You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Walker Udechukwu, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Andrew Yeatts, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5510, Silver Spring, MD 20993–0002, 301–796–4539; or Leigh Hayes, Office of Combination Products, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5127, Silver Spring, MD 20993–0002, 301–796–8938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Regulatory Considerations for Human Cells, Tissues, Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's good guidance practices regulation.

The guidance does not alter FDA's current thinking on the regulatory criteria of minimal manipulation and homologous use for human cells, tissues, and cellular and tissue-based product (HCT/P) as described in the November 2017 guidance of the same name and corrected in December 2017. The only substantive change to this guidance is to revise section V of the November 2017 guidance to communicate that FDA intends to exercise enforcement discretion for certain regulatory requirements for certain HCT/Ps for a longer period of time, *i.e.,* through May 31, 2021, instead of November 30, 2020. This will give manufacturers additional time to determine if they need to submit an investigational new drug (IND) or marketing application and, if such an application is needed, to prepare the IND or marketing application. Such additional time is warranted in light of the Coronavirus Disease 2019 (COVID–19) public health emergency, which has presented unique challenges in recruiting clinical trial participants and carrying out clinical trials.

As described in the guidance, FDA generally intends to exercise enforcement discretion with respect to the IND and the premarket approval requirements for HCT/Ps that do not meet one or more of the 21 CFR 1271.10(a) criteria, provided that use of the HCT/P does not raise reported safety concerns or potential significant safety concerns. FDA intends to continue to focus enforcement actions on products with higher risk, including based on the route and site of administration.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115(g)(2)). The guidance represents the current thinking of FDA on ''Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required.

However, this guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances; https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products; https://www.fda.gov/combination-products/guidance-regulatory-information;* or *https://www.regulations.gov.*

Dated: July 15, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15718 Filed 7–20–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2018–0780, EPA–HQ–OW–2008–0692, EPA–HQ–OW–2009–0297; FRL–10011–21–OW]

RIN 2040–AF28

Drinking Water: Final Action on Perchlorate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is announcing its withdrawal of the 2011 determination to regulate perchlorate in accordance with the Safe Drinking Water Act, (SDWA). On February 11, 2011, the EPA published a **Federal Register** document in which the Agency determined that perchlorate met the SDWA's criteria for regulating a contaminant. On June 26, 2019, the EPA published a proposed national primary drinking water regulation (NPDWR) for perchlorate and requested public comments on multiple alternative actions, including the alternative of withdrawing the 2011 regulatory determination for perchlorate. The EPA received approximately 1,500 comments on the proposed rulemaking. The EPA has considered these public comments and based on the best available information the Agency is withdrawing the 2011 regulatory determination and is making a final determination not to regulate perchlorate. The EPA has determined that perchlorate does not occur ''with a frequency and at levels of public health concern'' within the meaning of the SDWA. In addition, in the judgment of the EPA Administrator, regulation of perchlorate does not present a ''meaningful opportunity for health risk reduction for persons served by public water systems.'' Accordingly, the EPA is

withdrawing its 2011 determination and is making a final determination not to regulate perchlorate, and therefore will not issue a NPDWR for perchlorate at this time.

DATES: For purposes of judicial review, the regulatory determination in this document is issued as of July 21, 2020.

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564–1735; email address: *hernandez.samuel@epa.gov.*

SUPPLEMENTARY INFORMATION: This document is organized as follows:

I. General Information

A. Does this action apply to me?

This action will not impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's withdrawal of the 2011 regulatory determination for perchlorate and the final regulatory determination not to regulate perchlorate. Section IV of this document provides a summary of the key comments received on the June 26, 2019 (84 FR 30524) proposed NPDWR for perchlorate (referred to hereinafter as ''the 2019 proposal'').

B. How can I get copies of this document and other related information?

The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2018–0780. Publicly available docket materials are available electronically at *https://www.regulations.gov/docket?D=EPA-HQ-OW-2018-0780.*

II. Background

A. What is perchlorate?

Perchlorate is a negatively charged inorganic ion that is composed 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 by industrial processes, and the most commonly produced compounds include ammonium perchlorate and potassium perchlorate used primarily as oxidizers in solid fuels to power rockets, missiles, and fireworks. Perchlorate can also result from the degradation of hypochlorite solutions used for water disinfection. The degradation into perchlorate occurs when hypochlorite solutions are improperly stored and handled. For the general population, most perchlorate exposure is through the ingestion of contaminated food or drinking water. Above certain levels, perchlorate can prevent the thyroid gland from getting enough iodine, which can affect thyroid hormone production. The consequences of insufficient thyroid hormone levels during human growth and development are well known. For pregnant women with low iodine levels, sufficient changes in thyroid hormone levels may cause changes in the child's brain development. In a 2005 report entitled ''Health Implications of Perchlorate Ingestion'', the National Research Council stated that: ''*fetuses and preterm newborns constitute the most sensitive populations although infants and developing children are also considered sensitive populations*'' (NRC, 2005). 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 identifies an association between maternal thyroid hormone levels and the neurodevelopmental outcomes, and the state of the science on this relationship is constantly evolving.

B. What is the purpose of this action?

The purpose of this action is to publish the EPA's notice to withdraw the 2011 regulatory determination, one of the alternative options in the 2019 proposal, and to issue a final determination not to regulate perchlorate in drinking water. This document presents the EPA's basis for this withdrawal and final regulatory determination, and the EPA's response to key issues raised by commenters in response to the 2019 proposal.

C. What is the EPA's statutory authority for this action?

The SDWA sets forth three criteria that must be met for the EPA to issue a maximum contaminant level goal (MCLG) and promulgate a national primary drinking water regulation (NPDWR). Specifically, the Administrator must determine that (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 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 public water systems'' (SDWA 1412(b)(1)(A)).

SDWA 1412(b)(1)(B) sets out the process for the EPA to establish drinking water standards for an unregulated contaminant. As explained in more detail below, in 2011, the EPA issued a determination that perchlorate met the three statutory criteria outlined above and therefore should be regulated. Under the statute, a determination to regulate triggers a duty for the EPA to issue a proposed drinking water standard within two years and a final rule 18 months later (with the possibility of a 3 month extension). SDWA 1412(b)(1)(E). The EPA subsequently published a proposed drinking water standard for perchlorate, and alternatives including the withdrawal of the 2011 regulatory determination, in 2019. The promulgation of a final drinking water standard would, when effective, require monitoring of public water supplies for the contaminant and treatment as necessary to meet the regulatory standard.

