,c] | | | Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a,b,c] | | |
|---|---|---|---|---|---|---|---|---|---|
| analysis | | | | | | | | | |
| Pop et al., (2003) | MDI | $\Delta MDI = \beta \times \Delta fT4$ | 6.3 (1.92, 10.6) | -0.09 (1.0%) | -0.19 (2.8%) | -0.28 (4.2%) | 1.3 | 2.8 | 4.3 |
| Pop et al., (2003) | PDI | $\Delta PDI = \beta \times \Delta fT4$ | 8.4 (4.0, 12.8) | -0.08 (0.9%) | -0.16 (2.4%) | -0.23 (3.5%) | 1.1 | 2.3 | 3.5 |
| Pop et al., (1999) | PDI | $\Delta PDI = \beta \times \Delta fT4$ | 8.5 (0.01, 17.0) | -0.06 (0.6%) | -0.12 (1.8%) | -0.18 (2.6%) | 0.8 | 1.7 | 2.6 |
| Endendijk et al., (2017) | Anxiety/ depression score | $\Delta AD = \left(\frac{1}{\beta * fT4_2}\right) - \left(\frac{1}{\beta * fT4_1}\right)$ | 0.12 (0.11, 0.13) | -0.03 (0.45 %) | -0.08 (1.2%) | -0.12 (1.9%) | 0.4 | 1.1 | 1.8 |
| Finken et al., (2013) | SD of reaction time | ΔSD Reaction Time (ms) = β × Δ fT4 | -4.9 (-9.5, -0.2) | -0.28 (4.2%) | -0.57 (8.5%) | -0.85[d] (12.7 %) | 4.4 | 9.8 | 16.5[d] |

| Study | Endpoint | Dose-Response Function | β (95% CI) | ΔfT4 in pmol/L Associated with a 1% to 3% Decrease in Endpoint (% ΔfT4 from 0 dose perchlorate, iodine intake = 75 µg/day)[a,b,c] | Dose of Perchlorate per 1% to 3% Decrease in Endpoint (µg/kg/day)[a,b,c] |
|---|---|---|---|---|---|

[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.

### *H. 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).

The five identified papers evaluated a variety of endpoints with Korevaar et al., (2016) evaluating IQ, Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) using the Bayley Scale to evaluate PDI and MDI, Finken, van Eijsden, Loomans, Vrijkotte, and Rotteveel (2013) evaluating the SD of reaction time, and Endendijk, Wijnen, Pop, and van Baar (2017) evaluating anxiety/depression scores using the Child Behavioral Check List (CBCL). The SD of reaction time from Finken et al., (2013) was not well-received by the peer reviewers (External Peer Review for U.S. EPA, 2018) because it is difficult to ascertain the true implications of a change in the SD of reaction time. The Endendijk et al., (2017) study was identified after the peer review so no feedback was given on the appropriateness of the endpoint; however, the anxiety/depression raw score is not an intuitively interpretable endpoint. Further, neither the Endendijk et al., (2017) nor the Finken et al., (2013) analyses had functions for the sensitive life stage (i.e., their analyses were based on the full range of fT4 levels and did not concentrate on the impacts of low-end fT4 levels). For these reasons, the Endendijk et al., (2017) and Finken et al., (2013) papers were not selected for further evaluation.

The Korevaar et al., (2016) original and independent analyses are preferable compared to the Pop, Kuijpens, et al., (1999) and Pop, Brouwers, et al., (2003) studies because neither function derived from the Pop et al., studies was adjusted for confounders. Additionally, both

Pop et al., papers have an N < 50 compared to the Korevaar et al., analyses, which have an N of greater than 3,600.[8]

Although the original Korevaar et al., (2016) analysis was the most rigorous analysis available in the literature to date, the Korevaar et al., (2016) EPA reanalysis was chosen over the original analysis because it included modifications to the analysis at the suggestion of the peer review panel. The revised analysis controls for a more parsimonious set of confounders (e.g., previously included variables such as infant gender, maternal parity, birthweight, mother's body mass index (BMI), and gestational age at blood draw that are not related to both the exposure and the outcome were excluded), thus decreasing the chances of overfitting the estimation of the association between maternal fT4 and child IQ. The EPA was prompted to revisit the original Korevaar et al., (2016) model because of the feedback received during the peer review of the MCLG Approaches Report. Specifically, a member of the peer-review panel expressed the following suggestion:

> *Korevaar et al., [2016] controlled for instrumental variables (e.g. gestational week at fT4 measurement) as well as variables that are consequences of altered fT4 (e.g. maternal BMI), which may have biased estimates. This study also assumed a log-linear relation between fT4 and the outcome but it is unclear*

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[8] The original Korevaar et al. (2016) analysis included 3,839 mother/child pairs. The EPA reanalysis of the Korevaar et al. (2016) data had a slightly lower N of 3,609 due to the exclusion of subjects with imputed values for maternal fT4.

*whether the data fit this functional form better than a linear form. Reanalysis of the data performed by EPA should not include the variables noted above, which may have driven measures of association towards the null, and should investigate the most appropriate functional form to inform decisions about transformation of fT4 values* (External Peer Reviewers for U.S. EPA, 2018, pp. 61–62).

The EPA responded to this suggestion by developing a causal model for the effect of maternal fT4 on child IQ to identify the minimum set of confounding variables, testing the proper functional form of the relationship between maternal fT4 and child IQ in the Korevaar et al., (2016) data, and making decisions about data quality and influential data points in the analysis. That is, the EPA determined that there were values of the independent variable of interest, fT4, in the original analysis that were imputed using multiple imputations. This could have impacted the effect estimate of the independent variable of interest with data that were not directly measured. The EPA reanalysis excludes these non-measured values. Subsequently, the EPA selected the Korevaar et al., (2016) reanalysis as the most appropriate function from which to assess the relationship between fT4 and IQ [9].

As indicated above, the EPA has utilized a health protective approach to this analysis consistent with the SDWA definition of the MCLG. The peer reviewers commented that this approach was fit-for-purpose. In particular, the Agency assumed it could estimate risk reductions

[9] A more complete description of the EPA independent analysis of the Korevaar et al. (2016) data can be found in Section 6.3.2 of the MCLG Approaches Report.

based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes. The existence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes has strong support from the literature on the subject; however, not every study identified an association between maternal fT4 and the specified outcome of interest, and the state of the science on this relationship is constantly evolving. As explained earlier, the results of the EPA's dose-response literature review identified 31 studies that evaluated the association between maternal thyroid hormone levels and offspring neurodevelopment, with neurodevelopment defined using a variety of endpoints related to cognition, behavior, and other outcomes such as autism. Among these studies, only 16 were deemed to potentially possess information that could inform a dose-response relationship. The other 15 only presented data on categorical analyses assessing the impact of maternal hypothyroxinemia on the neurodevelopmental outcomes of interest. Therefore, because the data presented was only a comparison of two groups, there was not information that could be used to inform a dose-response function.

Of the 16 studies that potentially had data to inform a dose-response function, 10 evaluated cognition using a variety of tests including various IQ tests (three papers; Ghassabian et al., 2014; Korevaar et al., 2016; Moleti et al., 2016), Bayley Scales of Infant Development (two papers; Pop et al., 1999; Pop et al., 2003), and other validated tests associated with child cognition such as expressive language delay or test performance (five papers; Finken et al., 2013; Henrichs et al., 2010; Kastakina et al., 2006; Noten et al., 2015; Oken et al., 2009). Six of these

papers found a statistically significant relationship between maternal fT4, as a continuous variable, and offspring cognitive outcome (Korevaar et al., 2016; Pop et al., 1999; Pop et al., 2003; Finken et al., 2013; Henrichs et al., 2010, Kastakina et al., 2006). However, there were studies where maternal fT4 as a continuous variable was not significantly associated with the outcome of interest. For example, in Ghassabian et al., (2014) the authors found maternal hypothyroxinemia to be associated with an average of a 4.3-point reduction in IQ in their offspring compared to offspring of non-hypothyroxinemic mothers. Nevertheless, when assessing the relationship between the continuous measure of maternal fT4 as a continuous variable (across the entire range of fT4 levels) and child IQ, the authors did not find a significant relationship. Additionally, Moleti et al., (2016) found the relationship between maternal fT4 and child IQ to be consistently inversely associated with IQ scores, but their assessment failed to reach statistical significance. This study included fewer than 60 study participants and was considered by the authors to be a pilot assessment.

In addition to the cognitive effects assessed and modeled, the EPA identified four papers that assessed maternal fT4 status and behavioral outcomes (Endendijk et al., 2017; Ghassabian et al., 2011; Modesto et al., 2015; Oostenbroek et al., 2017), one paper that assessed maternal fT4 status and autism (Roman et al., 2013) and one paper that evaluated odds of a schizophrenia diagnosis as associated with maternal thyroid hormone status (Gyllenberg et al., 2016). From this group of papers, the majority of papers found an association either between maternal hypothyroxinemia or maternal fT4 as a continuous variable and the outcome of interest

(Endendijk et al., 2017; Modesto et al., 2015; Oostenbroek et al., 2017; Roman et al., 2013; Gyllenberg et al., 2016). However, this was not always the case as exemplified by Ghassabian et al., (2011) and Gyllenberg et al., (2016). Although Endendijk et al., (2017) found maternal fT4 to have a significant adverse impact on anxiety/depression using the Child Behavioral Check List (CBCL), Ghassabian et al., (2011) did not find any association between maternal thyroid hormone status and offspring score on various components of the CBCL. Additionally, Gyllenberg et al., (2016) found maternal hypothyroxinemia during early to mid-gestation was associated with 70% increased odds of schizophrenia diagnosis in offspring of hypothyroxinemic mothers compared to the offspring of non-hypothyroxinemic mothers. Gyllenberg et al., (2016) also found an association with odds of schizophrenia diagnosis using conditional logistic regression when assessing fT4 as a continuous variable across the entire fT4 range (i.e., not just the hypothyroxinemic range); however, this relationship was attenuated after controlling for smoking.

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 located in the EPA literature review, several meta-analyses (Fan & Wu, 2016; Thompson et al., 2018 and Wang et al., 2016), the American Thyroid Association (Alexander et al., 2017) and the U.S. EPA's SAB (2013) 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. In an attempt to minimize uncertainty, the EPA reanalyzed the data collected by Korevaar et al., (2016) using a spline function that estimates a coefficient specifically for the low range of the fT4 data.

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.

There are several different tests that are widely used to measure IQ in children, including the Stanford-Binet and the Wechsler Intelligence Scale for Children (WISC) (Sternberg et al., 2001). Each of these tests is intended to assess a child's global functioning and uses a numerical IQ point scale (Beres et al., 2000). IQ scores are standardized by age and sex group with a mean

score of 100 points and a standard deviation of 15 (Beres et al., 2000). Although the specific tasks differ by test, all IQ tests contain a number of tasks to assess diverse skills (Sternberg et al., 2001). For example, the WISC test evaluates full-scale IQ using a combination of verbal and performance scales (verbal IQ and performance IQ may also be assessed separately) (Beres et al., 2000). The verbal scale includes tasks such as arithmetic, vocabulary, and comprehension, while the performance scale includes tasks such as picture completion, block design, and object assembly (Beres et al., 2000). The WISC was standardized using a sample of 2200 U.S. children aged 6 to 16 years old (Seashore et al., 1950). It has been well validated and has demonstrated high reliability, with a reliability coefficient of 0.96 observed across age groups (Beres et al., 2000).

Associations have been found between IQ scores and both educational achievement and attainment, though observed correlations vary widely. In a review of the literature, Sternberg et al., (2001) suggest that IQ scores explain approximately 25% of the variance in academic achievement. Evidence also suggests that IQ is linked to career outcomes and job performance, with observed correlations ranging from approximately 0.2 to 0.6 (Sternberg et al., 2001). Research suggests that children's rearing environment, including parental education, while growing up may increase IQ scores in adolescence by several points (e.g., Kendler et al., 2015).

IQ scores have been used to help diagnose disorders such as intellectual disability and to identify children for placement into specialized learning programs (Beres et al., 2000). For example, in the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-V) IQ

scores are used in an individual's comprehensive assessment to determine intellectual disability, which pairs standardized testing of intelligence with a clinical assessment of adaptive functioning. Intellectual disability is considered for individuals with an IQ score of about 70 or below (American Psychiatric Association, 2013).

The EPA uses a variety of science policy approaches to select points of departure for developing regulatory values. For instance, in noncancer risk assessment the EPA often uses a percentage change in value. When assessing toxicological data, a 10 percent extra risk (for discrete data), or a 1 standard deviation (i.e., 15 IQ points) change from the mean (for continuous data) is often used (USEPA, 2012). A smaller response to inform a POD has been applied when using epidemiological literature because there is an inherently more direct relationship between the study results and the exposure context and health endpoint. Given the difficulty in identifying a response below which no adverse impact occurs when considering a continuous outcome in the human population, the EPA looked to its Benchmark Dose Guidance (2012) for insight regarding a starting point. Specifically, "[a] BMR of 1% has typically been used for quantal human data from epidemiology studies" (p. 21, USEPA, 2012).

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.

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 $10^{th}$ 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.

*I. Translate PODs to RfDs*

When deriving an RfD the EPA evaluates whether to apply uncertainty/variability factors to account for heterogeneity of effect in the target population and data gaps (USEPA, 2002). As presented in *A Review of the RfD & RfC Processes* (USEPA, 2002) the EPA considers the following uncertainty factors: inter-individual variability, interspecies uncertainty, extrapolating from subchronic to chronic exposure, extrapolating from a lowest-observed adverse effect level (LOAEL) rather than from a no-observed-adverse-effect-level (NOAEL), and an incomplete database. The factors are intended to account for: 1) variation in susceptibility among the members of the human population (i.e., inter-individual or intraspecies variability); 2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty); 3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); 4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL; and 5) uncertainty associated with extrapolation when the database is incomplete. (U.S. EPA, 2011b) The EPA has considered each of these factors in deriving an RfD to inform an MCLG for perchlorate.

The EPA considered variation and uncertainty in the relationship between exposure and response among the members of the human population (i.e., uncertainty factor (UF) for within-

human variability/ inter-individual variability, $UF_H$). For this analysis a UF of 3 is used. The approach taken to derive the RfD attempts to address variability between the general population and the sensitive population. Specifically, the EPA was able to modify the strength of the TSH feedback loop and iodine intake levels in the BBDR model and concentrate on the dose-response relationship between lower level (as opposed to median level) fT4 and neurodevelopmental outcomes. However, there is still uncertainty in the relationship between perchlorate exposure and subsequent neurodevelopmental outcomes[10]. There are very few toxicokinetic calibration data available for the perchlorate to thyroid hormone relationship described in the BBDR model. On the toxicodynamic side of the BBDR model, aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. There are also uncertainties linking maternal fT4 levels to offspring IQ. These uncertainties include the population for which dose-response information is available (i.e., no study is U.S. based), a lack of study information on the iodine intake status for the population for which the dose-response information is available, uncertainties around the methods used to assess maternal fT4 measurement during pregnancy, and uncertainties related to the true distribution of fT4 for a given iodine intake.

