Symbiosis

www.symbiosisonlinepublishing.com
ISSN Number: 2572-3162

International Journal of Scientific Research in Environmental Science and Toxicology

Opinion Article

Open Access

Perchlorate: The Two-Decade Journey to a Proposed Rule

Susan B. Goldhaber*

**MPH, SBG Consulting, Inc. 4112 Gardenlake Dr., Raleigh, North Carolina 27612, United States*

Received: August 19, 2019; Accepted: August 30, 2019; Published: September 03, 2019

***Corresponding author:** Susan B. Goldhaber, MPH, SBG Consulting, Inc. 4112 Gardenlake Dr., Raleigh, North Carolina 27612, United States, Email: suegold1984@gmail.com*

Abstract

Perchlorate, a manufactured and naturally occurring chemical, was first detected in drinking water supplies in California in the 1980s. In the 1990s, perchlorate contamination (in the parts-per-billion range) was detected in drinking water supplies across the U.S. EPA began evaluating perchlorate for regulation in drinking water in 1998 and has spent 21 years issuing various proposals and findings on perchlorate, with a proposed (not final) drinking water regulation issued on June 26, 2019. The lack of a drinking water standard has had ramifications, including lack of trust in public drinking water resulting in economic hardship, particularly among Department of Defense personnel and other low-wealth communities, the states setting a patchwork of their own regulations on perchlorate, and lack of monitoring or clean-up of perchlorate in Department of Defense water systems. The reasons for EPA's two-decade rulemaking process for perchlorate include the process EPA uses to determine regulatory feasibility under the Safe Drinking Water Act and the multi-year scientific review process. Key recommendations for shortening the process include amending the Safe Drinking Water Act and increasing transparency of the rulemaking process.

List of Abbreviations: BMDL- Benchmark Dose Level; CCL- Contaminant Candidate List; DOD- Department of Defense; DWEL- Drinking Water Equivalent Level; EPA- Environmental Protection Agency; GAO- General Accountability Office; HRL- Health Reference Level; IRIS- Integrated Risk Information System; LOAEL- Lowest-Observed-Adverse-Effect Level; MCL- Maximum Contaminant Level; MCLG- Maximum Contaminant Level Goal; NOAEL- No-Observed-Adverse-Effect Level; NRC- National Research Council; RfD- Reference Dose; RSC- Relative Source Contribution; SAB-Science Advisory Board; SDWA- Safe Drinking Water Act

Introduction

Chemistry of perchlorate

Perchlorate is an inorganic ion containing one chlorine atom bound to four oxygen atoms in a tetrahedral configuration (see Figure 1). Perchlorate does not exist on its own; it must be bound to other chemicals, such as ammonia, magnesium, and potassium. Perchlorate can form naturally in the air and is found at low levels in rain or snow. It is also found at high levels in certain rock and mineral deposits across the world from natural processes [1].

Perchlorate is also a manufactured compound, manufactured primarily as an oxidizer for use in solid fuels to power rockets, missiles, and fireworks [1].

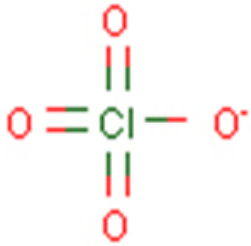

Figure 1: Chemical structure of perchlorate

Perchlorate contamination

Perchlorate has been found in lakes, rivers, and groundwater wells across the U.S. In 1997, a new method to measure perchlorate in water was developed that allowed the measurement of much lower levels of perchlorate in water (approximately 1 microgram (µg)/liter (L) of water, which is equal to one part of perchlorate per billion parts of water (1 ppb)). Perchlorate has been found in approximately 4% of over 3,800 public water systems across the U.S., with perchlorate levels ranging from 4 µg/L to 420 µg/L [1].

Due to perchlorate's use in rocket fuels and explosives, perchlorate contamination of water is of concern in Department of Defense (DOD) facilities across the country. As of 2005, perchlorate was found in surface water in 17 DOD facilities in 9 states and in ground water in 48 DOD facilities and 5 other federal agency facilities in 23 states. The levels of perchlorate ranged from 1 µg/L to 276,000 µg/L [1].

In 2017, the General Accountability Office (GAO) issued a report on DOD's actions regarding unregulated chemicals, including perchlorate, that have been found in DOD facilities and contaminating drinking water. DOD's public water systems are required to comply with legally enforceable drinking water regulations issued by EPA under the Safe Drinking Water Act (SDWA). The GAO issued five recommendations to improve DOD's reporting and use of data to comply with health-based regulations [2].

Regulation of drinking water contaminants

Regulatory process

The EPA, under the SDWA, may issue legally enforceable standards for contaminants in drinking water. These standards, known as the National Primary Drinking Water Regulations, generally limit the levels of contaminants in public water systems. EPA has regulations for approximately 90 drinking water contaminants [3].