The EPA has determined, based on reviewing data and analysis obtained since the issuance of the 2011 regulatory determination, that perchlorate does not meet the statutorily-prescribed criteria for regulation. As described in Sections III & VI of the 2019 proposal, the data

and analysis in the record indicate that perchlorate does not occur in public water systems with a frequency and at levels of public health concern. Specifically, the peer-reviewed health effects analysis indicates that the estimated concentrations of perchlorate that may represent levels of public health concern (*i.e.,* the proposed MCLG levels, 18–90 µg/L) is higher than the concentration considered in issuance of the 2011 regulatory determination (1–47 µg/L) (USEPA, 2019a). In addition, based on a re-evaluation of the nationally representative First Unregulated Contaminant Monitoring Rule (UCMR 1) data, the updated occurrence analysis shows that the frequency of occurrence of perchlorate in public water systems at levels exceeding any of the alternative proposed MCLGs (18 µg/L–90 µg/L) is significantly lower (0.03%–0.002%) than the frequency considered in the analysis for the 2011 regulatory determination (4%–0.39%) (USEPA, 2019b). The EPA estimates that, even at the most stringent regulatory level considered in the 2019 proposal (18 µg/L), not more than 15 systems (0.03% of all water systems in the U.S. serving approximately 620,000 people) would need to take action to reduce levels of perchlorate. Based on this information, the EPA determines that perchlorate does not occur in public water systems ''with a frequency and at levels of public health concern'' and thus does not meet the second criterion of the three required for regulation under the SDWA. In addition, while the third criterion is ''in the sole judgment of the Administrator,'' the small number of water systems with perchlorate levels greater than identified thresholds, and the correspondingly small population served, provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a ''meaningful opportunity for health risk reduction for persons served by public water systems,'' within the meaning of 1412(b)(1)(A)(iii). Accordingly, because perchlorate no longer meets the statutory criteria for regulation, the EPA does not have the authority to issue a MCLG or promulgate a NPDWR for perchlorate.

While the EPA has not previously withdrawn a regulatory determination, the decision is supported by the legislative history underlying the 1996 amendments to the SDWA, which repealed the statutory requirement for the EPA to regulate an additional 25 contaminants every 3 years and replaced it with the current requirement for the EPA to determine whether regulation is warranted for five contaminants every five years. In describing the need for such amendment, the legislative history points to the view expressed at the Committee Hearing that ''the current law is a one-size-fits-all program. It forces our water quality experts to spend scarce resources searching for dangers that often do not exist rather than identifying and removing real health risks from our drinking water'' (S. Rep. 104–169 (1995) at 12). This amendment reflected Congress' clear intent that the EPA prioritize actual health risks in determining whether to regulate any particular contaminant. *See id* at 12 (noting that the amendment ''repeals the requirement that the EPA regulate an additional 25 contaminants every 3 years replacing it with a new selection process that gives the EPA the discretion to identify contaminants that warrant regulation in the future'').

The EPA's decision to withdraw the regulatory determination is also consistent with Congress' direction to prioritize SDWA decisions based on the best available public health information. *See* 1412(b)(1)(B)(ii)(II) (findings supporting a determination to regulate ''shall be based on the best available public health information''); 1412(b)(2)(A) (requiring that the EPA use ''the best available, peer-reviewed science and supporting studies . . .'' in carrying out any actions under this section). Although the EPA determined in 2011 that perchlorate met the criteria for regulation, new data and analysis developed by the Agency as part of the 2019 proposal demonstrate that the occurrence and health effects information used as the basis for the 2011 determination no longer constitute ''best available information,'' are no longer accurate, and no longer support the Agency's prioritization of perchlorate for regulation. Accordingly, not only is the EPA not authorized to issue a MCLG or promulgate a NPDWR for perchlorate, but it would not be in the public interest for the EPA to do so.

The EPA recognizes that the SDWA does not include a provision explicitly authorizing withdrawal of a regulatory determination. However, such authority is inherent in the authority to issue a regulatory determination under 1412(b)(1)(B)(ii)(II), particularly given the requirement that such determination be based on the ''best available public health information,'' as discussed above. Accordingly, the EPA must have the inherent authority to withdraw a regulatory determination if the underlying information changes between regulatory determination and promulgation. In light of Congress's concern that the EPA focus new contaminant regulations on priority health concerns, Congress could not have intended that the EPA's regulatory decision-making be hamstrung by older data when newer, more accurate scientific and public health data are available, especially when those data demonstrate that regulation of a new contaminant would not present a meaningful opportunity for health risk reduction.

Moreover, the EPA notes that the statute specifically provides that a decision not to regulate a contaminant is a final Agency action subject to judicial review. SDWA 1412(b)(1)(B)(ii)(IV). Congress could have—but did not—specify the same with respect to determinations to regulate. Congress also did not explicitly prohibit the EPA from withdrawing or modifying a regulatory determination. Congress' silence with respect to determinations to regulate suggests that Congress intended that such a determination is not itself a final agency action, but rather a preliminary step in a decision-making process culminating in a NPDWR and thus subject to reconsideration based on new data and analysis considered during the 36 month promulgation process specified in the statute. Accordingly, reconsideration of this preliminary finding—and withdrawal of the determination based on subsequent analysis mandated for NPDWR development—is fully consistent with the statutory decision-making framework.

D. Statutory Framework and Perchlorate 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 federal drinking water regulations. The EPA uses the CCL to identify priority contaminants for regulatory decision-making and information collection. The placement of a substance on the CCL does not require that it be regulated under the SDWA. 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 (63 FR 10274, March 2, 1998), 2005 (70 FR 9071, February 24, 2005), and 2009 (74 FR 51850, October 8, 2009).

The EPA collects data on the CCL contaminants to better understand their potential health effects and to determine

the levels at which they occur in public water systems. SDWA 1412(b)(1)(B)(ii) requires that, every five years, the EPA, after consideration of public comment, issue a determination of whether or not to regulate at least five contaminants on each CCL. For any contaminant that the EPA determines meets the criteria for regulation under SDWA 1412(b)(1)(E), the EPA must propose a NPDWR within two years and promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional 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 systems. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems and non-transient, non-community water systems. The first four UCMRs collected 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). Water system monitoring data for perchlorate were collected from 2001 to 2005.