Further, as discussed in section III.C. of this preamble the EPA believes that protecting

[10] For a more complete discussion on the uncertainties in the analysis the reader is directed to Sections 3.5 and 6.5 of the MCLG Approaches Report.

the fetus of a hypothyroxinemic woman will protect other identified sensitive life stages. However, there is some uncertainty due to the lack of information linking incremental changes in infant thyroid hormone levels to adverse neuorodevelopmental outcomes. In addition, this analysis is assuming that protecting a first trimester fetus from alterations in maternal fT4 will protect the fetus throughout pregnancy. This is based on epidemiologic evidence that shows the relationship between first trimester maternal fT4 and neurodevelopmental outcomes. This is potentially because before mid-gestation, the mother is the only source of thyroid hormone for the fetus (Morreale de Escobar et al., 2004). Therefore, when evaluating maternal fT4 as associated with neurodevelopmental outcomes it is critical to understand the first-trimester levels. Later in gestation, when the fetal thyroid begins secreting thyroid hormones, maternal fT4 may no longer be a good surrogate for the thyroid hormone levels available to the fetus. Given that the fetal thyroid has had little time to develop, its iodine storage is much less than that of an adult, hence there may be more sensitivity to short-term fluctuations in iodine availability and uptake that may have little impact on maternal levels. Therefore, there is some uncertainty about the impact perchlorate may have on the fetal thyroid gland, and subsequent neurodevelopmental impacts, in later trimesters of pregnancy. The immature fetal HPT axis has very limited capacity to increase output of thyroid hormones (Savin, Cvejić, Nedić, & Radosavljević, 2003; van Den Hove, Beckers, Devlieger, De Zegher, & De Nayer, 1999), so the fetal HPT may not be able to adjust output in the face of reduced maternal fT4 supply and perchlorate exposure. Therefore, as described above, the EPA selected an intraspecies UF of 3 to account for the uncertainties in

modeling the impacts of perchlorate ingestion on the thyroid hormone levels for pregnant mothers with low iodide intake, and the uncertainties in predicting the neurodevelopmental effects of these thyroid hormone changes on their children.

The EPA considered but did not derive a Data-Dependent Extrapolation Factor (DDEF) for this analysis. As described above, the UFs are applied based on the uncertainties in the perchlorate to thyroid hormone and thyroid hormone to neurodevelopment relationship[11]. As noted above, the Agency has 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 (p 4-42) 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)" (p. xviii, USEPA, 2002).The EPA selected a UF of 3 instead of the full 10 because the modeled groups within the population that are identified as likely to be at greater risk to perchlorate in drinking 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).

Below we list the other uncertainty factors added and the justification.

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[11]As explained in U.S. EPA, 2014 "UFs incorporate both extrapolation components that address variability (heterogeneity between species or within a population) and components that address uncertainty (i.e., lack of knowledge)…whereas DDEFs focus on variability" (p. 7, US EPA, 2014).

- Uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty) (uncertainty factor, animal-to-human, $UF_A$). For this analysis an UF of 1 is used because this factor is not applicable since animal studies were not used to develop the BBDR model nor were they used to relate alterations in maternal fT4 to IQ.
- Uncertainty in extrapolating data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure, $UF_S$). An uncertainty factor of 1 is used. Extrapolating from subchronic to chronic exposures did not occur as the BBDR model was designed to assess long-term steady-state conditions in the non-pregnant woman and week-to-week variation in pregnancy, rather than short-term (hour-to-hour or day-to-day) fluctuations.
- Uncertainty in extrapolating from a LOAEL rather than from a NOAEL (uncertainty factor, LOAEL-to-NOAEL, $UF_L$). A more sophisticated BBDR modeling approach, coupled with extrapolation to changes in IQ using linear regression, was used to determine a POD that would not be expected to represent an adverse effect. Subsequently an uncertainty factor of 1 is used. LOAELs and NOAELs were not identified or used in this approach.
- Uncertainty factor for database deficiency to address the potential for deriving an inadequately protective RfD in the instance where the available database provides an incomplete characterization of the chemical's toxicity (database deficiency, $UF_{D;}$ USEPA, 2002). An uncertainty factor of 1 is used as "[t]he mode of action of perchlorate toxicity is well understood" (SAB for the U.S. EPA, 2013, p. 2).

- The product of all the uncertainty factors ($UF_H$) is 3 (3 x 1 x 1 x 1 x 1).

Below we generate RfD's for each of the points of departure.

Using the POD of 6.7 µg/kg/day based on a 2 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive a RfD by incorporating the $UF_H$, which results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{6.7}{3} = 2.2\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 3.1 µg/kg/day based on a 1 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the $UF_H$. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{3.1}{3} = 1.0\ \frac{\mu g/kg}{day}$$

Using an alternative POD of 10.8 µg/kg/day based on a 3 percent decrease in the population standardized mean IQ from the EPA's independent analysis of the Korevaar et al., (2016) data, the EPA can derive an RfD by incorporating the $UF_H$. This results in the following:

$$RfD = \frac{POD}{UF_H} = \frac{10.8}{3} = 3.6\ \frac{\mu g/kg}{day}$$

*J. Translate RfD into an MCLG*

To translate the RfD (µg/kg/day) to a concentration in drinking water (µg/L), the EPA used the following equation:

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

where:

W = drinking water concentration of perchlorate in micrograms per liter (µg/L);

RfD = reference dose (1.03 µg/kg/day for a 1 percent decrease in IQ, 2.23 µg/kg/day for a 2 percent decrease in IQ, or 3.6 µg/kg/day for a 3 percent decrease in IQ);

DWI = bodyweight-adjusted drinking water ingestion rate (L/kg/day); and

$RSC_w$ = relative source contribution of drinking water to overall perchlorate exposure.

To calculate the MCLGs, the EPA selected the 90th percentile body-weight adjusted drinking water ingestion rate specific to women of childbearing age (i.e., non-pregnant, non-lactating, 15–44 years of age (0.032 L/kg/day). This decision is consistent with the analysis used in deriving an RSC, which was performed using food consumption information for a population of women of childbearing age from NHANES. The $90^{th}$ percentile is chosen to account for variability in drinking water ingestion rates, but also adds another layer of health protection for 90% of women (Table III-3).

The EPA did not use water intake data for pregnant women because the sample sizes were too small to be statistically stable. The use of the drinking water intake for 15-44 year old women is consistent with the analysis used in deriving an $RSC_w$ (described below), which was performed using food consumption information for a population of women of childbearing age from NHANES. The EPA acknowledges there is a difference in the age range defining women of childbearing age used to develop the drinking water ingestion rate and that used to develop the RSC (20 – 44 years of age). The age range used to develop the RSC was based on the range of

ages used to define women of childbearing age in developing the BBDR model. However, the EPA's Exposure Factors Handbook (USEPA, 2011c) identifies drinking water ingestion rates for women 15-44 years of age as corresponding to women of childbearing age.

The age range used for women of childbearing age in the BBDR model fits within the age range used to develop the ingestion rates provided in the Exposure Factors Handbook. Thus, the Agency believes the difference in the age ranges will have minimal impact on the resulting MCLG analysis.

**Table III-3. Consumers-Only Estimated Direct and Indirect Community Water Ingestion Rates from Kahn and Stralka (2008) (L/kg/day)**

| Female Population Categories | Sample Size | Mean | 90th Percentile | 95th Percentile |
|---|---|---|---|---|
| Pregnant | 65 | 0.014[a] | 0.033[a] | 0.043[a] |
| Lactating | 33 | 0.026[a] | 0.054[a] | 0.055[a] |
| Non-pregnant, non-lactating, 15 to 44 years of age | 2,028 | 0.015 | 0.032 | 0.038 |

[a] The sample size does not meet minimum reporting requirements to make statistically reliable estimates as described in the *Third Report on Nutrition Monitoring in the United States*, 1994-1996 (FASEB/LSRO, 1995).

Individuals are exposed to perchlorate through ingestion of both food and drinking water (ATSDR 2008, Huber et al., 2011). In calculating the MCLGs, the EPA applies a relative source contribution (RSC) to the RfD to account for the percentage of the RfD remaining for drinking water after other sources of exposure to perchlorate have been considered. Thus, the RSC for drinking water is based on the following equation where "Food" is the perchlorate dose from food ingestion:

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

To estimate the dose of perchlorate for women of childbearing age coming from food, the EPA implemented a data integration methodology that combined demographic variables, food consumption estimates, and perchlorate contamination estimates in food from multiple sources (USEPA, 2019c). These sources include:

- The NHANES data available from the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) including the What We Eat in America (WWEIA) 24-hour food diary data (CDC & NCHS, 2007, 2009, 2011); and
- The Food and Drug Administration's (FDA's) Total Diet Study (TDS) (U.S. Food and Drug Administration (FDA), 2015), which analyzes contaminants in about 280 kinds of food and beverages commonly consumed by the U.S. population.

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 95$^{th}$ percentile perchlorate concentrations in food. The details of these assumptions are explained on page 5-5 of the Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water (USEPA 2019c). 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. While simple, this method avoids the need to assume a distributional shape for the samples, and has been used in recent publications of TDS data for iodine (Carriquiry et al., 2016). The aforementioned method for identifying the 95$^{th}$ percentile concentration of perchlorate from food was selected over other, more "statistically based" methods for estimating percentiles as it avoids the need to assume a distributional shape for the samples. The EPA determined that it was more reliable to assume the empirically derived distribution as the basis for selecting the 95$^{th}$ percentile (i.e., assuming the distribution was equal to the distribution of samples collected in the TDS), as opposed to forcing a distributional shape, such as normal or log-normal, onto the data that may not necessarily be appropriate. With the chosen method, we can at least be sure that the distributional shape is appropriate for the data at hand, whereas by choosing the alternative that assumes a distributional shape, in many instances we would not even be certain of that. The EPA used these individual bodyweight-adjusted perchlorate doses from food to calculate distributions of perchlorate dose from food for the population of women age 20-44.

Table III-4 presents the mean and selected percentiles of the distribution of perchlorate dose from food for women ages 20-44, for both mean and 95$^{th}$ percentile perchlorate concentrations in food based on the TDS. To calculate the RSC, the EPA selected the 90$^{th}$ percentile dose of perchlorate from food, assuming a scenario where the food contained the 95$^{th}$ 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. Given the range of perchlorate concentrations in food, and that food is the only other exposure source being considered in the RSC analysis, the EPA believes it is sufficiently protective to estimate the MCLG for drinking water using the 90th percentile bodyweight-adjusted perchlorate consumption based on the 95th percentile perchlorate food concentrations in TDS. This assures that highly exposed individuals from this most sensitive population are considered in the evaluation of whether perchlorate is found at levels of health concern.

**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

The EPA used the drinking water intake and perchlorate dose from food to calculate MCLGs for the three RfD values. Table III-5 shows the RSC values for the three RfD values and the corresponding MCLGs calculated using the EPA's standard equation.

**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).

## IV. Maximum Contaminant Level Goal and Alternatives

Section 1412(a)(3) of the SDWA requires the EPA to propose a maximum contaminant level goal (MCLG) simultaneously with the NPDWR. The MCLG is defined in Section

1412(b)(4)(A) as "the level at which no known or anticipated adverse effects on the health of persons occurs and which allows an adequate margin of safety." The EPA is proposing an MCLG of 56 µg/L based on the rationale and methodology described in Section III above. The derivation of the proposed MCLG uses a point of departure based upon a two percent decrease in IQ for offspring of hypothyroxinemic women of child bearing age have with low iodine intake. The EPA selected a 2 percent decrease in IQ for the proposed perchlorate MCLG because this represents a small change in IQ, well below one standard deviation for the subpopulation of interest.

As described in Section III, the EPA has selected model parameters and other factors for the derivation of the MCLG that are health protective, including the focus on the most sensitive life stage. The EPA believes that the selection of the combination of protective parameters and this point of departure assures no known or anticipated adverse effects on the health of the most sensitive subpopulation and allows for an adequate margin of safety. The EPA also acknowledges the uncertainties in the derivation of the proposed (and alternative) MCLGs. The EPA acknowledges in particular the challenge associated with selecting the decrement of IQ that represents an adverse effect at the population level and the uncertainties in predicting the dose of perchlorate that may result in a particular IQ decrement given the absence of robust human epidemiological data directly linking perchlorate exposure to IQ decrements. The Agency seeks comment on the alternative MCLG values of 18 µg/L and 90 µg/L, which the EPA derived using

the methodology described in Section III based on a one percent and three percent decrease in IQ, respectively.

## V. Maximum Contaminant Level and Alternatives

Under section 1412(b)(4)(B) of the SDWA, the EPA must establish a maximum contaminant level (MCL) as close to the MCLG as is feasible. The EPA evaluated available analytical methods to determine the lowest concentration at which perchlorate can be measured and evaluated the treatment technologies for perchlorate that have been examined under field conditions (USEPA 2018a, 2019b). 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.

As the occurrence analysis in section VI demonstrates, there is infrequent occurrence of perchlorate at 18 µg/L, 56 µg/L, or 90 µg/L. Therefore, the EPA did not evaluate alternative MCL values greater than the corresponding MCLG values. The purpose for evaluating alternative MCL values is to determine whether there is an MCL at which benefits justify the costs of setting an MCL. Given infrequent occurrence, the majority of the costs associated with establishing an NPDWR for perchlorate are for administrative and initial monitoring activities (see section XI.B), which will not be significantly affected by MCL values greater than corresponding MCLG values.

When proposing an MCL, the EPA must publish, and seek public comment on, the health risk reduction and cost analyses (HRRCA) of each alternative MCL considered (SDWA Section 1412(b)(3)(C)(i)), including: the quantifiable and nonquantifiable health risk reduction benefits attributable to MCL compliance; the quantifiable and nonquantifiable health risk reduction benefits of reduced exposure to co-occurring contaminants attributable to MCL compliance; the quantifiable and nonquantifiable costs of MCL compliance; the incremental costs and benefits of each alternative MCL; the effects of the contaminant on the general population and sensitive subpopulations likely to be at greater risk of exposure; any adverse health risks posed by compliance; and other factors such as data quality and uncertainty. The EPA provides this information in section XII in this preamble. The EPA must base its action on the best available, peer-reviewed science and supporting studies, taking into consideration the quality of the information and the uncertainties in the benefit-cost analysis (SDWA Section 1412(b)(3)). The

following sections, as well as the health effects discussion in section III document the science and studies that the EPA relied upon to develop estimates of benefits and costs and understand the impact of uncertainty on the Agency's analysis.

## VI. 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. Since UCMR 1 data was first used to inform the Agency actions on the 2008 preliminary regulatory determination and the 2011 final regulatory determination, the Agency has modified its analysis of the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions at some States that have enacted perchlorate regulations since the UCMR 1 data was collected. Despite these updates, the EPA continues to rely on the UCMR 1 data because they are the best available data collected in accordance with accepted methods from a census of the large water systems (serving more than 10,000 people) and a statistically representative sample of small water systems that provides the best available, national assessment of perchlorate occurrence in drinking water.

In 1999, the EPA developed the first round of the UCMR program in accordance with SDWA requirements to provide national occurrence information on unregulated contaminants (USEPA, 1999, 2000b). The UCMR 1 required sampling from systems in all 50 States, the District of Columbia, four U.S. territories, and tribal lands in five EPA Regions including:

- all 3,097 large (serving more than 10,000 people) CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources), or two samples collected 5 to 7 months apart (ground water sources); and
- a statistically representative selection of 800 small CWSs and NTNCWSs, which analyzed either four quarterly samples collected at 3-month intervals (surface water sources) or two samples collected 5 to 7 months apart (ground water sources).

Water systems submitted UCMR 1 sampling results to the EPA from 2001 until 2005. Water systems were required to analyze samples for 26 contaminants including perchlorate. The EPA established a minimum reporting level of 4 µg/L for perchlorate in the UCMR.

The EPA conducted a data quality review of the UCMR 1 data submitted by systems prior to analyzing the occurrence data for the 2011 perchlorate regulatory determination. The UCMR 1 dataset used by the EPA included 34,331 samples with 637 measurements of perchlorate above the minimum reporting level from 3,865 systems.

In September of 2012, the EPA received a "Request for Correction" letter from the United States Chamber of Commerce regarding information and data (i.e., the occurrence of perchlorate in drinking water) used by the EPA in its 2011 determination to regulate perchlorate. The U.S. Chamber of Commerce letter stated that the EPA relied upon: 1) data that did not comply with data quality guidelines and 2) data that was not representative of current conditions.