Under the SDWA, the process to issue regulations for new (unregulated) contaminants is to develop a list (the Contaminant Candidate List or CCL) of unregulated contaminants that present the greatest health concern in drinking water, establish a program to monitor for these contaminants in drinking water, and decide whether or not to regulate at least 5 contaminants from the list every 5 years. (EPA has not regulated any new contaminants using this process since 1996) [3].

EPA must base its determination on whether to regulate a contaminant on three criteria:

- The contaminant may have an adverse effect on the health of persons
- The contaminant is known to occur or there is a high chance that the contaminant will occur in public water systems often enough and at levels of public health concern
- In the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems [3].

If EPA decides to regulate a contaminant, EPA must first set a maximum contaminant level goal (MCLG). The MCLG is a non-enforceable health goal set at the level at which no known or anticipated health effects occur. After setting the MCLG, EPA sets the maximum contaminant level (MCL). The MCL is the enforceable drinking water standard that must be set as close to the MCLG as feasible. EPA must factor in cost of available treatment technologies in setting the MCL [3].

Perchlorate regulation

Perchlorate in drinking water is not currently regulated by EPA. Table 1 summarizes the various actions taken by EPA on perchlorate over the last 20 years. EPA recently (June 26, 2019) issued a proposed rule to regulate perchlorate in drinking water [4]. There is a two-month public comment period followed by EPA issuing the final rule on perchlorate.

Table 1: History of Perchlorate

Year	Action
1985	Perchlorate is first discovered in wells at Superfund sites in California [1].
1997	An analytical method is developed that achieves a detection limit of 1 µg/L for perchlorate. With this lower detection limit, perchlorate is detected in wells across the country [1].
1998	EPA first lists perchlorate on the Contaminant Candidate List [CCL] [4].
1999	EPA holds a scientific workshop in California to discuss the health effects of perchlorate [5]. EPA issues the Unregulated Contaminant Monitoring Rule; this rule requires a selected number of public drinking water systems to monitor for perchlorate and 25 other contaminants in drinking water [4].
2002	EPA issues a draft risk assessment on perchlorate that calculates a Reference Dose [RfD] of 0.03 µg/kg/day based on changes in the brain and thyroid in a rat study [6].
2005	At the request of the EPA and other Agencies, the National Research Council [NRC] evaluates EPA's 2002 Risk Assessment and RfD. The NRC [2005] recommends that EPA set its RfD at 0.7 µg/kg/day based on a human study that showed inhibition of iodine uptake by the thyroid [6]. EPA accepts these recommendations and establishes an RfD of 0.7 µg/kg/day and publishes it in EPA's Integrated Risk Information System [IRIS] [7].
2008	EPA issues a regulatory determination not to regulate perchlorate in drinking water systems, along with all other compounds listed on the CCL. This determination was based on the conclusion that perchlorate did not occur with a frequency and at levels of public health concern and the development of a regulation did not present a meaningful opportunity for health risk reduction, as required under the SDWA [8]. The U.S. Senate holds a hearing entitled, "Perchlorate and Trichloroethylene in water." Senator Boxer announces two bills, one of which would require EPA to monitor for perchlorate in drinking water and the other which would quickly require EPA to set a perchlorate standard in drinking water that protects pregnant women and children [9].
2009	EPA publishes an interim health advisory of 15 µg/L for perchlorate. A Health Advisory is a nonregulatory guideline that sets out levels of a contaminant at which adverse health effects are not likely to occur [4]. EPA receives over 33,000 comments in response to its 2008 regulatory determination not to regulate perchlorate [4]. EPA publishes a supplemental request for comment with a new analysis that derives alternative Health Reference Levels [HRLs] for perchlorate ranging from 1 µg/L to 47 µg/L [4].