The EPA and other federal agencies asked the National Research Council (NRC) to evaluate the health implications of perchlorate ingestion. In its 2005 report, the NRC concluded that perchlorate exposure inhibits the transport of iodide [1] into the thyroid by a protein molecule known as the sodium/iodide symporter (NIS), which may lead to decreases in the production of two thyroid hormones, thyroxine (T3) and triiodothyronine (T4), and increases in the production of thyroid-stimulating hormone (TSH) (National Research Council (NRC), 2005). 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 NRC's recommended RfD of 0.7 µg/kg/day for perchlorate. The reference dose is an estimate of a human's daily exposure to perchlorate 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, 2005a).

In October 2008, the EPA published a preliminary regulatory determination not to regulate perchlorate in drinking water and requested public comment (73 FR 60262, October 10, 2008). In that preliminary determination, the EPA found that perchlorate did not occur with a frequency and at levels of public health concern within the meaning of the SDWA, and that development of a regulation did not present a meaningful opportunity for health risk reduction for persons served by public water systems. In reaching this conclusion, the EPA derived and used a Health Reference Level (HRL) of 15 µg/L based on the RfD of 0.7 µg/kg/day and body weight and exposure information for pregnant women (USEPA, 2008a). Using 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 EPA found that perchlorate did not occur at a frequency and at levels of public health concern. The EPA also determined there was not a meaningful opportunity for a NPDWR for perchlorate to reduce health risks.

In August 2009, the EPA published a supplemental request for comment with new analysis that derived potential alternative Health Reference Levels (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, resulting in comparable perchlorate concentrations in drinking water, based on life stage, of between 1 µg/l to 47 µg/l (74 FR 41883; USEPA, 2009a).

In February 11, 2011, the EPA published its determination to regulate perchlorate (76 FR 7762; USEPA, 2011) after careful consideration of public comments on the October 2008 and August 2009 notices. The EPA found at that time that perchlorate may have an adverse effect on the health of persons; that it is known to occur, or that there is a substantial likelihood that it will occur, in public drinking water systems with a frequency and at levels that present a public health concern; and that regulation of perchlorate presented a meaningful opportunity for health risk reduction for persons served by public water systems. The EPA found that as many as 16 million people could potentially be exposed to perchlorate at levels of concern, up from 1 million people originally estimated in the 2008 notice.

As a result of the determination, and as required by SDWA 1412(b)(1)(E), the EPA initiated the process to develop a MCLG and a NPDWR for perchlorate.

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.[2] In the request, the Chamber claimed that the UCMR 1 data used in the EPA's occurrence analysis 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 in the analysis for systems in California and Massachusetts, using state compliance data to reflect current occurrence conditions after state regulatory limits for perchlorate were implemented. For more information on the Chamber's request and the EPA's response, see the Perchlorate Occurrence and Monitoring Report (USEPA, 2019b).

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. In May 2013, the SAB recommended that the EPA:

- Derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its 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

[1] For the purposes of this document, ''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.

[2] The U.S. Chamber of Commerce letter to the EPA and other corresponding records are available at *https://www.epa.gov/quality/epa-information-quality-guidelines-requests-correction-and-requests-reconsideration#12004.*

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
- ''[e]xtend 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).

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). The EPA considered the recommendations from the 2017 peer review and made necessary model revisions to increase the scientific rigor of the model and the modeling results, including extending the BBDR model to the first trimester and incorporating the TSH feedback mechanism.

The EPA convened a second independent peer review panel in January 2018 to evaluate the revisions to the BBDR model, including the transition from the third to the first trimester as the life stage of interest. The EPA also presented several approaches 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).

In response to a lawsuit brought to enforce the deadlines in SDWA 1412(b)(1)(E) triggered by the 2011 regulatory determination for perchlorate, on October 18, 2016, the U.S. District Court for the Southern District of New York entered a consent decree, requiring the EPA to sign for publication a proposal for a MCLG and NPDWR for perchlorate in drinking water no later than October 31, 2018, and to sign for publication a final MCLG and NPDWR for perchlorate in drinking water no later than December 19, 2019. The deadline for the EPA to propose a MCLG and NPDWR for perchlorate in drinking water was later extended to May 28, 2019, and the date for signature of a final MCLG and NPDWR was extended to no later than June 19, 2020. The consent decree is available in the docket for this action.

In compliance with the deadline established in the consent decree, on May 23, 2019, the EPA Administrator signed a proposed rulemaking document seeking public comment on a range of options regarding the regulation of perchlorate in public drinking water systems. The proposed rulemaking document was published in the **Federal Register** on June 26, 2019. 84 FR 30524. The EPA proposed a NPDWR for perchlorate with an MCL and MCLG of 56 µg/L. The proposed MCLG of 56 µg/L was based on avoiding an estimated 2 point IQ decrement associated with exposure to perchlorate in drinking water during the most sensitive life stage (the fetus) within a specific segment of the population (iodine deficient pregnant women).

The EPA also requested comment on two alternative MCL/MCLG values of 18 µg/L and 90 µg/L. These alternatives were based upon avoiding an estimated 1 point and 3 point IQ decrement respectively, associated with perchlorate exposure. Additionally, the EPA requested comment on whether the 2011 regulatory determination should be withdrawn, based on new information including updated occurrence data on perchlorate in drinking water and new analysis of the concentration of perchlorate in drinking water that represents a level of health concern.

III. Withdrawal of the 2011 Regulatory Determination and Final Determination Not To Regulate Perchlorate

In determining whether to regulate a particular contaminant, the EPA must follow the criteria mandated by the 1996 SDWA Amendments. Specifically, in order to issue a MCLG and NPDWR for perchlorate, the EPA must determine that perchlorate ''may have an adverse effect on the health of persons,'' that perchlorate occurs at ''a frequency and at levels of public health concern'' in public water systems, and that regulation of perchlorate in drinking water systems ''presents a meaningful opportunity for health risk reduction for persons served by public water systems.'' SDWA 1412(b)(1)(A). In preparing the 2019 proposal for perchlorate, the EPA updated and improved information on the levels of public health concern and the frequency and levels of perchlorate in public water systems. The following is the EPA's reassessment of the regulatory determination criteria applied to the best available health science and occurrence data for perchlorate.