In response[12] to the U.S. Chamber of Commerce, the EPA conducted a detailed assessment of the source water sample detections and determined that it was most appropriate to exclude the source water sample detections from the UCMR 1 perchlorate data set when those samples had appropriate follow-up entry point samples that were included in the UCMR 1 perchlorate data set. In contrast, any source water sample perchlorate detections for which no follow-up entry point sampling was conducted by PWSs were retained in the UCMR 1 perchlorate data set. As a result of the assessment, the EPA removed 199 source water samples (97 detections) that could be paired with a second follow-up sample located at the entry point to the distribution system. Following this convention, the resulting UCMR 1 data set contains 34,132 perchlorate samples from 3,865 systems with a total of 540 detections from 149 PWSs.

Table VI-1 shows sample distribution by system size category and measurement status. It also shows the number of entry points and systems where perchlorate measurements were reported. The entry point estimates differ from the system estimates because many water systems have more than one entry point. For example, a ground water system with two wells that has separate connections to the distribution system has two entry points.

In response to the U.S. Chamber of Commerce request, the EPA has also reassessed the UCMR 1 data in light of the adoption of regulatory limits in two states. Massachusetts promulgated a drinking water standard for perchlorate of 2 µg/L in 2006 (MassDEP, 2006), and

[12] See the EPA response letter at https://www.epa.gov/sites/production/files/2017-08/documents/12004-response_0.pdf

California promulgated a drinking water standard of 6 µg/L in 2007 (California Department of Public Health, 2007). Systems in these states are now required to keep perchlorate levels in drinking water below their state limits, which are lower than the proposed MCL and alternative MCLs. Therefore, the UCMR 1 sampling results from systems in these states do not reflect the current occurrence and exposure conditions. For the purpose of estimating the costs and benefits of the proposed rule, the EPA assumed that no additional monitoring and treatment costs would be incurred by the systems in the States of California and Massachusetts. Systems in California account for some of the perchlorate measurements reported below. The notes in the tables below indicate whether results include or exclude systems in California and Massachusetts.

To update the occurrence data for systems sampled during UCMR 1 from the States of California and Massachusetts, the EPA identified all systems and corresponding entry points which had reported perchlorate detections in UCMR 1. Once the systems and entry points with detections were appropriately identified, the EPA then used a combination of available data from Consumer Confidence Reports (CCRs) and perchlorate compliance monitoring data from California (https://sdwis.waterboards.ca.gov/PDWW/) and Massachusetts (https://www.mass.gov/service-details/public-water-supplier-document-search) to match current compliance monitoring data (where available) to the corresponding water systems and entry points sampled during UCMR 1.

Out of the 540 detections previously described the EPA updated data for 321 detections (320 from California systems and 1 from a Massachusetts system). The convention used by the

EPA to accomplish the substitution of data was to match entry points with compliance data for active entry points based on most recently reported compliance monitoring data, if more than one data point was reported for an entry point, the assigned value is an average of the annual monitoring results at the entry point. In cases were the EPA could not find updated entry point data, then the original data from UCMR 1 for such entry point was kept.

**Table VI-1. UCMR 1 Data Summary Statistics**

| Item | Small System Sample | Large System Census | Sum |
|---|---|---|---|
| Total samples | 3,295 | 30,837 | 34,132 |
| Sample measurements ≥ 4 µg/L | 15 | 525 | 540 |
| Sample measurements > 18 µg/L | 1 | 16 | 17 |
| Sample measurements > 56 µg/L | 0 | 2 | 2 |
| Sample measurements > 90 µg/L | 0 | 1 | 1 |
| Total entry points | 1,454 | 13,482 | 14,936 |
| Entry points at which measurements ≥ 4 µg/L | 8 | 328 | 336 |
| Entry points at which measurements > 18 µg/L | 1 | 16 | 17 |
| Entry points at which measurements > 56 µg/L | 0 | 2 | 2 |
| Entry points at which measurements > 90 µg/L | 0 | 1 | 1 |
| Total systems | 797 | 3,068 | 3,865 |
| Systems at which measurements ≥ 4 µg/L | 8 | 141 | 149 |
| Systems at which measurements > 18 µg/L | 1 | 14 | 15 |
| Systems at which measurements > 56 µg/L | 0 | 2 | 2 |
| Systems at which measurements > 90 µg/L | 0 | 1 | 1 |

Source: (USEPA, 2019b). The total row counts and counts of measurements ≥ 4 µg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 537 systems in total and 51 systems at which measurements ≥4 µg/L. The instances where perchlorate measurements equal or exceed either 18 µg/L, 56µg/L, or 90 µg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 µg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

Table VI-2 shows the service populations that correspond with the occurrence summary in Table VI-1. The entry point population estimates reflect the assumption that system population is uniformly distributed across entry points; e.g., the entry point population for a system with two entry points is one-half the total system population.

**Table VI-2. UCMR1 Data Service Population Summary Statistics**

| Item | Small System Sample | Large System Census | Sum |
|---|---|---|---|
| Total entry point population | 2,760,570 | 222,853,101 | 225,613,671 |
| Population served by entry points at which measurements ≥ 4 µg/L | 9,484 | 4,281,937 | 4,291,420 |
| Population served by entry points at which measurements > 18 µg/L | 2,155 | 618,406 | 620,560 |
| Population served by entry points at which measurements > 56 µg/L | 0 | 32,432 | 32,432 |
| Population served by entry points at which measurements > 90 µg/L | 0 | 25,972 | 25,972 |
| Total system population | 2,760,570 | 222,853,101 | 225,613,671 |
| Population served by systems at which measurements ≥ 4 µg/L | 13,483 | 16,159,082 | 16,172,565 |
| Population served by systems at which measurements >18 µg/L | 4,309 | 696,871 | 701,180 |
| Population served by systems at which measurements > 56 µg/L | 0 | 64,733 | 64,733 |
| Population served by systems at which measurements > 90 µg/L | 0 | 25,972 | 25,972 |

Source: (USEPA, 2019b). The populations for entry points/systems with measurements ≥ 4 µg/L identify all instances where perchlorate was detected at or above the minimum reporting level, including water systems in California and Massachusetts, which account for 39.6 million of the 225.6 million total population in UCMR 1, and 1.9 million of the 4.3 million population served by entry points at which measurements ≥4 µg/L. The instances where perchlorate measurements equal or exceed either 18 µg/L, 56µg/L, or 90 µg/L exclude results from California and Massachusetts because water systems in these States must meet limits below 18 µg/L. The small system counts reflect sample results that have not been extrapolated to small systems nationwide.

As shown in the tables, 149 systems serving 16.2 million people had measured levels of perchlorate greater than the minimum reporting level. However, many of these systems have several entry points with no measured levels of perchlorate greater than the minimum reporting level; at the entry point level, the exposed population is approximately 4.3 million people served by 336 entry points. Because the uniform population distribution assumption may over or underestimate the service population of any particular entry point, the entry point estimates are uncertain. The system population estimates serve as upper bounds on exposure.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the proposed MCL and alternative MCLs. The maximum measurements indicate perchlorate levels that occurred in at least one quarterly sample among surface water systems and at least one semi-annual sample among ground water systems.

Table VI-3 through Table VI-5 show the occurrence and exposure estimates based on the 56 µg/L, 18 µg/L MCL, and 90 µg/L values, respectively. Each table provides estimates of the entry points at which the maximum perchlorate concentrations exceed the MCL value. The tables also report the system-level information for these entry points.

**Table VI-3: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 56 µg/L**

| Affected Entity | Small Systems | Large Systems | Total Systems |
|---|---|---|---|
| Entry points | 0 | 2 | 2 |
| Population served | 0 | 32,432 | 32,432 |
| Water systems | 0 | 2 | 2 |
| Population served | 0 | 64,733 | 64,733 |

Source: (USEPA, 2019b).

**Table VI-4: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 18 µg/L**

| Affected Entity | Small Systems[1] | Large Systems | Total Systems |
|---|---|---|---|
| Entry points | 1 | 16 | 17 |
| Population served | 2,155 | 618,406 | 620,560 |
| Water systems | 1 | 14 | 15 |
| Population served | 4,309 | 696,871 | 701,180 |

Source: (USEPA, 2019b).

1. The values shown in the table are estimates based on the UCMR 1 data. The EPA also applied the statistical sampling weights to the results to extrapolate results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L.

**Table VI-5: Estimated Perchlorate Occurrence and Exposure: Entry Point Max Exceeds 90 µg/L**

| Affected Entity | Small Systems[1] | Large Systems | Total Systems |
|---|---|---|---|
| Entry points | 0 | 1 | 1 |
| Population served | 0 | 25,972 | 25,972 |
| Water systems | 0 | 1 | 1 |
| Population served | 0 | 25,972 | 25,972 |

Source: (USEPA, 2019b).

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.

## VII. Analytical Methods

The SDWA directs the EPA to set a contaminant's MCL as close to its MCLG as is ''feasible'', the definition of which includes an evaluation of the feasibility of performing chemical analysis of the contaminant at standard drinking water laboratories. Specifically, the SDWA directs the EPA to determine that it is economically and technologically feasible to ascertain the level of the contaminant being regulated in water in public water systems (Section 1401(1)(C)(i)). NPDWRs are also to contain ''criteria and procedures to assure a supply of drinking water which dependably complies with such [MCLs]; including accepted methods for quality control and testing procedures to insure compliance with such levels.'' (Section 1401(1)(D)).

To comply with these requirements, the EPA considers method performance under relevant laboratory conditions, their likely prevalence in certified drinking water laboratories, and the associated analytical costs. The EPA has developed five analytical methods for the identification and quantification of perchlorate in drinking water that meet these criteria. The proposed EPA methods for perchlorate are: 314.0, 314.1, 314.2, 331.0, and 332.0. A detailed description of these methods is presented in the Perchlorate Occurrence and Monitoring Report (USEPA, 2019b).

The EPA Methods 314.0, 314.1, 314.2, 331.0, and 332.0 underwent the EPA's analytical method development and validation processes. The validation process includes a protocol for modifications to any existing EPA-approved analytical methods and a protocol for new determinative techniques. Both validation protocols are rigorous and consider many technical aspects of analytical method performance, including: detection limits; instrument calibration; precision and analyte recovery; analyte retention times; evaluation of blanks; development of Quality Control acceptance criteria; analysis of field samples; and other technical aspects of sample analysis and data reporting. 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.

EPA Method 314.0, "Determination of Perchlorate in Drinking Water Using Ion Chromatography" (Revision 1.0, USEPA, 1999a) has a method detection limit (MDL) of 0.53 µg/L. Single-laboratory mean percent recovery in various aqueous matrices range from 86% to

113% with Relative Standard Deviations (RSDs) of 1.0% to 12.8%. A minimum reporting level (MRL) is not specified in the method; however, a range of 3.0 to 5.0 µg/L is cited as a benchmark range for quality assurance/quality control (QA/QC) procedures. The MRL is to be established as either a concentration that is greater than three times the laboratory MDL or at a concentration that yields a response greater than a signal to noise ratio of five. In either case, the MRL must not be below the lowest instrument calibration standard (USEPA, 1999a). Method 314.0 was widely adopted as the standard perchlorate method.

After the EPA published Method 314.0, the Agency adopted additional method development goals for the analysis of perchlorate in drinking water including: 1) reducing MRL to less than 1 µg/L through the application of sample concentration techniques, microbore analytical columns, and advanced detection systems (i.e., mass spectrometry), 2) further increasing the tolerance for high ionic strength matrices, and 3) enhancing measurement selectivity.

EPA Method 314.1, "Determination of Perchlorate in Drinking Water Using Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection" (Revision 1.0, USEPA, 2005b) documents the EPA single-laboratory Lowest Concentration Minimum Reporting Levels (LCMRLs) of less than 0.2 µg/L (DL = 0.03 µg/L) using online sample pre-concentration. The method uses matrix diversion to handle high ionic strength matrices (up to 1,000 mg/L TDS) and added confirmation analysis using a second analytical column (USEPA, 2005b).

EPA Method 314.2, "Determination of Perchlorate in Drinking Water Using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection" (USEPA, 2008c) documents the EPA single-laboratory LCMRLs of less than 0.1 µg/L (DLs < 0.02 µg/L) using large volume injection. The method uses 2-D chromatography to handle high ionic strength matrices (up to 1,000 mg/L total dissolved solids [TDS]) and eliminates the need for separate confirmation analysis (USEPA, 2008c).

EPA Method 331.0, "Determination of Perchlorate in Drinking Water by Liquid Chromatography Electrospray Ionization Mass Spectrometry" (Revision 1.0, USEPA, 2005c) documents the EPA single-laboratory LCMRLs of less than 0.1 µg/L (DLs < 0.01 µg/L), applied multiple analytical advancements to a liquid chromatography (LC) analysis including a perchlorate selective LC column (AS-21), mass spectrometry (MS) or MS/MS detection for selectivity and sensitivity, and a custom labeled internal standard ($Cl^{18}O_4^-$) (USEPA, 2005c).

EPA Method 332.0, "Determination of Perchlorate in Drinking Water by Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry" (USEPA, Revision 1.0, 2005d) documents the EPA single-laboratory LCMRL of 0.1 µg/L (DL = 0.02 µg/L), applied multiple analytical advancements in an IC analysis including suppressed conductivity IC, MS or MS/MS selectivity and sensitivity, and a custom labeled internal standard ($Cl^{18}O_4$) (USEPA, 2005d).

## VIII. Monitoring and Compliance Requirements

### *A. What are the Proposed Monitoring 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).

Under the Standardized Monitoring Framework, the monitoring frequency for a public water system is dependent on previous monitoring results and whether a monitoring waiver has been granted. 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)).

*B. Can States Grant Monitoring Waivers?*

Under this proposal, water systems may apply to the state, and states may grant, a 9-year monitoring waiver for perchlorate if the conditions described in 40 CFR 141.23(c)(3)-(6) are met. A state may grant a waiver for surface water systems after three rounds of annual monitoring with results less than the MCL and for groundwater systems after conducting 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.

*C. How are System MCL Violations Determined?*

Under this proposal, violations of the perchlorate MCL would be determined in a manner consistent with 40 CFR 141.23(i)(3). Compliance with the perchlorate MCL would be determined based on one sample if the level is 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 of the system's receipt of notification of the analytical result of the first sample, in accordance with 141.23(f)(1). Compliance shall be determined based on the average of the initial and confirmation samples.

*D. 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. NTNCWS and CWSs serving 10,000 persons or less must collect 4 quarterly samples during the third compliance period of the fourth compliance cycle (January 1, 2026 – December 31, 2028) of the Standardized Monitoring Framework.

*E. Can Systems use Grandfathered Data to Satisfy the Initial Monitoring Requirements?*

As proposed today, systems would be allowed to use grandfathered perchlorate data collected after January 1, 2020, to satisfy the initial monitoring requirements. To satisfy initial perchlorate monitoring requirements, a system with appropriate historical monitoring data for each entry point to the distribution system could use the monitoring data from the compliance monitoring period between January 1, 2020, and December 31, 2022, for CWSs serving greater than 10,000 persons and between January 1, 2023, and December 31, 2025, for NTNCWs and for CWSs serving 10,000 or fewer persons.

## IX. Safe Drinking Water Act Right to Know Requirements

*A. What are the Consumer Confidence Report Requirements?*

A community water system must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR 141 Subpart O. A CCR provides customers with information about their local drinking water quality as well as

information regarding the water system compliance with drinking water regulations. Under this proposal CWSs would be required to report perchlorate information in their CCR.

*B. What are the Public Notification Requirements?*

All public water systems must give the public notice for all violations of NPDWRs and for other situations. Under this proposal, violations of the perchlorate MCL would be designated as Tier 1 and as such, public water systems would be required to comply with 40 CFR 141.202. As described in Section III of this proposal, fetuses of first trimester pregnant women with low iodine are the most sensitive subpopulation, therefore, per 40 CFR 141.202(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 24 hours after the system learns of the violation under this proposal.