2011	EPA reverses its 2008 decision and publishes a regulatory determination to regulate perchlorate in drinking water systems. This determination was based on the alternative HRLs that showed that the likelihood of perchlorate occurring at levels of concern had significantly increased compared to the levels described in the 2008 negative regulatory determination [10].
2012	EPA requests comments from EPA's Science Advisory Board [SAB] on how best to derive a MCLG for perchlorate. The SAB responds that EPA should derive a perchlorate MCLG that addresses sensitive life stages through the use of specialized modeling approaches [4]. EPA receives a "Request for Correction" from the U.S. Chamber of Commerce regarding information and data used by EPA in its 2011 determination to regulate perchlorate [4].
2016	The U.S. District Court for the Southern District of New York enters a consent decree which requires EPA to publish in the Federal Register a proposed MCLG and MCL for perchlorate by Oct. 30, 2018 and issue a final MCLG and MCL by December 19, 2019. The deadline for EPA to propose an MCLG for perchlorate was later extended to May 28, 2019 [4].
2017	The Government Accountability Office [GAO] issues a report on management by the DOD of contaminants in drinking water, including perchlorate. The GAO makes five recommendations to improve DOD's reporting and use of data on compliance with health-based drinking water regulations [2]. EPA convenes an independent review panel to evaluate the models that EPA has developed in response to the SAB comments. The review panel recommends that EPA use a model that specifically considers the effects of perchlorate on the fetuses of pregnant women with low iodine levels and infants exposed to perchlorate though breast milk or formula [4].
2018	EPA convenes a second review panel to review the model that EPA has updated based on the recommendations of the first review panel. The second review panel is largely supportive of EPA's revised model [4].
2019	On June 26, 2019, EPA proposes an MCLG of 56 µg/L and an enforceable MCL of 56 µg/L for perchlorate, based on the revised model. The MCLG is calculated based on an RfD of 2.2 µg/kg/day, calculated to protect the fetus of a pregnant woman with low iodine levels from a 2-point loss in IQ, and uses a relative source contribution factor [RSC] of 80%. EPA requests comments on alternative MCLGs of 18 µg/L or 90 µg/L [4].

Criteria for regulating perchlorate

As discussed above in Section 'Regulatory process', EPA must base its determination on whether to regulate a contaminant on three criteria:

- The contaminant may have an adverse effect on the health of persons
- The contaminant is known to occur or there is a high chance that the contaminant will occur in public water systems often enough and at levels of public health concern
- In the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems.

In 1999, EPA prepared an answer to the first part of the second criterion, that "the contaminant is known to occur in public water systems" when EPA issued the "Unregulated Monitoring Rule" for perchlorate. This rule required all large public water systems (serving greater than 10,000 people) and a representative sample of small water systems to monitor for perchlorate in drinking water. The results were available within a few years and showed that perchlorate was detected in public water systems across the country [4].

In 2002, EPA prepared an answer to the first criterion for perchlorate, preparing a Toxicological Review Document for Perchlorate that summarized studies showing that perchlorate presents adverse health effects in humans [6].

The second part of the second criterion, that "perchlorate will occur in public water systems often enough and at levels of public health concern" is not an objective decision. The SDWA presents no guidance as to what constitutes "occurrence often enough and at levels of public health concern."

- It is a subjective decision as to whether a finding of perchlorate in 0.1%, 1%, or 10% of public water supplies, constitutes "often enough".
- For the last few decades, the determination of "levels of public health concern" has been determined using the risk assessment process. For chemicals in water, the process involves determining the Reference Dose (RfD). The RfD is a nonregulatory value that is established by EPA and is published, along with its rationale, on EPA's Integrated Risk Information System (IRIS) (https://www.epa.gov/iris). The RfD establishes the level of a contaminant that is expected to be without adverse health effects after oral exposure for a lifetime. The IRIS assessment is often used by EPA's Office of Water, and other EPA offices, as the basis for their regulations.
- **Determining the RfD:**

o A comprehensive review of the available health effects data consisting of epidemiology (human) and toxicology (animal) studies is carried out.

o The "critical study" is selected, based on the health effects endpoints being studied and the levels at which health effects were seen.

o The highest concentration from the critical study at which adverse health effects were not observed (termed the no-observed-adverse-effect level (NOAEL)) or the lowest concentration at which adverse health effects were observed (termed the lowest-observed-adverse-effect level (LOAEL)), is selected from the study. Alternatively, scientists carry out

modeling on the critical study; modeling the concentration levels to determine a benchmark dose level (BMDL). The NOAEL, LOAEL, or BMDL selected from the study are termed the "point of departure".

- An uncertainty factor is applied to the point of departure. This uncertainty factor traditionally has ranged from 3 to 1000 and is used to extrapolate from the study population to the general human population, which includes sensitive subpopulations.

Example: NRC (2005) selected the following as the critical study for the RfD for perchlorate:

- Greer et al. (2002) study in which groups of healthy men and women were administered perchlorate at 7 – 500 μg/kg/day for 14 days. The study reported no effects on the thyroid at 7 μg/kg/day [11].
- The NRC recommended the selection of a point of departure of 7 μg/kg/day.
- The NRC recommended application of an uncertainty factor of 10 to the point of departure, resulting in a health level of 0.7 μg/kg/day. The NRC concluded that this level "should protect the health of even the most sensitive populations" [6].
- EPA selected this level as the RfD and published it in IRIS [7].

EPA then converted the RfD to a concentration level in water, termed the Drinking Water Equivalent Level (DWEL). For perchlorate, the DWEL was the RfD (0.7 μg/kg/day) multiplied by an average adult body weight of 70 kg and divided by an average water consumption of 2 liters/day, equaling a concentration of 25 μg perchlorate per liter of water [8].