A. May perchlorate have an adverse effect on the health of persons?

Yes, perchlorate may have adverse health effects above certain exposure levels. The perchlorate anion is biologically significant specifically with respect to the functioning of the thyroid gland. Above certain exposure levels, perchlorate can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid, resulting in a deficiency of iodide in the thyroid. Perchlorate inhibits (or blocks) iodide transport into the thyroid by chemically competing with iodide, which has a similar shape and electric charge. The transfer of iodide from the blood into the thyroid is an essential step in the synthesis of thyroid hormones. Thyroid hormones play an important role in the regulation of metabolic processes throughout the body and are also critical to developing fetuses and infants, especially for brain development. Because the developing fetus depends on an adequate supply of maternal thyroid hormones for its central nervous system development during the first and second trimester of pregnancy, iodide uptake inhibition from perchlorate exposure has been identified as a concern in connection with increasing risk of neurodevelopmental impairment in fetuses of pregnant women with low dietary iodine. Poor iodide uptake and subsequent impairment of the thyroid function in pregnant and lactating women have been linked to delayed development and decreased learning capability in their infants and children (NRC, 2005). There is scientific evidence to support that perchlorate can reduce iodide uptake and therefore alter the level of thyroid hormones. There is also scientific evidence that changes in thyroid hormone levels in a pregnant woman may be linked to changes in the neurodevelopment of her offspring. 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 identifies an association between maternal thyroid hormone levels and the neurodevelopmental outcomes and

the state of the science on this relationship is constantly evolving.

Therefore, the EPA continues to find that perchlorate may have an adverse effect on the health of persons above certain exposure levels based on its ability to interfere with thyroid hormone production.

B. Is perchlorate known to occur or is there a substantial likelihood that perchlorate will occur in public water systems with a frequency and at levels of public health concern?

The EPA has determined that perchlorate does not occur with a frequency and at levels of public health concern in public water systems. The EPA has made this determination by comparing the best available data on the occurrence of perchlorate in public water systems with potential MCLGs for perchlorate.

In past regulatory determinations, the EPA has identified HRLs as benchmarks against which the EPA compares the concentration of a contaminant found in public water systems to determine whether it occurs at levels of public health concern. For the 2011 regulatory determination, the EPA identified potential alternative HRL values ranging from 1 to 47 µg/L for 14 different life stages. These HRLs were not final decisions about the level of perchlorate in drinking water that is without adverse effects. For the 2019 proposal, the EPA derived three potential MCLGs for perchlorate of 18, 56, and 90 µg/L for the most sensitive life stage using the best available peer reviewed science in accordance with the SDWA. After considering public comment, the EPA used these potential MCLGs as the levels of public health concern in assessing the frequency of occurrence of perchlorate in this regulatory determination. These MCLGs were set at levels to avoid estimated IQ decrements of 1, 2, and 3 points respectively in the most sensitive life stage, the children of hypothyroxinemic women with low iodine intake. The EPA proposed an MCLG of 56 µg/L and alternative MCLG values of 18 and 90 µg/L.

The rationale used in deriving the numerical values is presented in greater detail in the EPA technical support document entitled ''Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water'' (USEPA, 2019a).

The EPA compared these potential MCLG values with the updated perchlorate UCMR 1 occurrence data set. A comprehensive description of the perchlorate occurrence data is presented in Section VI of the 2019 proposal. It is also available in the ''Perchlorate Occurrence and Monitoring Report'' (USEPA, 2019a).

The occurrence data for perchlorate were collected from 3,865 PWSs between 2001 and 2005 under the UCMR 1. In the 2019 proposal, the EPA modified the UCMR 1 data set in response to concerns raised by stakeholders regarding the data quality and to represent current conditions in California and Massachusetts, which have enacted perchlorate regulations since the UCMR 1 data were collected. Massachusetts promulgated a drinking water standard for perchlorate of 2 µg/L in 2006 (MassDEP, 2006), and 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. As discussed below, the EPA finds that perchlorate levels in drinking water and sources of drinking water have decreased since the UCMR 1 data collection. The main factors contributing to the decrease in perchlorate levels are the promulgation of drinking water regulations for perchlorate in California and Massachusetts and the ongoing remediation efforts in the state of Nevada to address perchlorate contamination in groundwater adjacent to the lower Colorado River upstream of Lake Mead.

To update the occurrence data for systems sampled during UCMR 1 from 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 publicly available California and Massachusetts monitoring data for perchlorate, to replace the original UCMR1 data with more recent data where available (Perchlorate Occurrence and Monitoring Report, USEPA, 2019b).

The EPA has determined that the UCMR 1 data with these updates are the best available data collected in accordance with accepted methods regarding the frequency and level of perchlorate nationally. The UCMR 1 data are 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.

The EPA used entry point maximum measurements to estimate potential baseline occurrence and exposure at levels that exceed the potential MCLG thresholds. The maximum measurements indicate highest perchlorate levels reported in at least one quarterly sample from surface water systems and at least one semi-annual sample from ground water systems.

TABLE 1—PERCHLORATE OCCURRENCE AND EXPOSURE (UPDATED UCMR 1 DATA SET)

Threshold concentration (µg/L)	Entry points with detections above threshold	Water systems with detections above threshold	Percent of U.S. water systems with detections above threshold (percent)	Population served
18 µg/L	17	15	0.03	620,560
56 µg/L	2	2	0.004	32,432
90 µg/L	1	1	0.002	25,972

Table 1 presents the number and percentage of water systems that reported perchlorate at levels exceeding the three proposed MCLG threshold concentrations. In summary, the updated perchlorate occurrence information suggests that at an MCLG of 18 µg/L, there would be 15 systems (0.03% of all water systems in the U.S.) that would exceed the threshold, at an MCLG of 56 µg/L, two systems (0.004% of all water systems in the U.S.) would exceed the threshold, and finally one system would exceed the MCLG threshold of 90 µg/L. Based on the analysis of drinking water occurrence presented in the 2019 proposal and the data summarized in Table 1 and the range of potential MCLGs, the EPA concludes that perchlorate does not occur with a frequency and at levels of

public health concern in public water systems.

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 mg/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 concluded 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, 2008b).

While the EPA has made its conclusion that perchlorate does not occur at a frequency and at levels of public health concern in public water systems based on the updated UCMR 1 data in Table 1 above, the EPA also sought to find additional information about the perchlorate levels at the 15 water systems that had at least one reported result greater than 18 µg/L in the updated UCMR 1 data. The EPA found that perchlorate levels have been reduced at many of these water systems. Although these water systems were not required to take actions to reduce perchlorate in drinking water, many had conducted additional monitoring for perchlorate and found decreased levels or had taken mitigation efforts to address perchlorate, confirming the EPA's conclusion described above. The status of each of these systems is described in Table 2 below and confirms the Agency's conclusion that is based upon the information in Table 1.