## X. Treatment Technologies

Systems that exceed the perchlorate MCL will need to adopt new treatment or another strategy to reduce perchlorate to a level that meets the MCL. When the EPA establishes an MCL for a drinking water contaminant, Section 1412(b)(4)(E) of the SDWA requires that the Agency "list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL]," which are referred to as best available technologies (BAT). These BATs are used by states to establish conditions for source water variances under Section 1415(a). Furthermore, Section 1412(b)(4)(E)(ii) requires that the Agency identify small system compliance technologies (SSCT), which are affordable treatment technologies, or other means that can achieve compliance with the MCL (or treatment technique, where applicable).

The lack of an affordable SSCT for a contaminant triggers certain additional procedures which can result in states issuing small system variances under Section 1412(e) of the SDWA.

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

*A. What are the Best Available Technologies?*

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.

*Ion Exchange*.

Ion exchange is a physical and chemical separation process that can achieve high perchlorate removal rates. Feed water passes through a vessel containing a bed of resin made of synthetic beads or gel. As feed water moves through the resin, an ionic contaminant such as perchlorate exchanges for an ion (typically chloride) on the resin. Demonstrated removal efficiencies for perchlorate are typically in the high 90 percent range and can achieve concentrations less than 4 µg/L in treated water (Drago & Leserman, 2011; Membrane Technology, 2006; Siemens Water Technologies, 2009; The Interstate Technology & Regulatory Council (ITRC) Team, 2008). The operation continues until enough of the resin's available ion exchange sites have ions from the feed water and the resin no longer effectively removes the target contaminant, i.e., the contaminant "breaks through" the treatment process. At this point, the resin must be disposed and replaced or regenerated. The length of time until resin must be replaced or regenerated is known as bed life and is a critical factor in the cost effectiveness of ion exchange as a treatment technology. One measurement of bed life is the volume of water that can be treated before breakthrough – called bed volumes – the number of times the resin bed can be filled before breakthrough. Several factors affect bed life, including the presence of competing ions such as nitrate and the type of resin used. Resin types tested for perchlorate removal include strong-base polyacrylic, strong-base polystyrenic (including nitrate-selective), weak-base polyacrylic, weak-base polystyrenic, and perchlorate-selective. Based on studies of the effect of competing ions on performance, perchlorate-selective resins can achieve bed lives ranging from

105,000 to 170,000 bed volumes (Blute, Seidel, McGuire, Qin, & Byerrum, 2006; Russell, Qin, Blute, McGuire, & Williams, 2008; Wu & Blute, 2010).

Perchlorate-selective resin cannot be easily regenerated for reuse; the exhausted resin must be disposed (i.e., operated on a 'throw-away' basis). This mode of operation, however, avoids the production of liquid residuals in the form of spent regenerant. Therefore, in combination with the long bed life, single-use perchlorate-selective ion exchange can be a cost-effective treatment option in spite of the need to dispose of the perchlorate-contaminated resin. Build-up of arsenic or uranium on the resin may affect waste disposal options, although studies of perchlorate-selective resins show that arsenic concentrations remain below regulatory limits for hazardous waste disposal and uranium concentrations generally remain below those that require special handling as radioactive waste (Blute et al., 2006; Russell et al., 2008; Wu & Blute, 2010). Ion exchange can increase the corrosivity of treated water (Berlien, 2003; Betts, 1998; USEPA, 2005b) because of the addition of chloride ions and/or removal of carbonates and bicarbonates. Such instances can be addressed by adding or adjusting corrosion control.

*Biological Treatment*.

Biological treatment uses bacteria to reduce perchlorate to chlorate, chlorite, chloride, and oxygen. Biological treatment can destroy the perchlorate ion, eliminating the need for management of perchlorate-bearing waste streams. Removal effectiveness exceeds 90 percent for bench-scale tests and full-scale treatment plant studies (Kotlarz, Upadhyaya, Togna, & Raskin, 2016; Upadhyaya, Kotlarz, Togna, & Raskin, 2015; U.S. Department of Defense (U.S. DoD),

2008, 2009; T. D. Webster & Crowley, 2010, 2016; T. D. Webster & Litchfield, 2017). Although biological treatment is a relatively new technology for treatment of drinking water in the United States, the State of California has identified biological treatment (along with ion exchange) as one of two best available technologies for achieving compliance with its standard for perchlorate in drinking water (California Code of Regulations, Title 22, Chapter 15, Section 64447.2). The California BAT specifies a fluidized bed, although studies suggest that a fixed bed is also effective. The first full-scale fluidized bed facility using biological treatment of perchlorate to supply municipal drinking water began operation in 2016 (T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017). Raw water quality will affect process design, in particular, temperature affects the rate of biomass growth; at temperatures below 10 degrees Celsius, growth is inhibited and bioremediation becomes infeasible (Dugan, 2010b, 2010a; Dugan et al., 2009). This factor limits the feasibility of biological treatment in areas that experience low water temperatures during winter. In addition, bacteria in bioreactors require nutrients to grow and effectively reduce perchlorate. Therefore, some source waters may require supplemental addition of nutrients such as nitrogen or phosphorus (Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008a, 2009).

Although the process does not produce perchlorate-contaminated wastes, periodic removal of excess biomass, e.g., through backwash, will be required. The backwash water is non-toxic and can be discharged to a sanitary sewer (U.S. Department of Defense (U.S. DoD), 2008, 2009) or recycled following clarification. Typically, post-treatment of treated water also

will be required because biological treatment increases soluble microbial organic products, depletes oxygen, and can add turbidity and sulfides (Dordelmann, 2009; Harding Engineering and Environmental Services (ESE), 2001; U.S. Department of Defense (U.S. DoD), 2008; T. D. Webster & Crowley, 2016; T. D. Webster & Litchfield, 2017). The treatment process, however, can result in removal of co-occurring contaminants such as nitrate (Upadhyaya et al., 2015; Webster and Crowley, 2010; Webster and Lichfield, 2017).

*Reverse Osmosis*.

Reverse osmosis is a membrane filtration process that physically removes perchlorate ions from drinking water. This process separates a solute such as perchlorate ions from a solution by forcing the solvent to flow through a membrane at a pressure greater than the normal osmotic pressure. The membrane is semi-permeable, transporting different molecular species at different rates. Water and low-molecular weight solutes pass through the membrane and are removed as permeate, or filtrate. Dissolved and suspended solids are rejected by the membrane and are removed as concentrate or reject. This technique does not destroy the perchlorate ion and, therefore, creates a subsequent need for disposal or treatment of perchlorate-contaminated waste (the concentrate).

Membranes may remove ions from feed water by a sieving action (called steric exclusion), or by electrostatic repulsion of ions from the charged membrane surface. Across multiple bench- and pilot-scale studies, reverse osmosis membranes consistently achieve perchlorate removal greater than 80 percent and up to 98 percent (Liang, Scott, Palencia, &

Bruno, 1998; Nam et al., 2005; Yoon, Amy, & Yoon, 2005; Yoon, Yoon, Amy, & Her, 2005). While water quality affects process design (e.g., recovery rate, cleaning frequency, and antiscalant selection), it has relatively little effect on perchlorate removal effectiveness of reverse osmosis membranes. Reverse osmosis generates a relatively large concentrate stream, which will contain perchlorate as well as other rejected dissolved solids, which will require disposal. The large concentrate stream also means less treated water is available for distribution (e.g., 70 to 85 percent of source water), which is a disadvantage for systems with limited water supply. Because reverse osmosis can increase the corrosivity of the treated water, it may require post-treatment or blending with bypass water. Reverse osmosis can, however, remove co-occurring contaminants including arsenic and chromium-VI (Amy, Yoon, and Amy, 2005).

*B. What are the Small System Compliance Technologies?*

The EPA is proposing the SSCT shown in Table X-1. The table shows which of the BAT listed above are also affordable for each small system size category listed in Section 1412(b)(4)(E)(ii) of the SDWA. The Agency identified these technologies based on an analysis of treatment effectiveness and affordability (USEPA, 2018a).

**Table X-1: Proposed SSCT for Perchlorate Removal**

| System Size (Population Served) | Ion Exchange | Biological Treatment | Reverse Osmosis | Point-of-Use Reverse Osmosis |
|---|---|---|---|---|
| 25-500 | Yes | No | No | Yes |
| 501-3,300 | Yes | Yes | Yes | Yes |
| 3,301-10,000 | Yes | Yes | Yes | Not applicable[a] |

a. For perchlorate, the EPA has determined that implementing and maintaining this option for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

The SSCT listed in Table X-1 include a point-of-use (POU) version of reverse osmosis in addition to the ion exchange, biological treatment and reverse osmosis technologies described in the previous section. This technology can be used by small systems to comply with the proposed MCL and, therefore, meets the effectiveness requirement for an SSCT. For perchlorate removal, NSF/ANSI Standard 58: Reverse Osmosis Drinking Water Treatment Systems includes a protocol that requires a reverse osmosis unit to be able to reduce perchlorate from a challenge level of 130 µg/L to a target level of 4 µg/L (NSF, 2004). Organizations (e.g., NSF International, Underwriters Laboratories, Water Quality Association) provide third-party testing and certification that POU devices meet drinking water treatment standards. There are no perchlorate certification standards for other types of POU devices such as those using ion exchange media.

The operating principle for POU reverse osmosis devices is the same as centralized reverse osmosis: steric exclusion and electrostatic repulsion of ions from the charged membrane surface. In addition to a reverse osmosis membrane for dissolved ion removal, POU reverse osmosis devices often have a sediment pre-filter and a carbon filter in front of the reverse osmosis membrane, a 3- to 5-gallon treated water storage tank, and a carbon filter between the tank and the tap.

The EPA identified the SSCT using the affordability criteria methodology it developed for drinking water rules (USEPA, 1998). The analysis method is a comparison of estimated incremental household costs for perchlorate treatment to an expenditure margin, which is the difference between baseline household water costs and a threshold equal to 2.5% of median

household income. Table X-2 shows the expenditure margins derived for the analysis. These margins show the cap on affordable incremental annual expenditures.

**Table X-2: Expenditure Margins for SSCT Affordability Analysis**

| System Size (Population Served) | Median Household Income[a] (a) | Affordability Threshold[b] (b) = 2.5% x a | Baseline Water Cost[c] (c) | Expenditure Margin (d) = b - c |
|---|---|---|---|---|
| 25-500 | $52,791 | $1,320 | $341 | $979 |
| 501-3,300 | $51,093 | $1,277 | $395 | $883 |
| 3,301-10,000 | $55,975 | $1,399 | $412 | $987 |

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* (USEPA, 2018a)
a. MHI based on U.S. Census 2010 American Community Survey (ACS) 5-year estimates (U.S. Census Bureau, 2010) stated in 2010 dollars, adjusted to 2017 dollars using the CPI (for all items) for areas under 50,000 persons (Bureau of Labor Statistics (BLS), 2018b).
b. Affordability threshold equals 2.5 percent of MHI.
c. Household water costs derived from 2006 Community Water System Survey (USEPA, 2009c), based on residential revenue per connection within each size category, adjusted to 2017 dollars based on the CPI (for all items) for areas under 50,000 persons.

Table X-3 shows the estimates of per-household costs by treatment technology and size category generated using the treatment cost method described in section XII.B as well as *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* (USEPA, 2018a) and *Technologies and Costs for Treating Perchlorate-Contaminated Waters* (USEPA, 2018c). Costs in bold font do not exceed the corresponding expenditure margin and, therefore, meet the SSCT affordability criterion. Therefore, the EPA has determined that there are affordable small system compliance technologies available and the Agency is not proposing any variance technologies.

**Table X-3: Annual Incremental Cost Estimates for SSCT Affordability Analysis**

| System Size (Population Served) | Ion Exchange | Biological Treatment | Reverse Osmosis | Point-of-Use Reverse Osmosis |
|---|---|---|---|---|
| 25-500 | **$378 to $610** | $2,146 to $3,709 | $2,272 to $2,671 | **$265 to $271** |
| 501-3,300 | **$98 to $148** | **$324 to $566** | **$561 to $688** | **$250 to $251** |
| 3,301-10,000 | **$104 to $153** | **$211 to $315** | **$431 to $493** | Not applicable[a] |

Source: *Best Available Technologies and Small System Compliance Technologies for Perchlorate in Drinking Water* (USEPA, 2018a), which describes the different WBS model input assumptions that result in ranges of per-household costs shown; bold font indicates cost estimates that do not exceed the corresponding expenditure margin.
a. For perchlorate, the EPA has determined that implementing and maintaining a POU program for systems larger than 3,300 people (greater than 1 MGD design flow) is likely to be impractical.

## XI. Rule Implementation and Enforcement

### *A. What are the Requirements for Primacy?*

This section describes the regulations and other procedures and policies primacy entities must adopt, or have in place, to implement the proposed perchlorate rule. States must continue to meet all other conditions of primacy in 40 CFR part 142. Section 1413 of the SDWA establishes requirements that primacy entities (States or Indian Tribes) must meet to maintain primary enforcement responsibility (primacy) for its public water systems. These include: (1) Adopting drinking water regulations that are no less stringent than federal NPDWRs in effect under sections 1412(a) and 1412(b) of the Act, (2) Adopting and implementing adequate procedures for enforcement, (3) Keeping records and making reports available on activities that the EPA requires by regulation, (4) Issuing variances and exemptions (if allowed by the State) under conditions no less stringent than allowed by SDWA Sections 1415 and 1416, and (5)

Adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations.

40 CFR part 142 sets out the specific program implementation requirements for States to obtain primacy for the Public Water Supply Supervision Program, as authorized under section 1413 of the Act.

To implement the perchlorate rule, States would be required to adopt revisions at least as stringent as the proposed provisions in 40 CFR 141.6 (Effective Dates); 40 CFR 141.23 (Inorganic chemical sampling and analytical requirements); 40 CFR 141.51 (Maximum contaminant level goals for inorganic contaminants); 40 CFR 141.60 (Effective Dates); 40 CFR 141.62 (Maximum contaminant levels for inorganic contaminants); Appendix A to Subpart O ([Consumer Confidence Report] Regulated contaminants); Appendix A to Subpart Q (NPDWR violations and other situations requiring public notice); Appendix B to Subpart Q (Standard health effects language for public notification); and 40 CFR 142.62 (Variances and exemptions from the maximum contaminant levels for organic and inorganic contaminants). Under 40 CFR 142.12(b), all primacy States/territories/tribes would be required to submit a revised program to the EPA for approval within two years of promulgation of any final perchlorate NPDWR or could request an extension of up to two years in certain circumstances.

*B. What are the State Record Keeping Requirements?*

The current regulations in 40 CFR 142.14 require States with primary enforcement responsibility (i.e., primacy) to keep records of analytical results to determine compliance,

system inventories, sanitary surveys, State approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The State record keeping requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant.

*C. What are the State Reporting Requirements?*

Currently, States must report to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs. The State reporting requirements remain unchanged and would apply to perchlorate as with any other regulated contaminant. However, the perchlorate MCL could result in a greater frequency of reporting by certain states. See discussion of Paperwork Reduction Act compliance in Section XVI for more information.

## XII. Health Risk Reduction Cost Analysis

Section 1412(b)(3)(C) of the 1996 Amendments to the SDWA requires the EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWR that includes an MCL. This section addresses the HRRCA requirements as indicated:

- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level (Sections XII.C and XII.D);
- Quantifiable and non-quantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur

from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations (Section XII.C);

- Quantifiable and non-quantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations (Section XII.B and XII.D);
- The incremental costs and benefits associated with each alternative MCL considered (Section XII.D);
- The effects of the contaminant on the general population and on groups within the general population, such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other sensitive populations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population (Section XII.C and Section III);
- Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants (Section XII.C); and
- Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk (Section XII.E).