TABLE 2—UPDATE ON SYSTEMS WITH PERCHLORATE LEVELS ABOVE 18 µg/L IN THE UCMR 1

State	System name	Range of UCMR 1 results (µg/L) **	Update on mitigation and levels of perchlorate ++
Florida	Sebring Water	ND–70	The EPA contacted the Sebring system in January 2020. Operations personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
Florida	Manatee County Utilities Dept.	ND–30	Researchers contacted the system to identify the source of perchlorate. System personnel attributed the sole perchlorate detection under UCMR 1 to analytical error. System personnel indicated that three other quarterly samples collected under UCMR 1 as well as other subsequent perchlorate sampling efforts were non-detect. Source: AWWA (2008).
Georgia	Oconee Co.—Watkinsville	38 (single sample)	Researchers contacted the system and found that a perchlorate contaminated well was removed from service in 2003. The system indicates that perchlorate is no longer detected. Source: Luis et al. (2019).
Louisiana	St. Charles Water District 1 East Bank.	ND–24	The EPA was not able to identify updated data on perchlorate levels for this system.
Maryland	City of Aberdeen	ND–19	The system's 2018 Consumer Confidence Report (CCR) indicates that perchlorate was not detected. According to the Maryland Department of Environment, perchlorate was not detected in this system in 2019. In addition, researchers contacted the system and found that there has been no detection of perchlorate since treatment was installed in 2009. Source: Luis et al. (2019).
Maryland	Chapel Hill—Aberdeen Proving Grounds.	ND–20	The EPA contacted the Chapel Hill System in January 2020. Water system personnel indicate that the Chapel Hill WTP was taken off-line and was replaced with a new treatment plant and five new production wells. The new treatment plant started operations on January 27, 2020. System personnel also indicate that monitoring was conducted in November 2019 and perchlorate was not detected in either the source well water or the finished water. In addition, according to the Maryland Department of Environment, perchlorate was not detected in this system in 2019.

TABLE 2—UPDATE ON SYSTEMS WITH PERCHLORATE LEVELS ABOVE 18 μg/L IN THE UCMR 1—Continued

State	System name	Range of UCMR 1 results (μg/L) **	Update on mitigation and levels of perchlorate ++
Mississippi	Hilldale Water District	ND–20	The EPA contacted the Hilldale System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
New Mexico	Deming Municipal Water System.	15–20	Data from the EPA's SDWIS/FED database indicates that the entry point that reported detections in UCMR 1 (Well #3) is now inactive (*i.e.,* the contaminated source is no longer in use).
Nevada	City of Henderson	6–23	Researchers report that the perchlorate levels described in the system's CCR ranged from non-detect to 9.7 μg/L. Source: AWWA (2008).
Ohio	Fairfield City PWS	6–27	The EPA contacted the Fairfield City System in January 2020. Water system personnel indicated that follow-up monitoring was conducted after UCMR 1, between 2002 and 2004. The Ohio EPA provided copies of the follow-up monitoring results which indicate that results at the entry point ranged from non-detect to 13 μg/L.
Ohio	Hecla Water Association—Plant PWS.	ND–32	The EPA contacted the Hecla Water Association System in January 2020. Water system personnel indicated that that no follow-up/updated monitoring data for perchlorate are available.
Oklahoma	Enid	ND–30	The EPA reviewed Oklahoma's monitoring data and did not find any monitoring results reported for perchlorate.
Pennsylvania	Meadville Area Water Authority.	ND–33	The EPA contacted the Meadville System in January 2020. Water system personnel indicated that no follow-up/updated monitoring data for perchlorate are available.
Puerto Rico	Utuado Urbano	ND–420	The EPA contacted the Puerto Rico Aqueduct and Sewer Authority (PRASA) in January 2019. PRASA personnel indicated that no updated monitoring data for perchlorate are available. *NOTE: The PRASA personnel stated that the Utuado water system was significantly impacted by Hurricane Maria and that monitoring records from years prior to 2017 were lost.*
Texas	City of Levelland	ND–32	Researchers found that a water storage tank was the source of perchlorate contamination. The wells feeding the tank were tested by the state and perchlorate was not detected. The water tank was shut off from service. Source: Luis et al. (2019).

**Values have been rounded. ND describes a sampling event where perchlorate was not detected at or above the UCMR 1 minimum reporting level of 4 μg/L. UCMR 1 results collected between 2001 and 2005.

++To obtain updated data and/or information regarding perchlorate levels, the EPA reviewed Consumer Confidence Reports and other publicly available data, as well as published studies. In addition, the EPA contacted some water systems for information about current perchlorate levels. (USEPA, 2020a)

C. Is there a meaningful opportunity for the reduction of health risks from perchlorate for persons served by public water systems?

The EPA's analysis presented in the 2019 proposal demonstrates that a NPDWR for perchlorate does not present a meaningful opportunity for health risk reduction for persons served by public water systems. As discussed above, the EPA found that perchlorate occurs with very low frequency at levels of public health concern. Based on updated UCMR 1 occurrence information, there were 15 water systems (0.03% of all water systems in the U.S.) that detected perchlorate in drinking water above the lowest proposed alternative MCLG of 18 μg/L, and only 1 system had a detection above the proposed alternative MCLG of 90 μg/L. Specifically, Table 1 presents the population served by PWSs that were monitored under UCMR 1 for which the highest reported perchlorate concentration was greater than the identified thresholds. The EPA estimates [3] that the number of people who may be potentially consuming water containing perchlorate at levels that could exceed the levels of concern for perchlorate could range between 26,000 and 620,000.

The small number of water systems with perchlorate levels greater than identified thresholds, and the correspondingly small population served, provides ample support for the EPA's conclusion that the regulation of perchlorate does not present a ''meaningful opportunity for health risk reduction for persons served by public water systems,'' within the meaning of SDWA 1412(b)(1)(A)(iii).

While the EPA does not believe that a national primary drinking water regulation presents a meaningful opportunity for health risk reduction, the Agency remains committed to

[3] The values shown in Table 1 are based on the revised UCMR 1 data. The EPA also applied statistical sampling weights to the small systems results to extrapolate to national results. There was one small system included in the statistical sample stratum which had a perchlorate measurement exceeding 18 μg/L. Accordingly, the EPA estimates that approximately 41,000 small system customers may be exposed to perchlorate greater than 18 μg/L.

working with States and communities in addressing perchlorate contamination of drinking water. For example, the EPA has issued a document entitled ''Perchlorate Recommendations for Public Water Systems'' which provides recommendations for actions that systems may take if there are concerns about perchlorate (USEPA, 2020b). The document outlines steps public systems can take to address perchlorate in drinking water, including testing, installing treatment equipment, and communication with customers.