### *A. Identifying Affected Entities*

If the EPA issues a final NPDWR for perchlorate, it would affect the following entities: CWSs and NTNCWSs that must meet the proposed MCL and monitoring and reporting requirements; and primacy agencies that must adopt and enforce the MCL as well as the monitoring and reporting requirements. All of these entities would incur costs, including administrative costs, monitoring and reporting costs, and – in a limited number of cases – costs to reduce perchlorate levels in drinking water to meet the proposed MCL using treatment or nontreatment options. Section B below summarizes the method the EPA used to estimate these costs.

The systems that reduce perchlorate concentrations will reduce associated health risks. The EPA developed a method to estimate the potential benefits of reduced perchlorate exposure among the service populations of systems with elevated baseline perchlorate levels. Section C below summarizes this method used to estimate these benefits.

Section D below provides the cost and benefit estimates. The EPA prepared the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a), which is available in the docket for the proposed rule. Section XIII summarizes and discusses key uncertainties in the cost and benefit analyses.

### *B. Method for Estimating Costs*

Some costs associated with an NPDWR are incurred by all CWS and NTNCWS (e.g. monitoring and reporting) while others are only incurred by systems with perchlorate levels

exceeding the MCL. 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. If site-specific nontreatment options are available and lower cost, then this assumption might overstate costs. The EPA also estimated the costs for States and other primacy agencies to assure systems implement the rule and to report information to the EPA.

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. Table XII-1 summarizes the frequency and labor hour assumptions for this analysis.

**Table XII-1: Labor Hours for Drinking Water Systems Administrative and Monitoring Requirements**

| Activity | Frequency | Small System Hours | Large System Hours |
|---|---|---|---|
| Read the rule | one time per system | 4 | 4 |
| Provide initial training | one time per system | 16 | 32 |
| Apply to State for monitoring waiver | once every 9 years per eligible system | 16 | 16 |

| Activity | Frequency | Small System Hours | Large System Hours |
|---|---|---|---|
| Collect a single finished water sample[1] | per monitoring event | 1 | 1 |

Source (USEPA, 2000a). The EPA's cost analysis reflects full MCL compliance and therefore the EPA did not estimate Tier 1 notification costs.
1. The estimate is per sample. Therefore, a system conducting a year of quarterly monitoring at three entry points incurs a total of 12 hours of labor to complete the task (3 entry points x 4 samples x 1 hour per sample).

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. The estimated number of monitoring samples over the analysis period shown in Table XII-2 reflect the following phases:

1. Initial monitoring; four quarterly samples at every CWS and NTNCWS entry point.

2. Preliminary regular monitoring before waiver application: three regular monitoring samples for every CWS and NTNCWS entry point (collected annually at surface water system entry points and triennially at ground water system entry points).

3. Long-term monitoring at either (a) regular monitoring frequency for entry points at systems not granted waivers (60% of surface water system and 10% of ground water systems), or (b) reduced monitoring frequency for entry points at systems receiving waivers from primacy agencies (40% of surface water systems and 90% of ground water systems), which is one sample during every nine-year compliance monitoring cycle.

**Table XII-2: Estimates of Compliance Monitoring Samples by Phase and System Type, Size, and Source Water**

| Monitoring Phase (sampling frequency) | System Type, Size, and Source Water | Number of Entry Points[1] | Aggregate Samples[2] |
|---|---|---|---|
| 1. Initial monitoring (4 quarterly samples in one year) | All CWS and NTNCWS | 92,656 | 370,624 |
| 2. Preliminary regular monitoring (3 annual entry point samples for surface water systems and 3 triennial entry point samples for ground water systems) | All CWS and NTNCWS | 92,654 | 277,962 |
| 3a. Long-term monitoring, no waiver (annual entry point samples) | 60% of large surface water CWS | 3,324 | 86,424 |
| | 60% of small surface water CWS and all surface water NTNCWS | 6,064 | 139,472 |
| 3a. Long-term monitoring, no waiver (triennial entry point samples) | 10% of large ground water CWS | 680 | 4,080 |
| | 10% of small ground water CWS and all ground water NTNCWS | 7,021 | 35,105 |
| 3b. Long-term monitoring, waiver (1 sample every 9 years) | 40% of large surface water CWS | 2,216 | 4,432 |
| | 40% of small surface water CWS and all surface water NTNCWS | 4,043 | 8,086 |
| 3b. Long-term monitoring, waiver (1 sample every 9 years) | 90% of large ground water CWS | 6,117 | 12,234 |
| | 90% of small ground water CWS and all ground water NTNCWS | 63,189 | 63,189 |

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780).

1. The EPA estimated a total of 92,656 entry points based on the total number of potentially affected systems in SDWIS/FED and the average number of entry points per system in the UCMR 1 data by size category and source water. The initial monitoring phase includes all entry points. The EPA assumed that the two entry points with MCL exceedances at the proposed MCL of 56 µg/L would continue to take quarterly samples for the duration of the analysis period, for a total of 232 samples. Thus, they are excluded from the estimates for the subsequent phases of regular and long-term monitoring. Primacy agencies may, however, allow monitoring to return to a regular schedule if treatment process operation can reliably and consistently reduce perchlorate below the MCL.
2. For Phase 3, the estimate of aggregate samples is the product of the number of entry points and the frequency of sampling during the remaining years of the analysis period. For example, large surface water CWS without a waiver conduct long-term annual monitoring for 26 years because they complete preliminary regular monitoring in year 9. In contrast, large ground water CWS without a waiver begin long-term triennial monitoring in year 16 because their preliminary regular monitoring phase lasts for 9 years (3 triennial samples) instead of 3 years (3 annual samples). The estimates also reflect schedule differences by size because large CWS begin monitoring schedules three years earlier than small CWS and all NTNCWS.

To estimate costs to CWSs and NTNCWSs associated with time spent on compliance monitoring and other administrative costs, the EPA generally uses the labor rate[13] 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.

[13] Updated to 2017$ using the BLS Employment Cost Index for Total Compensation for Private industry workers in Utilities.

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 WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS approach involves breaking a process down into discrete components for the purpose of estimating costs and produce a comprehensive assessment of the capital and operating requirements for a treatment system[14]. 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

[14] The document *Technologies and Costs for Treating Perchlorate-Contaminated Waters* (USEPA, 2018c) contains more complete discussion of the WBS models and the cost estimating approach.

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. For each entry point in the UCMR 1 dataset outside of these two States, the EPA compared the maximum observed perchlorate concentration to the MCL to identify those that have an exceedance of the proposed MCL. The EPA assumed that these entry points would incur costs for an additional confirmation sample and would need to implement treatment to meet the MCL. For each entry point, the EPA estimated the design flow and the average flow by service populations based on the Agency's prior analysis of the relationships between these values (USEPA, 2000b). The Agency assumed blending of treated water and untreated water would be used to meet an average treatment target equal to 80 percent of the MCL (for an MCL of 56 µg/L the blending target would be 45 µg/L) given a 95 percent removal effectiveness until perchlorate breakthrough. The Agency applied the capital cost and O&M cost curves from the WBS models to the design and average flows adjusted for blending. When small systems in the UCMR 1 sample incurred treatment costs, the EPA extrapolated the costs on a per capita basis to the estimate of national population exposure derived using the small system population sampling weights.

For the primacy agencies that will implement and enforce the rule (including 49 States, one tribal nation and 5 territories), the EPA estimated upfront costs incurred during the three years between rule promulgation and the effective date to read and understand the rule, adopt regulatory changes, and provide training to CWSs and NTNCWSs and Agency staff. Primacy agencies will also have recurring costs to review waiver applications and monitoring reports. Table XII-3 summarizes the labor hour assumptions for these activities. The EPA requests comments on these assumptions.

**Table XII-3: Labor Hours for Primacy Agency Administrative Requirements**

| Activity | Frequency | Hours |
|---|---|---|
| Read and understand the rule, adopt regulatory changes[1] | one time per Agency | 416 |
| Provide initial training and assistance to water systems[2] | total per Agency | 2,080 |
| Provide initial training to staff[2] | total per Agency | 250 |
| Review waiver applications | once every 9 years per eligible system | 8 |
| Review monitoring reports | per monitoring event | 1 |

Source (USEPA, 2000a)
1. The EPA assumed that two States that already regulate perchlorate in drinking water would not incur the incremental burdens in this table to regulate perchlorate under the proposed rule because they already incur baseline costs for perchlorate regulation including monitoring costs. The Agency assumed, however, that the two States would incur an average of 40 hours to confirm that their existing requirements are at least as protective as the proposed rule.
2. The EPA assumed that all training hours occur in a single year, although the hours may actually occur over time. The total hour estimates are average values across States.

State labor rates are based on the mean hourly wage rate from Bureau of Labor Statistics (BLS) Standard Occupational Classification code 19-2041 (State Government –Environmental Scientists and Specialists, Including Health). Wages are loaded using a factor calculated from the BLS Employer Costs for Employee Compensation report (Bureau of Labor Statistics (BLS),

2016 Table 3), for a fully loaded hourly wage rate for States of $50.67. The EPA requests comments on these labor rate assumptions.

The proposed rule provides three years between the effective dates and compliance dates for systems. For the purpose of estimating costs, the EPA assumed that large CWSs would phase in administrative costs, including initial monitoring, and upfront administrative costs uniformly over the 3 years following the effective date (i.e., years 4 to 6 of the analysis period). Similarly, the EPA assumed that small CWSs and NTNCSs will phase in these costs over the subsequent three-year period (i.e., years 7 to 9 of the analysis period). The EPA assumed that, within these periods, all systems would conduct initial monitoring – one year of quarterly monitoring to determine whether perchlorate concentrations are consistently and reliably below the proposed MCL. Thereafter, systems with MCL exceedances would continue to monitor quarterly, while systems below the MCL that obtain waivers will monitor annually for three years (surface water systems) or triennially for 9 years (ground water systems), then incur costs for a waiver application. Thereafter, these systems will continue reduced monitoring - once every nine years - under subsequent waivers. Systems that are below the MCL without waivers will monitor once per year (surface water systems) or once every three years (groundwater). Consistent with USEPA (2008b), the EPA assumed that 90% of groundwater and 40% of surface water systems that have all entry points below the MCL would obtain waivers.

The EPA estimated the costs over a 35-year analysis period, which includes a 3-year period prior to the effective date to allow for State rule adoption activities, a 3-year period after

the effective date to allow initial monitoring among large CWSs, and a 3-year period after that to allow initial monitoring for small CWSs and NTNCWSs. Evaluating costs over 35 years covers a full life cycle of the capital investments that large systems make in the 6th year; the WBS estimates of composite useful life of the equipment and infrastructure investment is approximately 30 years. The EPA assumed that treatment modifications will be completed in the final year of the initial monitoring period (i.e., year 6 of the analysis for large CWSs and year 9 for small CWSs and NTNCWSs). The EPA calculated the present value of total costs in each year of the analysis period and discounted to year 1 using both a 3% and 7% discount rate and annualized total present value of costs at the same rates over 35 years to obtain a constant total annual cost estimate to compare to total annual benefits.

Water systems typically recover costs through increased household rates, resulting in increased costs at the household level[15]. 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.

[15] For systems with monitoring costs only, household-level costs will be negligible.

### *C. Method for Estimating Benefits*

The EPA has taken an approach in evaluating the benefits for perchlorate that is consistent with the SAB's recommendations for the methodology to inform the MCLG for perchlorate. This approach involves a) using a BBDR model to estimate the impact of perchlorate on maternal thyroid hormone levels during the first trimester of pregnancy, and b) using a dose-response function from the epidemiological literature to model the relationship between altered maternal thyroid hormone levels and offspring IQ. 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. Uncertainties regarding the quantifiable benefits are also 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).

The EPA used 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. Because the dose-response relationship between perchlorate exposure and maternal fT4 is dependent on maternal iodine intake status, this first-step analysis is repeated for several categories of iodine intake. For the BBDR simulations, the EPA used the 90$^{th}$ percentile ingestion rate to be consistent with the MCLG modeling approach, which may overstate the exposure in the simulation.

The second step of the dose-response model subsequently relates the predicted changes in maternal fT4 from the BBDR model to changes in child IQ using the function estimated in the EPA independent analysis of the Korevaar et al., (2016) study data. Ultimately, the changes in IQ are estimated for each impacted iodine intake group, and all of the impacted iodine intake groups' IQ decrements are averaged together based on the proportion of individuals in each

iodine intake category. Table XII-4 shows the specific iodine intake groups and the proportion of non-pregnant women of childbearing age that fall into each group.

**Table XII-4: Proportion of Population based on Maternal Iodine Intake Status**

| Iodine Intake Range (µg/ day) used for Benefits Analysis | Proportion of the population |
|---|---|
| 0 to <55 | 7.14% |
| 55 to <60 | 2.15% |
| 60 to <65 | 1.06% |
| 65 to < 70 | 1.86% |
| 70 to <75 | 1.31% |
| 75 to <80 | 3.10% |
| 80 to <85 | 2.62% |
| 85 to <90 | 1.20% |
| 90 to <95 | 1.83% |
| 95 to <100 | 2.94% |
| 100 to <125 | 13.56% |
| 125 to <150 | 9.08% |
| 150 to <170 | 10.31% |
| 170 to <300 | 24.47% |
| ≥300 | 17.36% |

Source: U.S. EPA (2019a).

These changes in child IQ are then monetized using the EPA's estimate of the value of an IQ point. This estimate reflects the discounted present value of lifetime income reductions attributable to a 1-point reduction in IQ at birth. Therefore, the present value depends on the discount rate. At a 3 percent discount rate, the estimate is $18,686 per IQ point; at a 7 percent discount rate the estimate is $3,631.

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.

*D. Comparison of Costs and Benefits*

This section provides the estimates of costs and benefits that the EPA derived using the methods described above. It includes estimates for the proposed and alternative MCLs.

For the proposed MCL of 56 µg/L, Table XII-5 summarizes the total estimated cost of the proposed rule to water systems and primacy agencies, and Table XII-6 summarizes the estimated per-household cost for the system incurring treatment costs[16]. Table XII-7 summarizes the estimated benefits. In both instances, the estimates based on the UCMR 1 sample are also national estimates because treatment costs occur only at large systems; there are no small system treatment costs or related benefits to extrapolate.

[16] For all households served by all of the systems subject to the monitoring costs as well as MCL compliance, the average annual cost is less than $0.20.

**Table XII-5: Summary of Total Annualized Costs at MCL of 56 µg/L (Millions; 2017$)**

| Cost Component | 3% Discount | 7% Discount |
|---|---|---|
| Drinking Water Systems Treatment Costs | $0.65 | $0.70 |
| Drinking Water Systems Monitoring and Administration Costs[1] | $5.93 | $6.38 |
| Drinking Water Systems Costs Subtotal | $6.58 | $7.07 |
| State Administration Costs | $3.09 | $3.20 |
| Total Costs | $9.67 | $10.28 |

Source: (USEPA, 2019a). Detail may not sum to total because of independent rounding.
1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

**Table XII-6: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 56 µg/L (2017$)**

| Cost Range | 3% Discount | 7% Discount |
|---|---|---|
| Minimum | $11 | $14 |
| Average | $40 | $47 |
| Maximum | $69 | $80 |

Source: (USEPA, 2019a).

**Table XII-7: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 56 µg/L (Millions; 2017$)**

| Korevaar β distribution | Annual Delta IQ | 3% Discount | 7% Discount |
|---|---|---|---|
| Upper | 243 | $3.57 | $0.60 |
| Central | 136 | $2.00 | $0.34 |
| Lower | 30 | $0.44 | $0.07 |

Source: (USEPA, 2019a)

For the alternative MCL of 18 µg/L, Table XII-8 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-9 summarizes the per-household cost for systems requiring treatment, which vary across the systems. Table XII-10 summarizes the quantified benefits. At this threshold, one entry point for one small system in the UCMR 1 data had an exceedance. Therefore, the EPA extrapolated the treatment costs and benefits from the UCMR 1 estimates to national estimates based on sampling weights.