Although a cost benefit analysis is not one of the three SDWA criteria for making a regulatory determination, the EPA also considered the findings of the Health Risk Reduction and Cost Analysis (HRRCA, USEPA 2019c) as additional information confirming the appropriateness of the withdrawal of the regulatory determination. The HRRCA for perchlorate (which was presented in the 2019 proposal) provides a unique set of economic data indicators that are not available for regulatory determinations because the HRRCA is required for a proposed NPDWR under SDWA 1412(b)(3)(C), but is not required to support a regulatory determination. Accordingly, because the EPA initially determined that perchlorate met the criteria for regulation and began the regulatory analysis process, the HRRCA was available with respect to perchlorate at this stage in the SDWA process, and the Agency considered this comprehensive economic analysis in informing its decision to withdraw the regulatory determination.

Specifically, the HRRCA provides a description of the potential benefits and costs of a drinking water regulation for perchlorate. For all potential regulatory levels considered for perchlorate (18, 56, and 90 μg/L), the total costs associated with establishing a regulation (ranging from $9.5 to $18.0 million across discount rates and levels) were substantially higher than the potential range of benefits (ranging from $0.3 to $3.7 million) (USEPA, 2019c). The infrequent occurrence of perchlorate at levels of health concern imposes high monitoring and administrative cost burdens on public water systems and the states, while having little impact on health risk reductions and the associated low estimates of benefits. The EPA is not finalizing the HRRCA for this final action nor is the EPA conducting an analysis in accordance with the Regulatory Flexibility Act because the Agency is not promulgating a final regulation.

Based on a comparison of costs and benefits estimated at the three potential regulatory levels, the EPA determined in the 2019 proposal that the benefits of establishing a drinking water regulation for perchlorate do not justify the potential costs.

A drinking water regulation for perchlorate would impose significant burdens on states and water systems, mainly associated with requirements for monitoring, including initial monitoring and long-term monitoring for over 60,000 systems (see Section VIII of the 2019 proposal for more information), but would result in very few systems having to take action to reduce perchlorate levels. It is of paramount importance that water systems (particularly medium, small, and economically distressed systems) focus their limited resources on actions that ensure compliance with existing NPDWRs and maintain their technical, managerial, and financial capacity to improve system operations and the quality of water being provided to their customers, rather than spending resources monitoring for contaminants that are unlikely to occur.

D. What is the EPA's final regulatory determination on perchlorate?

Based on the EPA's analysis of the best available public health information, and after careful review and consideration of public comments on the June 2019 proposal, the Agency is withdrawing its 2011 determination and is making a final determination not to regulate perchlorate. Accordingly, the EPA will not issue a NPDWR for perchlorate at this time. While the EPA has found that perchlorate may have an adverse effect on human health above certain exposure levels, based on the analysis presented in this document and supporting record, the EPA has determined that perchlorate does not occur in public water systems with a frequency and at levels of public health concern and that regulation of perchlorate does not present a meaningful opportunity to reduce health risks for persons served by public water systems. This conclusion is based on the best available peer reviewed science and data collected in accordance with accepted methods on perchlorate health effects and occurrence.

IV. Summary of Key Public Comments on Perchlorate

The EPA received approximately 1,500 comments from individuals or organizations on the June 2019 proposal. This section briefly discusses the key technical issues raised by commenters and the EPA's response. Comments are also addressed in the ''Comment Response Document for the Final Regulatory Action for Perchlorate'' (USEPA, 2020c) available at *http://www.regulations.gov* (Docket ID No. EPA–HQ–OW–2018–0780).

A. SDWA Statutory Requirements and the EPA's Authority

The EPA received comments stating that the Agency should promulgate an MCLG and MCL for perchlorate and comments stating that the Agency should not promulgate a regulation. After considering these comments, the EPA has re-evaluated perchlorate in accordance with SDWA 1412(b)(1)(A), which requires that the Agency promulgate a NPDWR if (i) the contaminant may have an adverse effect on the health of persons; (ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and (iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The EPA has determined, based upon the best available peer reviewed science and data collected in accordance with accepted methods, that perchlorate does not occur at a frequency and at levels of public health concern, and that regulation of perchlorate does not present a meaningful opportunity for health risk reduction. Because perchlorate does not meet the statutory criteria for regulation, the EPA lacks the authority to issue a MCLG or NPDWR for perchlorate, and, is therefore withdrawing its 2011 regulatory determination and issuing this final determination not to regulate perchlorate. For more information regarding the EPA's statutory authority to withdraw its regulatory determination, see Section II.C above.

B. Health Effects Assessment

Health Effects/MCLG Derivation

The EPA received comments indicating that the Agency should utilize different approaches to derive the MCLG for perchlorate including approaches that some states used to develop their perchlorate advisory levels or drinking water standards. The EPA considered a number of alternative approaches to develop the MCLG for perchlorate and in accordance with SDWA 1412(e), the Agency sought recommendations from the Science Advisory Board. The EPA derived the proposed MCLG for perchlorate based on the approach recommended by the Science Advisory Board (SAB) (SAB for

the U.S. EPA, 2013). The SAB recommended that ''*the EPA derive a perchlorate MCLG that addresses sensitive life stages through physiologically-based pharmacokinetic/pharmacodynamic modeling based upon its mode of action rather than the default MCLG approach using the RfD and specific chemical exposure parameters.*'' The EPA has implemented these recommendations and has obtained two independent peer reviews of the analysis. These peer reviewers stated that: ''*[o]verall, 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 below, the current models are fit-for-purpose to determine an MCLG*'' (External Peer Reviewers for USEPA, 2018, p. 2).