**Table XII-8: Summary of Total Annualized Costs at MCL of 18 µg/L (Millions; 2017$)**

| Cost Component | 3% Discount (UCMR 1)[1] | 7% Discount (UCMR 1)[1] | 3% Discount (National)[1] | 7% Discount (National)[1] |
|---|---|---|---|---|
| Drinking Water Systems Treatment Costs | $6.92 | $7.29 | $7.92 | $8.37 |
| Drinking Water Systems Monitoring and Administration Costs | $5.94 | $6.38 | $5.94 | $6.38 |
| Drinking Water Systems Costs Subtotal | $12.85 | $13.67 | $13.86 | $14.75 |
| State Administration Costs | $3.09 | $3.21 | $3.09 | $3.21 |
| Total Costs | $15.95 | $16.88 | $16.95 | $17.96 |

Source: (USEPA, 2019a). Detail may not sum to total because of independent rounding.

1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 775,000 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L. The EPA calculated per-capita costs for the system and extrapolated to national level based on this population estimate.

2. Costs include monitoring for all CWS and NTNCWS. Under 40 CFR 141.29 some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided primacy agencies, with EPA concurrence, allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and primacy agency decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

**Table XII-9: Summary of Household-Level Annual Costs for Systems Treating to Comply with the MCL at 18 µg/L (2017$)**

| Cost Range | 3% Discount (UCMR 1)[1] | 7% Discount (UCMR 1)[1] | 3% Discount (National)[1] | 7% Discount (National)[1] |
|---|---|---|---|---|
| Minimum | $18 | $24 | $18 | $24 |
| Average | $38 | $46 | $38 | $46 |
| Max | $72 | $84 | $72 | $84 |

Source: (USEPA, 2019a)
1. National cost estimates include extrapolation for one small system entry point to national estimates based on sampling weights. The per-household costs are the same for the sample and national extrapolations because the small system cost extrapolation occurs on a per-capita basis.

**Table XII-10: Total and Annualized Benefits of Avoided Lost IQ Decrements at 18 µg/L (Millions; 2017$)**

| Korevaar β distribution | Annual Delta IQ | | UCMR 1 | | National[1] | |
|---|---|---|---|---|---|---|
| | UCMR 1 | National[1] | 3% Discount | 7% Discount | 3% Discount | 7% Discount |
| Upper | 442 | 447 | $6.50 | $1.10 | $6.56 | $1.11 |
| Central | 248 | 251 | $3.65 | $0.62 | $3.68 | $0.62 |
| Lower | 54 | 55 | $0.80 | $0.13 | $0.80 | $0.14 |

Source: (USEPA, 2019a)
1. The EPA applied statistical sampling weights to the results to extrapolate small system results to national results. The entry point at which a measurement exceeds 18 µg/L is one of 20 in its sample stratum; no other sample in the stratum had a measurement of perchlorate greater than the minimum reporting level. The entry point population of 2,155 represents 5.31% of the total population served by the six UCMR 1 systems in the stratum (40,574). Currently, the stratum population of 774,780 accounts for 1.32% of the 58.7 million national population served by small systems. Thus, the UCMR 1 results indicate that 0.07% (5.31% x 1.32%) of small system customers (approximately 41,100) may be exposed to perchlorate greater than 18 µg/L. The EPA assumed that this population would incur benefits equivalent to the sampled entry point's population.

For the alternative MCL of 90 µg/L, Table XII-11 summarizes the total cost of the proposed rule to water systems and primacy agencies, and Table XII-12 summarizes the per-

household cost for systems requiring treatment, which vary across the systems. Table XII-13 summarizes the quantified benefits. At this threshold, no small systems in the UCMR 1 data had an exceedance. Therefore, treatment costs and benefits for the UCMR 1 data are the national estimates.

**Table XII-11: Summary of Total Annualized Costs at MCL of 90 µg/L (Millions; 2017$)**

| Cost Component | 3% Discount | 7% Discount |
|---|---|---|
| Drinking Water Systems Treatment Costs | $0.49 | $0.52 |
| Drinking Water Systems Monitoring and Administration Costs[1] | $5.93 | $6.37 |
| Drinking Water Systems Costs Subtotal | $6.42 | $6.89 |
| State Administration Costs | $3.09 | $3.20 |
| Total Costs | $9.51 | $10.10 |

Source: (USEPA, 2019a). Detail may not sum to total because of independent rounding.
1. Costs include monitoring for all CWS and NTNCWS. Some consecutive systems that purchase 100% of their water from wholesale systems may not be required to monitor for perchlorate provided States allow integrated system agreements to include perchlorate among the monitoring requirements that the wholesale system fulfills for the consecutive system. The potential number of consecutive systems excluded from perchlorate monitoring depends on system and State decisions and, therefore, is unknown. Excluding monitoring costs for approximately 8,400 consecutive systems that do not report a water source facility (e.g., well or intake) in SDWIS/FED from the monitoring cost analysis reduces annualized monitoring costs by $0.8 million.

**Table XII-12: Summary of Household-Level Annual Costs for Systems Treating to Comply with MCL at 90 µg/L (2017$)**

| Cost Range | 3% Discount | 7% Discount |
|---|---|---|
| Minimum | $65 | $76 |
| Average | $65 | $76 |
| Maximum | $65 | $76 |

Source: (USEPA, 2019a). There is no variation in costs because treatment costs occur at one entry point. The household costs are slight lower compared to the maximum cost at 56 µg/L because treatment costs to meet an MCL of 90 µg/L are lower than the costs to meet an MCL of 56 µg/L.

**Table XII-13: Summary of Total Annualized Benefits of Avoided Lost IQ Decrements at MCL of 90 µg/L (Millions; 2017$)**

| Korevaar β distribution | Annual Delta IQ | 3% Discount | 7% Discount |
|---|---|---|---|
| Upper | 222 | $3.26 | $0.55 |
| Central | 124 | $1.83 | $0.31 |
| Lower | 27 | $0.40 | $0.07 |

Source: (USEPA, 2019a)

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.

**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.

## XIII. Uncertainty Analysis

The EPA has presented an extensive discussion of the uncertainties in the key analyses informing this proposal in the uncertainty section of the MCLG Approaches Report and the uncertainties section of the Economic Analysis document (*USEPA, 2018b; USEPA, 2019a)*. A summarized description of these uncertainties are presented below.

### *A. Uncertainty in the MCLG Derivation*

Each input into the analysis to inform the MCLG is a decision point associated with uncertainty. There is uncertainty in different aspects of the BBDR model, ranging from structural and functional relationships to specific parameter values for early pregnancy. There are very few data available to calibrate the pharmacokinetic aspects of the model, particularly at the life stage of interest. Also, the BBDR model does not explicitly consider the effect of the presence of other goitrogens (e.g. thiocyanate, nitrate) or effects of thyroid disease states. Toxicodynamic aspects such as competitive inhibition at the NIS, depletion of iodide stores under different iodine intake levels and physiological states, and the ability of the TSH feedback loop to compensate for perturbations in thyroid function each have their own uncertain features. Additional uncertainty

is introduced by linking the BBDR model estimates of maternal fT4 to altered neurodevelopment in offspring. None of the studies used to evaluate potential adverse neurodevelopmental outcomes in offspring born to hypothyroxinemic mothers was performed in the U.S. None of the studies measured perchlorate exposure. Not all the studies measured iodide levels in the study populations. The state of the science on the relationship between maternal fT4 levels and offspring neurodevelopment is constantly evolving. There are numerous indices used to assess neurodevelopmental impacts and there is some uncertainty regarding the selection of IQ as the critical endpoint for setting the MCLG.

A recently published paper evaluating the EPA's BBDR model and MCLG Approaches, reiterated the uncertainties the Agency identified in its analyses and questions the use of these quantitative tools for perchlorate in a regulatory context (Clewell et al., 2019).

*B. Uncertainty in the Economic Analysis*

The EPA provides discussions regarding several sources of uncertainty in the benefit and cost estimates in the Health Risk Reduction and Cost Analysis (USEPA, 2019a). Table XIII-1 provides a summary of sources of uncertainty and their potential effects on estimated costs and benefits. The following discussion addresses uncertainties specific to the benefits analysis.

**Table XIII-1. Sources of Uncertainty in Economic Analysis**

| Description | Potential effect[1] |
|---|---|
| ***Baseline Occurrence*** | |
| UCMR 1 data are more than one decade old; actual occurrence could be lower (e.g., because of contaminant cleanup) or higher (e.g., because new systems use perchlorate-contaminated source water). | ± (benefits and costs will change in the same direction) |

| Description | Potential effect[1] |
|---|---|
| UCMR 1 data include a sample of small systems; the Stage 1 results (entry point maximums) indicate that no small systems would exceed 56 µg/L or 90 µg/L and that one small system would exceed 18 µg/L; it is possible that there are additional small systems where the baseline perchlorate is greater than the MCLs that are not captured in the national extrapolation results. | − (benefits and costs will change in the same direction) |
| The EPA assumed a uniform distribution of system population served across the entry points; the actual entry point service population could be greater than or less than the estimates. | ± (benefits and costs will change in the same direction) |
| | |
| ***Benefits Analysis*** | |
| The health risks and risk reductions are based on maximum recorded concentration estimates and thus do not account for exposures to concentrations greater than or less than this recorded maximum. | ± (benefits only) |
| The EPA assumed that baseline fT4 is equal to the median, which likely underestimates disease benefits as the logarithmic relationship between maternal fT4 and child IQ leads to larger relative changes in fT4, with increasing levels of perchlorate and lower levels of baseline fT4. | − (benefits only) |
| The EPA assumed a median TSH feedback loop strength for the exposed population does not incorporate the variability in the feedback mechanism of the body's creation of TSH in response to decreasing fT4. | ± (benefits only) |
| The EPA used a 90$^{th}$ percentile water intake rate to derive the MCLG and the dose-response equations for the benefits analysis. This approach results in a protective MCLG value, but may overstate intake for the benefits analysis[2]. | + (benefits only) |
| The IQ valuation uses estimates that the EPA derived using the same approach as Salkever (1995). Results from other IQ valuation studies might result in higher or lower benefit estimates. | ± (benefits only) |
| The benefits analysis is based on a single health endpoint and the value of the endpoint is based solely on lost earnings. | − (benefits only) |
| ***Cost Analysis*** | |
| The EPA assumed that systems requiring treatment would incorporate a safety factor – treating to 80% of the proposed MCL or alternative MCL, which increases costs and benefits. | + (benefits and costs will change in the same direction) |

| Description | Potential effect[1] |
|---|---|
| The EPA assumed that all entry points requiring treatment would implement ion exchange, which may overestimate costs if non-treatment is an option for one or more entry points or underestimate costs if site-specific conditions result in higher costs at one or more entry points. | ± (costs only) |
| The EPA developed a monitoring schedule that assumed a uniform distribution of initial monitoring costs over three years; actual costs will vary. | ± (costs only) |
| The EPA assumed that long-term monitoring costs would occur in the last year of the applicable three-year monitoring period or nine-year monitoring cycle; systems may conduct monitoring in an earlier year of the period or cycle. | − (costs only) |
| The EPA assumed that 90% of ground water systems and 40% of surface water systems obtain perchlorate monitoring waivers; the actual percentages may vary. | ± (costs only) |

1. A "−" symbol indicates that benefits and/or costs will tend to be underestimated. A "+" symbol indicates that benefits and/or costs will tend to be overestimated. A "±" symbol indicates an unknown direction of uncertainty, i.e., benefits and/or costs could be underestimated or overestimated.
2. The EPA did not include a perchlorate dietary dose in the benefits analysis, which would be unchanged between baseline and proposed MCL scenarios if many areas do not irrigate with drinking water. For people who obtain a significant portion of their fruit, vegetables, and milk from areas irrigated with the water from the same sources as the drinking water, we would expect their exposure may drop with the reduction of perchlorate in food products used locally. Because of this and the natural log form of the IQ response function, this approach may slightly understate the avoided IQ decrement estimates.

The EPA acknowledges the uncertainty regarding the quantitative health risk reduction. In particular, the Agency assumed it could estimate risk reductions based on evidence of a quantifiable relationship between thyroid hormone changes and neurodevelopmental outcomes.

There are a number of potential benefits of reducing perchlorate in drinking water that were not quantified as part of this analysis, which may result in an underestimate of actual benefits. As described by the SAB "children exposed gestationally to maternal hypothyroxinemia

(without hypothyroidism) show reduced levels of global and specific cognitive abilities, as well as increased rates of behavior problems including greater dysregulation in early infancy and attentional disorders in childhood (Man et al., 1991; Pop et al., 1999; Pop et al., 2003; Kooistra et al., 2006)" (p. 10, SAB for the U.S. EPA, 2013). The EPA's literature review identified potential relationships between maternal thyroid hormone alterations and the risk of schizophrenia, ADHD, expressive language delay, reduced school performance and increased odds of autism, among others, none of which are being currently quantified in this assessment. Other potentially omitted benefits include risks associated with effects of thyroid disorders in adults, including cardiovascular disease risk; changes in thyroid hormone levels and their relationship with total cholesterol, LDL cholesterol, and triglycerides; as well as a possible relationship between increases in TSH and risk of fatal coronary heart disease. Treating for perchlorate in drinking water could also potentially remove nitrate, which is a co-occurring contaminant and a goitrogen. These additional potential health endpoints are not monetized in this benefits analysis. The assumptions used to account for the previously mentioned variability of the BBDR model inputs and uncertainty surrounding the relationship between maternal fT4 and child IQ discussed above may result in an overestimate of the monetized benefits. Because IQ is a surrogate for broad range of potential neurodevelopmental risks, it is unclear whether the analysis as a whole over- or under-estimates the monetized benefits of a reduction of perchlorate in drinking water.

## XIV. Request for Comment on Proposed Rule

While all comments relevant to the national primary drinking water regulation for perchlorate proposed today will be considered by the EPA, comments on the following issues will be especially helpful to the EPA in developing a final rule. The EPA specifically requests comment on the following topics.

- The adequacy and uncertainties of the BBDR model developed by the EPA to predict thyroid hormone level changes caused by perchlorate exposure to pregnant women with low iodide intake, including the model and model parameters and assumptions (Section III and Approaches Report).
- The adequacy and uncertainties of the EPA's review and application of the epidemiologic literature to quantify the relationship between thyroid hormone changes in pregnant women and neurodevelopmental effects including the assumptions, the selection of the approach used, and the study used (Section III and Approaches Report).
- The adequacy and uncertainties of the methodology to derive the MCLG including points of departure, assumptions, uncertainty factor, and relative source contribution (Section III and Technical Support Document: Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water).
- 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 adequacy of the underlying assumptions and analysis of occurrence (Section VI).
- 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).
- The adequacy of the underlying estimates, assumptions and analysis used to estimate benefits and describe unquantified benefits (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.

**XV. Request for Comment on Potential Regulatory Determination Withdrawal**

The EPA is soliciting comments on withdrawing the 2011 Regulatory Determination (see Section II-C, Regulatory History) based on several factors. 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[17] and suggest that the regulation of perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. The proposed regulation would require over sixty thousand public water systems to monitor for perchlorate, but the available data indicates that very few would find it at levels of public health concern. 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

[17] As shown in Section VI of this notice there is infrequent occurrence of perchlorate at either 56 µg/L, 18 µg/L or 90 µg/L, which are the possible levels expected to cause adverse human health effects.

U.S.) that would exceed the regulatory threshold. Only one system would exceed the alternative MCL of 90 µg/L.

The EPA notes that in 2008, the EPA stated in its preliminary regulatory determination that perchlorate did not occur with a frequency and at levels of public health concern in public water systems based upon the health effects and occurrence information available at that time, which indicated that 0.8% of public water system had perchlorate at levels exceeding the HRL of 15 µg/L. The EPA also stated that there was not a meaningful opportunity for a NPDWR to reduce health risks based upon the estimates at that time that 0.9 million people had perchlorate levels above the HRL.

The EPA further notes that the Agency has previously determined CCL1 and CCL2 contaminants did not occur with frequency at levels of public health concern when the percentage of water systems exceeding the HRL were greater than the frequency of perchlorate occurrence level at the proposed MCL (0.004% of all water systems in the U.S.). For example, in 2003 the EPA determined that aldrin did not occur with a frequency and at levels of public health concern based upon data that showed 0.2% of water systems had aldrin at levels greater than the HRL. The EPA also concluded that there was not a meaningful opportunity for health risk reduction for persons served through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 1 million people (USEPA, 2003). In 2008 the EPA determined that DCPA Mono- and Di-Acid degradates did not occur with a frequency and at levels of public health concern based on data that showed 0.03%

of water systems exceeded the HRL. The EPA also included that there was not a meaningful opportunity for health risk reduction through a drinking water regulation based on this occurrence data and the estimate that these systems above the HRL served approximately 100,000 people (USEPA, 2008e).

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. As with other unregulated contaminants, the EPA could address the limited instances of elevated levels of perchlorate by working with the states or using its SDWA Section 1431 imminent and substantial endangerment or Section 1412(b)(1)(f) health assessment authorities, as appropriate. The EPA also requests comments on what guidance it could provide the public if the regulatory determination for perchlorate is withdrawn.

## XVI. Statutory and Executive Order Reviews

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action since it raises novel legal or policy issues. It was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

The EPA evaluated the potential costs to States and utilities and the potential benefits of the proposed rule. This analysis, *Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a)* is available in the docket and is summarized in section XI.

*B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs*

This action is expected to be an Executive Order 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the EPA's analysis of the potential costs and benefits associated with this action.

*C. Paperwork Reduction Act*

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. The information collection requirements are not enforceable until OMB approves them.

The monitoring information collected as a result of this rule will allow the States and the EPA to evaluate compliance with the rule. For the first 3-year period following rule

promulgation, the major information requirements concern primacy agency activities to implement the rule including adopting the NPDWR into state regulations, providing training to state and PWS employees, updating their monitoring data systems, and reviewing system monitoring data and waiver requests. Compliance actions for drinking water systems (including monitoring, administration, and treatment costs) would not begin until after Year 3 due to the proposed effective date of this rule.

The estimate of annual average burden hours for the proposed rule during the first three years following promulgation is 48,539 hours. The annual average cost estimate is $7.4 million for labor. The burden hours per response is 2,648 hours and the cost per response is $134,159. The frequency of response (average responses per respondent) is 1 for primacy agencies, annually (for upfront administrative activities to implement the rule). The estimated number of likely respondents is 55 over the three-year period (for an average of 18.3 each year).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, to the EPA at the public docket established for this rule, which includes the ICR, Docket ID No. **EPA-HQ-OW-2018-0780**. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to OIRA_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The EPA will respond to any ICR-related comments in the final rule.

*D. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The Agency has determined that the proposed MCL of 56 µg/L will not result in annual costs that exceed one percent of revenue for small systems affected by the proposed rule.

The small entities subject to the requirements of this action are public water systems serving 10,000 or fewer persons. This is the threshold specified by Congress in the 1996

Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, the EPA proposed using this alternative definition in the Federal Register, (63 FR 7620, February 13, 1998), requested public comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). As stated in that final rule, the alternative definition is applied to this proposed regulation.

The proposed rule contains provisions that would affect 58,325 CWS and NTNCWS serving 10,000 or fewer people. In order to meet the proposed rule requirements, all of these systems will need to conduct perchlorate monitoring. At the proposed MCL of 56 µg/L, the UCMR 1 monitoring data indicate that no small systems would be required to incur costs to reduce the levels of perchlorate in drinking water, therefore, all small PWSs will incur monitoring costs only. Impacts on small entities are described in more detail in Chapter 7 of the Health Risk Reduction Cost Analysis of the Proposed Perchlorate Rule (USEPA, 2019a). Table XII-1 and Table XII-2 show the annual compliance costs of the proposed rule on the small entities by system size for public and private systems, respectively. Based on a comparison of annual costs with annual revenue estimates, the EPA has determined that no small systems will experience an impact of one percent or greater of average annual revenues (USEPA 2019a).

**Table XII-1: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Public CWSs by Size Category**

| Size Category | Average Annual Revenues[a] | 3% Discount[b] | 7% Discount[b] |
|---|---|---|---|
| Population served <100 | $224,248 | $88 (0.04%) | $94 (0.04%) |
| Population served 101-500 | $197,315 | $88 (0.04%) | $94 (0.05%) |
| Population served 501-3,300 | $202,382 | $88 (0.04%) | $94 (0.05%) |
| Population served 3,301-10,000 | $1,092,187 | $88 (0.01%) | $94 (0.01%) |

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS (USEPA, 2009c Table 65) and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers (BLS, 2018a). Revenues include all sources of revenue including water revenue, non-water revenue, and municipal transfers to water systems.

b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

**Table XII-2: Annualized Monitoring and Administrative Costs as a Percentage of Average Annual Revenue for Small Private CWSs by Size Category**

| Size Category | Average Annual Revenues[a] | 3% Discount[b] | 7% Discount[b] |
|---|---|---|---|
| Population served <100 | $139,911 | $88 (0.06%) | $94 (0.07%) |
| Population served 101-500 | $351,974 | $88 (0.03%) | $94 (0.03%) |
| Population served 501-3,300 | $254,706 | $88 (0.03%) | $94 (0.03%) |
| Population served 3,301-10,000 | $951,692 | $88 (0.01%) | $94 (0.01%) |

Source: Perchlorate Benefit-Cost Analysis Spreadsheet available in the proposed rule docket (EPA-HQ-OW-2018-0780)

a. Based on the CWSS (USEPA, 2009c Table 65) and updated to 2017$ based on the chained consumer price index for fuels and utilities in U.S. city average, all urban consumers (BLS, 2018a). Revenues include all sources of revenue including water revenue and non-water revenue.

b. Total annual monitoring and administrative costs for PWSs are approximately $6.6 million to $7.1 million annually (Exhibit 5 5), with $5.1 million to $5.5 million accruing to small PWSs. Based on 58,325 small systems, this yields an average annual per-system cost of $88 (3% discount rate) to $94 (7% discount rate).

*E. Unfunded Mandates Reform Act*

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538. The action imposes minimal enforceable duty on any state, local or tribal governments or the private sector

Based on the cost estimates detailed in Section XI, the EPA determined that compliance costs in any given year would be below the threshold set in UMRA, with maximum single-year costs of approximately $10.2 million. The EPA has determined that this rule contains a federal mandate that would not result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year.

*F. Executive Order 13132: Federalism*

This action does not have federalism implications. It will not have substantial direct effects of greater than $25 million on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Annual costs are estimated to range from $9.6 million at a 3 percent discount rate to $10.2 million using a 7 percent, with $6.5 million to $7.0 million annually accruing to public entities. The EPA has concluded that this proposed rule may be of interest because it may impose direct compliance costs on State or local governments, and the federal government will not provide the funds necessary to pay those costs.

*G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

The EPA has concluded that this proposed rule may have Tribal implications, because it may impose direct compliance costs on Tribal governments, and the federal government would not provide the funds necessary to pay those costs. The EPA has identified 768 water systems with 1,167 entry points under Native American ownership that may be subject to the proposed rule. They would bear an estimated total annualized cost of $74,100 at a 3 percent discount rate ($79,625 at 7 percent) to implement this rule as proposed, with all costs attributable to monitoring and administrative costs. Estimated average annualized cost per system ranges from $96 at a 3 percent discount rate to $104 at a 7 percent discount rate.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of Executive Order 13175. The EPA consulted with representatives of Tribal officials early in the process of developing this proposed regulation to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes which included a webinar with interested tribes on February 28, 2012, to request input and provide rulemaking information to interested parties. A meeting summary report is available on the docket for public inspection (USEPA 2012a). The EPA notes that 751 of the 768 Tribal systems identified by the Agency as subject to the proposed rule are small systems that are expected to incur only monitoring costs. Due to the health risks associated with perchlorate, capital expenditures needed for compliance with the rule would be eligible for federal funding sources, specifically the Drinking Water State Revolving Fund. In the spirit of Executive Order

13175, and consistent with the EPA policy to promote communications between the EPA and Tribal governments, the EPA specifically solicits additional comment on this proposed rule from Tribal officials.

*H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks*

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866; however, the environmental health risk addressed by this action may have a disproportionate effect on children. Accordingly, the EPA evaluated the environmental health or safety effects of perchlorate on children. The results of this evaluation are contained in the Health Effects Technical Support Document (USEPA 2018a) and described in section III of this preamble. The EPA has evaluated the risk associated with perchlorate in drinking water for the sensitive subpopulation – offspring of pregnant women exposed to perchlorate during the first trimester – and established a proposed MCLG that is protective of this subpopulation as well as other children. The EPA also estimated the health risk reduction of the proposed and alternative MCLs. This analysis is described in the Health Risk Reduction and Cost Analysis for the proposed rule (USEPA 2019a) and is summarized in section XI of this preamble. Copies of the Health Effects Technical Support Document and Economic Analysis and supporting information are available in the public docket for today's proposal.

*I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or

Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This determination is based on the following analysis.

The first consideration is whether the proposed rule would adversely affect the supply of energy. The proposed rule does not regulate power generation, either directly or indirectly. The public and private water systems that the proposed rule regulates do not generate power. Further, the cost increases borne by customers of water utilities as a result of the proposed rule are a low percentage of the total cost of water, except for a few water systems that might install treatment technologies and would likely spread that cost over their customer base. In sum, the proposed rule does not regulate the supply of energy, does not generally regulate the utilities that supply energy, and is unlikely to affect significantly the customer base of energy suppliers. Thus, the proposed rule would not translate into adverse effects on the supply of energy.

The second consideration is whether the proposed rule would adversely affect the distribution of energy. The proposed rule does not regulate any aspect of energy distribution. The water systems that are regulated by the proposed rule already have electrical service. At the proposed MCL, one entry point at one system may require incremental power to operate new treatment processes. The increase in peak electricity demand at water utilities is negligible. Therefore, the EPA estimates that the existing connections are adequate and that the proposed rule has no discernable adverse effect on energy distribution.

The third consideration is whether the proposed rule would adversely affect the use of energy. Because only one system is expected to add treatment technologies that use electrical power, this potential impact on sector demand or overall national demand for power is negligible.

Based on its analysis of these considerations, the EPA has concluded that proposed rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

*J. National Technology Transfer and Advancement Act of 1995 and 1 CFR part 51*

The proposed rule could involve voluntary consensus standards in that it would require monitoring for Perchlorate. The EPA proposed five analytical methods for the identification and quantification of perchlorate in drinking water. The EPA methods 314.0, 314.1, 314.2, 331.0, and 332.0 incorporate quality control criteria which allow accurate quantitation of perchlorate. Additional information about the analytical methods is available in section VII of this notice. The EPA has made, and will continue to make, these documents generally available through www.regulations.gov and at the U.S. Environmental Protection Agency Drinking Water Docket, William Jefferson Clinton West Building, 1301 Constitution Ave NW, Room 3334, Washington, DC 20460, call (202) 566-2426

The EPA's monitoring and sampling protocols generally include voluntary consensus standards developed by agencies such as ASTM International, Standard Methods and other such bodies wherever the EPA deems these methodologies appropriate for compliance monitoring. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically,

invites the public to identify potentially-applicable voluntary consensus standards and to explain why such standards should be used in this regulation. The Director of the Federal Register approved the voluntary consensus standards incorporated by referenced in § 141.23 of the proposed regulatory text as of April 11, 2007.

*K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

The EPA has determined that this proposed rule would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it would increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

The public is invited to comment on this aspect of the proposed rulemaking and, specifically, to recommend additional methods to address Environmental Justice concerns from establishing a drinking water rule for perchlorate in drinking water.

## XVII. Consultations with the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the Safe Drinking Water Act (SDWA), the Agency consulted with the National Drinking Water Advisory Council (NDWAC or the Council); the Secretary of Health and Human Services; and with the EPA Science Advisory Board. The Agency consulted with NDWAC during the Council's October 4-5, 2012

meeting. A summary of the NDWAC recommendations is available in the National Drinking Water Advisory Council, Fall 2012 Meeting Summary Report (NDWAC, 2012b) and the docket for this proposed rule. The EPA carefully considered NDWAC recommendations during the development of a proposed drinking water rule for perchlorate.

On May 29, 2012, the EPA sought guidance from the EPA Science Advisory Board (SAB) on how best to consider and interpret life stage information, epidemiological and biomonitoring data since the publication of the National Research Council 2005 report, the Agency's physiologically-based pharmacokinetic (PBPK) analyses, and the totality of perchlorate health information to derive a Maximum Contaminant Level Goal (MCLG) for perchlorate (USEPA, 2012; NRC, 2005). On May 29, 2013, the EPA received significant input from SAB, summarized in the report, SAB Advice on Approaches to Derive a Maximum Contaminant Level Goal for Perchlorate (USEPA, 2013a).

On July 15, 2013, the EPA responded by stating that the Agency would consider all the recommendations from the SAB, as it continued working on the development of the rulemaking process for perchlorate (USEPA 2013b). To address SAB recommendations, the EPA collaborated with Food and Drug Administration (FDA) scientists to develop PBPK/pharmacodynamic (PD), or biologically based dose-response (BBDR), models that incorporate all available health related information on perchlorate to predict changes in thyroid hormones in sensitive life stages exposed to different dietary iodide and perchlorate levels (USEPA 2017). As recommended by SAB, the EPA developed these models based upon

perchlorate's mode of action (i.e., iodide uptake inhibition by the thyroid) (USEPA 2013a). Additional details are in section III.C. of this notice and in the Health Effects of Perchlorate support document located in the docket for this proposed rule.

In accordance with SAB recommendations, the EPA developed a two-stage approach to integrate BBDR model results with data on neurodevelopmental outcomes from epidemiological studies, this approach allowed the Agency to link maternal thyroid hormones levels as a result of low iodine intake and perchlorate exposure, to derive an MCLG that directly addresses the most sensitive life stage (USEPA 2013a).

On March 25, 2019, the EPA consulted with the Department of Health and Human Services (HHS). The EPA provided information to HHS officials on the draft proposed perchlorate regulation and considered HHS input as part of the interagency review described in section XVII.A.

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**List of Subjects**

**40 CFR Part 141**

Chemicals, Incorporation by reference, Indians-lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

**40 CFR Part 142**

Administrative practice and procedure, Chemicals, Indians-lands, Radiation protection, Reporting and recordkeeping requirements, Water supply.

Dated: May 23, 2019.

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Andrew R. Wheeler,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency proposes to amend 40 CFR parts 141 and 142 as follows:

**PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS**

1. The authority citation for part 141 continues to read as follows:

   **Authority:** 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11**.**

2. Amend § 141.6 by revising paragraph (a) and adding paragraph (l) to read as follows:

**Subpart A—General**

**§ 141.6 Effective dates.**

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part shall take effect on June 24, 1977.

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(l) The regulations contained in the revisions to §§ 141.23(a)(4)(i), 141.23(a)(5), 141.23(c),141.23(f)(1), 141.23(i)(1)-(2), 141.23(k)(1)-(3), 141.23(k)(3)(ii), 141.51(b), 141.60(b)(5), 141.62(b), 141.62(c), 141.62(e), Appendix A to Subpart O and Appendix A and B to Subpart Q are effective for the purposes of compliance on [**DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER**].