The EPA received comments indicating that the most sensitive life stages were not selected and/or considered in the Agency's approach. The EPA disagrees. Gestational exposure to perchlorate during neurodevelopment is the most sensitive time period. The NRC concluded that the population most sensitive to perchlorate exposure are ''the fetuses of pregnant women who might have hypothyroidism or iodide deficiency'' (p. 178, NRC 2005). In addition, there is clear evidence that disrupted maternal thyroid hormone levels during gestation can impact neurodevelopment later in life (Alexander et al., 2017; Costeira et al., 2011; Endendijk et al., 2017; Ghassabian, Bongers-Schokking, Henrichs, Jaddoe, & Visser, 2011; Glinoer & Delange, 2000; Glinoer & Rovet, 2009; Gyllenberg et al., 2016; Henrichs et al., 2010; Korevaar et al., 2016; Morreale de Escobar, Obregón, & Escobar del Rey, 2004; Noten et al., 2015; Pop et al., 2003, 1999; SAB for the U.S. EPA, 2013; Thompson et al., 2018; van Mil et al., 2012; Wang et al., 2016; Zoeller & Rovet, 2004; Zoeller et al., 2007). The available data demonstrate that the fetus of the first trimester pregnant mother, when compared to other life-stages, experiences the greatest impact from the same dose of perchlorate, which is described in detail in Section 6 of the document ''Deriving a Maximum Contaminant Level Goal for Perchlorate in Drinking Water'' (USEPA, 2019a). Some commenters suggested that the bottle-fed infant is a more sensitive life-stage. The EPA disagrees. As described in the January 2017 Peer Review Report on the original Biologically Based Dose Response (BBDR) model, the bottle-fed infant's thyroid hormone levels were not impacted by doses of perchlorate up to 20 µg/day (External Peer Reviewers for USEPA, 2017). This lack of any impact is due primarily to the iodine in the formula, which offsets the impact of perchlorate on the thyroid.

The EPA received comments advocating for the use of the population-based approach evaluating the shift in the proportion of a population that would fall below a hypothyroxinemic cut point under a perchlorate exposure scenario. 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 a MCLG to avoid adverse health effects and because it is most consistent with the SAB recommendations. In addition, given that thyroid hormone levels vary by reference population and that there is not a defined threshold for the concentration of fT4 representing hypothyroxinemia makes the population-based approach less desirable than the approach selected (USEPA, 2018).

End Point Selection/Basis

The EPA received comments regarding the magnitude of an IQ change which should be used in deriving the MCLG. The EPA's proposed MCLG was based upon avoiding a 2% change in IQ in the most sensitive life stage, and the EPA also requested comment on alternative options for the MCLG that would respectively avoid 1% or 3% change in IQ in the most sensitive life stage. Many comments stated that the EPA should at most consider a 1% IQ change. However, several commenters stated that a 3% change is too small to have a meaningful impact and suggested that the EPA consider a higher IQ percent change.

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% 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 evaluated the level of perchlorate in water associated with a 1% decrease, a 2% decrease, and a 3 percent decrease in the mean population IQ (*i.e.,* 1, 2 and 3 IQ points).

In evaluating the frequency and level of occurrence of perchlorate in drinking water, the EPA has found that perchlorate does not occur with frequency even at the lowest alternative MCLG of 18 µg/L, which is based upon avoiding a 1% change in IQ in the most sensitive life stage.

The EPA received comments that the proposed MCLG did not incorporate an adequate margin of safety to comply with the SDWA. The EPA disagrees that it failed to use an adequate margin of safety. The EPA's assessment focused upon the most sensitive subset of the population, specifically offspring whose mothers had low (75 µg/day) iodine intake and were hypothyroxinemic (fT4 in the lowest 10th percentile of the population). In addition, to account for uncertainties and to ensure that the most sensitive subset of the population is protected with an adequate margin of safety, a 3-fold uncertainty factor was applied to the proposed MCLG calculation (USEPA, 2019a). More discussion on the uncertainty factor is presented below, in the section entitled ''Consideration of Uncertainties.''

The EPA received some comments stating that the selection of the study for informing the relationship between maternal hormone levels (fT4) and IQ was inadequately described. Other comments supported the EPA's study selection. The EPA concludes that selection of the Korevaar et al. (2016) study is appropriate because that study provides the most robust data available with a clear measure of neurodevelopment that can be expressed as a function of changing maternal fT4 exposure, which is necessary to the development of the model.

BBDR and PBPK Models

The EPA received comments indicating that the BBDR model was not transparent, scientifically valid, or based on robust data. The EPA disagrees. The model represents the best available peer reviewed science and uses the best available data to inform a MCLG for perchlorate. The EPA disagrees with the suggestion that there is a significant lack of transparency with respect to the assumptions related to the BBDR model. Appendix A of the EPA's Proposed MCLG Approaches report outlines the justification for all assumptions used in the development of the BBDR model (USEPA, 2019a). The EPA also disagrees with the assertion that the BBDR model is far too uncertain to be relied upon as the basis for the derivation of the RfD. The EPA has used the best available science to calibrate the pharmacokinetic aspects of the BBDR model. The development of the BBDR model was in response to SAB recommendations, and a model was deemed to be a more refined approach to estimating a dose-response relationship between perchlorate exposure and maternal fT4 than anything that was available in the current scientific literature. The EPA disputes the claim that the BBDR model is not scientifically valid, as the Agency conducted a peer review of the approach proposed and the reviewers concluded that the approach was ''fit for purpose'' to inform a MCLG for perchlorate (External Peer Reviewers for U.S. EPA, 2018, p. 2).

Consideration of Uncertainties

The EPA received comments on the Agency's use of Uncertainty factors (UFs); with most commenters suggesting that the EPA should consider a higher UF for inter-individual variability. The EPA thoroughly considered the application of UFs when deriving the RfDs and followed guidance presented in ''A review of the reference dose and reference concentration processes'' (USEPA, 2002). The EPA concluded that the UFs are adequately justified, and subsequently no changes have been made. Justification for each of the UFs can be found in Section 11 of the Agency's MCLG Derivation report (USEPA, 2019a).

The EPA selected a UF of 3 for inter-individual variability, because the Agency specifically modeled groups within the population that are identified as likely to be at greater risk of the adverse effects from perchlorate in drinking water (*i.e.,* the fetus of the iodide deficient pregnant mother). The EPA selected model parameters to account for the most sensitive individuals in that group (*i.e.,* muted TSH feedback, low fT4 values, low-iodine intake). As discussed in the MCLG Derivation report, the EPA has attempted to select the most appropriate inputs to protect the most sensitive population with an adequate margin of safety (USEPA, 2019a). The EPA has determined that the selection of a UF of 3 for inter-individual variability is justified. As described in the MCLG Derivation report, because the output from the BBDR model is specific to the sensitive population, the EPA concluded that the UF of 3 is appropriate. In regard to variation in sensitivity among the members of the human population (*i.e.,* inter-individual variability), section 4.4.5.3 of the EPA guidance ''A review of the reference dose and reference concentration process'' (USEPA, 2002) document states, ''In general, the Technical Panel reaffirms the importance of this UF, recommending that reduction of the intraspecies UF from a default of 10 be considered only if data are sufficiently representative of the exposure/dose-response data for the most susceptible subpopulation(s). Similar to the interspecies UF, the intraspecies UF can be considered to consist of both a toxicokinetic and toxicodynamic portion (*i.e.* 10∧0.5 each)'' (USEPA, 2002). Given that the BBDR model significantly accounts for differences within the human population, the full UF of 10 is not warranted.