3. Amend § 141.23 by:

   a. In paragraph (a)(4)(i) table:

i. Revising the table heading; and

ii. Adding an entry for "Perchlorate" in alphabetical order;

b. In paragraph (a)(5), after the text "nickel," adding the text "perchlorate,";

c. In paragraph (c), after the text "nickel," adding the text "perchlorate,";

d. Adding paragraph (c)(10);

e. In paragraph (f)(1), after the text "nickel," adding the text "perchlorate,";

f. In paragraphs (i)(1) and (2), after the text "nickel," adding the text "perchlorate,";

g. Revising paragraph (i)(3);

h. In paragraph (k)(1):

i. Revising the introductory text; and

ii. In the table, adding the table designation, redesignating entries 21 through 26 as 22 through 27, and adding a new entry 21;

i. In paragraph (k)(2):

i. In the introductory paragraph, after the text "nitrite," adding the text "perchlorate,"; and

ii. In the table, adding the table designation and adding, in alphabetical order, an entry for "Perchlorate";

j. In paragraph (k)(3):

i. In the introductory paragraph, after the text "nitrite" adding the text ", perchlorate,"; and

ii. In paragraph (ii) table, adding the table designation, and adding in alphabetical order, an entry for "Perchlorate";

The revisions and additions read as follows:

**Subpart C—Monitoring and Analytical Requirements**

**§141.23 Inorganic chemical sampling and analytical requirements.**

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(a)***

(4)***

(i)***

**TABLE 1 TO PARAGRAPH (a)(4)(i) -- DETECTION LIMITS FOR INORGANIC CONTAMINANTS (COMPOSITED SAMPLES)**

| Contaminant | MCL (mg/l) | Methodology | Detection limit (mg/l) |
|---|---|---|---|
| ** | ** | ** | * |

| | | | |
|---|---|---|---|
| Perchlorate | 0.056 | Ion Chromatography | 0.00053 |
| | | Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection | 0.00003 |
| | | Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection | 0.000012-0.000018 |
| | | Liquid Chromatography Electrospray Ionization Mass Spectrometry | 0.000005 (Tandem Mass Spectrometry [MS/MS])<br>0.000008 (Selected Ion Monitoring [SIM]) |
| | | Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry | 0.00002 |
| ** | ** | ** | * |

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(c)***

(10) Community water systems and non-transient non-community water systems must conduct initial monitoring for perchlorate as follows:

(i) Community water systems serving greater than 10,000 persons without acceptable historic data, as defined below, must collect four consecutive quarterly samples at all sampling points between January 1, 2023 and December 31, 2025.

(ii) Community water systems serving 10,000 or fewer persons and non-transient non-community water systems without acceptable historic data, as defined below,

must collect four consecutive quarterly samples at all sampling points between January 1, 2026 and December 31, 2028.

(iii) Grandfathering of data: States may allow historical monitoring data collected at a sampling point to satisfy the initial monitoring requirements for that sampling point, for the following situations.

(A) To satisfy initial monitoring requirements, community water systems serving greater than 10,000 persons having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020 and December 31, 2022. Community water systems serving 10,000 or fewer persons and non-transient non-community water systems having only one entry point to the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2023 and December 31, 2025.

(B) To satisfy initial monitoring requirements, a system with multiple entry points and having appropriate historical monitoring data for each entry point to the distribution system may use the monitoring data from the compliance monitoring period that began between January 1, 2020 and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023 and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems.

(C) To satisfy initial monitoring requirements, a system with appropriate historical data for a representative point in the distribution system may use the monitoring data from the compliance monitoring period between January 1, 2020 and December 31, 2022, for community water systems serving greater than 10,000 persons and between January 1, 2023 and December 31, 2025, for community water systems serving 10,000 or fewer persons and for non-transient non-community water systems, provided that the State finds that the historical data satisfactorily demonstrate that each entry point to the distribution system is expected to be in compliance based upon the historical data and reasonable assumptions about the variability of contaminant levels between entry points. The State must make a written finding indicating how the data conforms to these requirements.

(iv) The State may waive the final two quarters of initial monitoring for perchlorate for a sampling point if the results of the samples from the previous two quarters are below the detection limit.

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(i)***

(3) Compliance with the maximum contaminant level for nitrate, nitrite and perchlorate is determined based on one sample if the levels of these contaminants are below the MCLs. If the level of perchlorate exceeds the MCL in the initial sample, a confirmation sample is required in accordance with paragraph (f)(1) of this section

and compliance shall be based on the average of the initial and confirmation sample. If the levels of nitrate and/or nitrite exceed the MCLs in the initial sample, a confirmation sample is required in accordance with paragraph (f)(2) of this section and compliance shall be based on the average of the initial and confirmation sample.

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(k)***

(1) Analysis for the following contaminants shall be conducted in accordance with the methods in the following table, or the alternative methods listed in Appendix A to Subpart C of this part, or their equivalent as determined by the EPA. Criteria for analyzing arsenic, barium, beryllium, cadmium, calcium, chromium, copper, lead, nickel, selenium, sodium, and thallium with digestion or directly without digestion, and other analytical test procedures are contained in Technical Notes on Drinking Water Methods, EPA-600/R-94-173, October 1994. This document is available from the National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242-0419 or http://www.epa.gov/nscep/.

Table 2 to paragraph (k)(1)

| **Contaminant** | **Methodology[13]** | **EPA** | **ASTM[3]** | **SM[4] (18th, 19th ed.)** | **SM[4] (20th ed.)** | **SM Online[22]** | **Other** |
|---|---|---|---|---|---|---|---|
| * | * | * | * | * | * | * | |
| 21. Perchlorate | Ion Chromatography | 314.0[23] | | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection<br><br>Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection<br><br>Liquid Chromatography Electrospray Ionization Mass Spectrometry<br><br>Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry | 314.1[24]<br><br>314.2[25]<br><br>331.0[26]<br><br>332.0[27] | | | | | |
| * | * | * | * | * | * | * | |

The approved compliance methods for determining perchlorate in drinking water listed in table 1 to paragraph (k) of this section, are incorporated by reference. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the material incorporated by reference in this paragraph (k) may be inspected at the U.S. Environmental Protection Agency, EPA Headquarters Library, in the Water Docket, at the EPA Docket Center (EPA/DC), EPA WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20460. If you wish to obtain this material

from the EPA Docket Center, call (202) 566-2426. Copies of this material also may be inspected at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

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[3]Annual Book of ASTM Standards, ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428, http://www.astm.org.; Annual Book of ASTM Standards 1994, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1996, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 1999, Vols. 11.01 and 11.02; Annual Book of ASTM Standards 2003, Vols. 11.01 and 11.02.

[4]Standard Methods for the Examination of Water and Wastewater, American Public Health Association, 800 I Street NW., Washington, DC 20001-3710; Standard Methods for the Examination of Water and Wastewater, 18th edition (1992); Standard Methods for the Examination of Water and Wastewater, 19th edition (1995); Standard Methods for the Examination of Water and Wastewater, 20th edition (1998).The following methods from this edition cannot be used: 3111 B, 3111 D, 3113 B, and 3114 B.

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[13]Because MDLs reported in EPA Methods 200.7 and 200.9 were determined using a 2x preconcentration step during sample digestion, MDLs determined when samples

are analyzed by direct analysis (i.e., no sample digestion) will be higher. For direct analysis of cadmium and arsenic by Method 200.7, and arsenic by Method 3120 B, sample preconcentration using pneumatic nebulization may be required to achieve lower detection limits. Preconcentration may also be required for direct analysis of antimony, lead, and thallium by Method 200.9; antimony and lead by Method 3113 B; and lead by Method D3559-90D, unless multiple in-furnace depositions are made.

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[22]Standard Methods Online, American Public Health Association, 800 I Street NW., Washington, DC 20001, available at http://www.standardmethods.org. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

[23] Determination of Perchlorate in Drinking Water Using Ion Chromatography (Revision 1.0, USEPA, 1999a).

[24] Determination of Perchlorate in Drinking Water Using Inline Column Concentration/Matrix Elimination Ion Chromatography with Suppressed Conductivity Detection (Revision 1.0, USEPA, 2005b).

[25] Determination of Perchlorate in Drinking Water Using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection (USEPA, 2008c).

[26] Determination of Perchlorate in Drinking Water by Liquid Chromatography Electrospray Ionization Mass Spectrometry" (Revision 1.0, USEPA, 2005c).

[27] Determination of Perchlorate in Drinking Water by Ion Chromatography with Suppressed Conductivity and Electrospray Ionization Mass Spectrometry" (USEPA, Revision 1.0, 2005d).

*****

(2)***

Table 3 to paragraph (k)(2)

| **Contaminant** | **Preservative[1]** | **Container[2]** | **Time[3]** |
|---|---|---|---|
| ** | ** | ** | * |
| Perchlorate[7] | 4 °C | P or G | 28 days |
| ** | ** | ** | * |

[1]For cyanide determinations samples must be adjusted with sodium hydroxide to pH 12 at the time off collection. When chilling is indicated the sample must be shipped and stored at 4 °C or less. Acidification of nitrate or metals samples may be with a concentrated acid or a dilute (50% by volume) solution of the applicable concentrated acid. Acidification of samples for metals analysis is encouraged and allowed at the laboratory rather than at the time of sampling provided the shipping time and other instructions in Section 8.3 of EPA Methods 200.7 or 200.8 or 200.9 are followed.

[2]P = plastic, hard or soft; G = glass, hard or soft.

[3]In all cases samples should be analyzed as soon after collection as possible. Follow additional (if any) information on preservation, containers or holding times that is specified in method.

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[7] Sample collection for perchlorate shall be conducted following the requirements specified in the approved methods in 141.23(k)(1) or the alternative methods listed in appendix A of subpart C of this part, or their equivalent as determined by the EPA.

*****

(3)***

(ii)***

Table 4 to paragraph (k)(3)(ii)

| Contaminant | Acceptance limit |
|---|---|
| ******* | ******* |
| Perchlorate | ± 20% at ≥0.004 mg/L |
| ******* | ******* |

*********

4. In § 141.51 amend paragraph (b) by adding a designation to the table and by adding in alphabetical order, an entry for "Perchlorate" to read as follows:

**Subpart F—Maximum Contaminant Level Goals and Maximum Residual Disinfectant Level Goals**

**§141.51 Maximum contaminant level goals for inorganic contaminants.**

*********

**(b)*****

**Table 1 to paragraph (b)**

| Contaminant | MCLG (mg/l) |
|---|---|
| **** | *** |
| Perchlorate | 0.056 |
| **** | *** |

*****

5. Amend § 141.60 by adding paragraph (b)(5) to read as follows:

**Subpart G—National Primary Drinking Water Regulations: Maximum Contaminant Levels and Maximum Residual Disinfectant Levels**

**§141.60 Effective dates.**

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(b)***

(5) The effective date for § 141.62(b)(17) is [**DATE OF PUBLICATION OF FINAL RULE IN THE FEDERAL REGISTER**].

6. Amend § 141.62 by:

a. In the table in paragraph (b), adding a designation to the table and an entry for "(17) Perchlorate" at the end of the table;;

b. In the table in paragraph (c), adding a designation to the table, an entry for "Perchlorate" in alphabetical order, and an entry "14 = Biological Treatment" under the undesignated heading entitled "Key to BATs; and

c. Adding paragraph (e).

The revisions and additions read as follows:

**§141.62 Maximum contaminant levels for inorganic contaminants.**

*****

(b)***

Table 1 to paragraph (b)

| Contaminant | MCL (mg/l) |
|---|---|
| **** | *** |
| (17) Perchlorate | 0.056 |

(c)***

**TABLE 2 TO PARAGRAPH (C) -- BAT FOR INORGANIC COMPOUNDS LISTED IN SECTION 141.62(B)**

| Chemical Name | BAT(s) |
|---|---|
| **** | *** |
| Perchlorate | 5, 7, 14 |
| **** | *** |

*****

*Key to BATs in Table*

*****

14 = Biological Treatment

*****

(e) The Administrator, pursuant to section 1412 of the Act, hereby identified in the following table the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant level for perchlorate:

Table 3 to paragraph (e) -- **SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTS) FOR PERCHLORATE**

| **Small system compliance technology** | **Affordability for listed small system categories** |
|---|---|
| Ion exchange | All size categories. |
| Reverse osmosis (point of use) | All size categories |

7. Amend Appendix A to Subpart O of Part 141 table, under "Inorganic contaminants", by adding an entry for "Perchlorate" in alphabetical order to read as follows:

**Subpart O—Consumer Confidence Reports**

**APPENDIX A TO SUBPART O OF PART 141—REGUATED CONTAMINANTS**

| **Contaminant (units)** | **Traditional MCL in mg/L** | **To convert for CCR, multiply by** | **MCL in CCR units** | **MCLG** | **Major sources in drinking water** | **Health effects language** |
|---|---|---|---|---|---|---|
| * | * | * | * | * | * | * |
| Inorganic contaminants | | | | | | |
| * | * | * | * | * | * | * |

| | | | | | | |
|---|---|---|---|---|---|---|
| Perchlorate | 0.056 | 1000 | 56 | 56 | Perchlorate is commonly used in solid rocket propellants, munitions, fireworks, airbag initiators for vehicles, matches and signal flares. Perchlorate may occur naturally, particularly in arid regions such as the southwestern United States and is found as a natural impurity in nitrate salts used to produce nitrate fertilizers, explosives and other products. | Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development. |
| * | * | * | * | * | * | * |

8. Amend Appendix A to Subpart Q of Part 141 table, under "B. Inorganic contaminants", by adding an entry for "Perchlorate" in alphabetical order to read as follows:

**Subpart Q Public Notification of Drinking Water Violations**

*****

**APPENDIX A TO SUBPART Q OF PART 141—NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE[1]**

| Contaminant | MCL/MRDL/TT violations[2] | | Monitoring & testing procedure violations | |
|---|---|---|---|---|
| | Tier of public | Citation | Tier of public | Citation |

| | | | | |
|---|---|---|---|---|
| | notice required | | notice required | |
| ******* | | | | |
| B. Inorganic Chemicals (IOCs) | | | | |
| ******* | | | | |
| 14. Perchlorate | 1 | 141.62(b) | 3 | 141.23(a), (c), 141.23(f)(1) |
| ******* | | | | |

[1] Violations and other situations not listed in this table (e.g., failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (e.g., Tier 1 instead of Tier or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under 141.202(a) and 141.203(a).

[2] MCL-Maximum contaminant level, MDRL-Maximum residual disinfectant level, TT-treatment technique

*****

9. Amend Appendix B to Subpart Q of Part 141 table, under "C. Inorganic contaminants", by adding an entry for "Perchlorate" in alphabetical order to read as follows :

**APPENDIX B TO SUBPART Q OF PART 141—STANDARD HEALTH EFFECTS LANGUAGE FOR PUBLIC NOTIFICATION**

| Contaminant | MCLG[1] mg/L | MCL[2] mg/L | Standard health effects language for public notification |
|---|---|---|---|
| ******* | | | |
| C. Inorganic Chemicals (IOCs) | | | |
| ******* | | | |

| | | | |
|---|---|---|---|
| 21. Perchlorate | 0.056 | 0.056 | Offspring of pregnant women and infants who drink water containing perchlorate in excess of the MCL could experience delays in their physical or mental development. |
| ******* | | | |

[1] MCLG – Maximum contaminant level goal

[2] MCL – Maximum contaminant level

**PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION**

10. The authority citation for part 142 continues to read as follows:

**Authority:** 42 U.S.C. 300f, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-4, 300j-9, and 300j-11**.**

11. In § 142.62 amend the table in paragraph (b) by adding a designation to the table, an entry for "Perchlorate" in alphabetical order; and an entry "13 = Biological Treatment" under the undesignated heading entitled "Key to BATs".

**Subpart G—Identification of Best Technology, Treatment Techniques or Other Means Generally Available.**

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**§142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.**

*****

(b)***

Table 1 to paragraph (b) -- BAT FOR INORGANIC COMPOUNDS LISTED IN §141.62(b)

| **Chemical Name** | **BAT(s)** |
|---|---|
| **** | **** |
| Perchlorate | 5, 7, 14 |
| **** | *** |

*****

*Key to BATs in Table*

*****

13 = Biological Treatment

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[FR Doc. 2019-12773 Filed: 6/25/2019 8:45 am; Publication Date: 6/26/2019]