One commenter suggested using a UF greater than 1 to account for the extrapolation of the lowest-observed adverse effect level (LOAEL) to the no-observed-adverse-effect-level (NOAEL). LOAELs and NOAELs were not identified or used by the EPA in its assessment because the Agency employed a sophisticated BBDR modeling approach, which was coupled with extrapolation to changes in IQ using linear regression, to determine a POD that would not be expected to represent an adverse effect. Therefore, a UF of 1 is appropriate. Other commenters suggested incorporating UFs for database deficiencies. Based on the findings of the NRC report, the EPA has previously concluded that this UF was not needed for deficiencies in the perchlorate database (NRC, 2005; USEPA, 2005a). The EPA determined that a UF of 1 to account for database deficiencies is still appropriate, given that the comprehensiveness of the perchlorate database has only increased since 2005.

Health Advisory

Several commenters suggest that the EPA should withdraw the 2011 determination to regulate perchlorate and instead issue an updated health advisory for perchlorate. The EPA issued an interim health advisory level for perchlorate in 2008. Health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to state agencies on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination. State and local public health officials have the discretion to use the perchlorate health advisory as they deem necessary. The EPA will consider updating the 2008 perchlorate health advisory in the future.

C. Occurrence Analysis

The EPA received comments suggesting that the revised UCMR 1 data did not provide an adequate estimate of the perchlorate occurrence in drinking water systems. Some commenters indicated that the age of the collected data rendered the occurrence analysis obsolete and overestimated, because it no longer captures current lower contamination conditions that have been achieved due to mitigation measures taken in the Colorado River Basin. Other commenters criticized the EPA for replacing UCMR 1 data for systems located in the States of California and Massachusetts with more recent state compliance data for perchlorate.

The EPA recognizes that changes in perchlorate levels (increasing or decreasing) may have occurred in water systems since the UCMR 1 samples were collected between 2001 to 2005. The EPA updated the UCMR 1 data set to improve its accuracy in representing the current conditions for states that have enacted perchlorate regulations since the UCMR 1 monitoring was conducted. As outlined in the June 26, 2019 proposal, the EPA updated occurrence data for California and Massachusetts with current compliance data as reported by the states. Systems from these two states that were sampled during the UCMR 1 and that had reported perchlorate detections were updated with more recently measured values taken from current compliance monitoring data from Consumer Confidence Reports and state-level perchlorate compliance monitoring data

to match corresponding water systems and entry points.

The EPA has determined that the updated UCMR 1 data are the best available data collected in accordance with accepted methods on the frequency and level of perchlorate occurrence in drinking water on a national scale.

V. Conclusion

With this withdrawal of the 2011 perchlorate regulatory determination and final determination not to regulate perchlorate, the EPA announces that there will be no NPDWR for perchlorate at this time. The EPA could consider re-listing perchlorate on the CCL and could proceed to regulation in the future if the occurrence or health risk information changes. As with other unregulated contaminants, the EPA will consider addressing limited instances of elevated levels of perchlorate by working with the affected system and state, as appropriate.

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List of Subjects

40 CFR Part 141

Environmental protection, Administrative practice and procedure, Chemicals, Indians—lands, Intergovernmental relations, Radiation protection, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

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

Andrew Wheeler,

Administrator.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–2003–0010; FRL–10011–67–Region 7]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Partial Deletion of the Omaha Lead Superfund Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; partial deletion.

SUMMARY: The Environmental Protection Agency (EPA) Region 7 announces the deletion of 117 residential parcels of the Omaha Lead Superfund site (Site or OLS) located in Omaha, Nebraska, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Nebraska, through the Nebraska Department of Environment and Energy, determined that all appropriate Response Actions under CERCLA were completed at the identified parcels. However, this deletion does not preclude future actions under CERCLA. This partial deletion pertains to 117 residential parcels. The remaining parcels will remain on the NPL and are not being considered for deletion as part of this action.

DATES: This action is effective July 21, 2020.

ADDRESSES: EPA has established a docket for this action under Docket ID no. EPA–HQ–SFUND–2003–0010. All documents in the docket are listed on *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically *https://www.regulations.gov* or in hard copy at the site information repositories. Locations, contacts, and viewing hours of the Site information repositories are:

- EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219, open from 8:00 a.m. and 4:00 p.m. Monday through Friday, excluding Federal holidays and facility closures due to COVID–19. We recommend that you contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section before visiting the Region 7 office.
- W. Dale Clark Library, located at 215 S 15th Street, Omaha, NE 68102, open 10:00 a.m. to 8:00 p.m. Monday through Thursday; 10:00 a.m. to 6:00 p.m. Friday and Saturday; and 1 p.m. to 6 p.m. Sunday, excluding closures due to COVID–19.

The EPA has temporarily suspended many Regional Records Centers for public visitors to reduce the risk of transmitting COVID–19. In addition, many site information repositories are closed and information in these repositories, including the deletion docket, has not been updated with hardcopy or electronic media. For further information and updates on EPA Docket Center services, please visit us online *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID.

FOR FURTHER INFORMATION CONTACT: Elizabeth Hagenmaier, Remedial Project Manager, U.S. Environmental Protection Agency, Region 7, SEMD/LMSE, 11201 Renner Boulevard, Lenexa, KS 66219, telephone (913) 551–7939, email: *hagenmaier.elizabeth@epa.gov.*

SUPPLEMENTARY INFORMATION: The portion of the site to be deleted from the NPL are 117 residential parcels of the Omaha Lead Superfund site, Omaha, Nebraska. A Notice of Intent for Partial Deletion for this Site was published in the **Federal Register** on May 12, 2020 (85 FR 27979).

The closing date for comments on the Notice of Intent for Partial Deletion was June 11, 2020. No public comments were received, and EPA has determined it will proceed with the partial deletion.