EPA then converted the DWEL to the Health Reference Level (HRL), a level of a contaminant at which no adverse health effects would occur after exposure from all sources. For perchlorate, the HRL consisted of the DWEL (25 μg/L) multiplied by a relative source contribution (RSC) of 62%, equaling a concentration of 15 μg/L. The RSC is the percentage of the RfD remaining for drinking water exposure for the general population, after other sources of exposure (air, food) have been considered. The RSC was calculated for pregnant women as the dose remaining for water after considering levels of perchlorate found in food in the National Health and Nutrition Examination Survey (NHANES) [8].

In 2008, EPA made the determination not to regulate perchlorate. This was based on EPA's finding that perchlorate did not occur in public water systems often enough and at levels of public health concern to warrant regulation. EPA justified this decision based on calculations using the HRL of 15 μg/L. Based on the data from the Unregulated Contaminant Monitoring Rule, EPA estimated that less than 1% of drinking water systems had perchlorate levels above the HRL, and that perchlorate did not occur frequently at levels of health concern. The EPA also determined that there was not a meaningful opportunity for a drinking water regulation to reduce health risks [8].

In 2011, EPA reversed this decision and proposed to regulate perchlorate in drinking water. This was based on the calculation of 7 different HRLs for different life stages. The HRL of 15 μg/L which EPA used in 2008 to justify not regulating perchlorate was based on exposure to the pregnant woman and her fetus, which the NRC identified as "the most sensitive population." In 2011, EPA calculated 7 different HRLs, ranging from 1 μg/L to 47 μg/L based on infants and developing children as additional life stages. EPA determined that approximately 4% of the public water supplies had at least one detection of perchlorate at levels greater than 4 μg/L. EPA used this analysis to justify that perchlorate occurred frequently at levels of public health concern [10].

Role of scientific review in perchlorate regulation

In 2002, EPA prepared a draft risk assessment on perchlorate with an RfD of 0.03 μg/kg/day [6]. Shortly afterwards, EPA asked the NRC to evaluate the risk assessment and the RfD. The NRC (2005) issued a report and recommended that EPA set its RfD at 0.7 μg/kg/day (see Section 'Criteria for regulating perchlorate' above). EPA accepted this recommendation and published the RfD in IRIS.

In 2012, EPA requested comments from EPA's Science Advisory Board (SAB) on how best to derive an MCLG for perchlorate and the SAB responded (in the same year) that EPA should use specialized modeling approaches. In 2017, EPA convened an independent review panel to evaluate the models that were developed by EPA in response to the SAB comments. In 2018, EPA convened a second review panel to review the model that EPA had updated based on the recommendations of the first review panel. On June 26, 2019, EPA proposed an RfD of 2.2 μg/kg/day and an MCLG and MCL of 56 μg/L based on the model [4].

The role of scientific review in setting drinking water regulations is discussed in Section 1413e of the SDWA [12]. This section states that "The Administrator shall request comments from the Science Advisory Board prior to proposal of the MCLG and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay the final promulgation of any national primary drinking water standard".

Although the SDWA clearly states that the EPA may request comments from the SAB prior to proposing an MCLG, it also states that this review process should not be used to delay promulgation of a drinking water standard. For perchlorate, EPA has held four review processes with scientific experts: the first in 2002 when EPA asked the NRC to evaluate EPA's risk assessment and RfD for perchlorate; the second in 2012 when EPA requested comments from the SAB on how best to derive an MCLG for perchlorate; the third in 2017 when EPA convened an independent review panel to review the models that were developed in response to the SAB comments; and the fourth to review the model that EPA updated based on the recommendations of the first review panel.

Although the SDWA does not specify what length of review time is considered to constitute "delay of promulgation of a drinking water standard", it appears that the SDWA envisioned a short, one-time review by the SAB and not the four review processes occurring over a 17-year period.

Ramifications of lack of federal drinking water regulation for perchlorate

United States

A recent survey found that 52% of Americans think that federal laws are not strict enough regarding drinking water quality, with 26% agreeing that "I am concerned about the health risks associated with drinking water [13]. A 2016 survey found that only 7% of those surveyed wanted less federal involvement in drinking water quality, while 50% wanted to see more federal involvement, and 40% thought the current level of involvement was about right. In addition, this survey reported that only one-third of Americans drink water straight from the tap, with one-third using water filters and another one-third using bottled water. This survey also found that the lead water crisis in Flint, Michigan was closely followed by the majority (60%) of Americans, with 56% of respondents believing that the problems in Flint are signs of a more widespread problem [14].

This survey also reported that whites (54%) are significantly more likely than blacks (40%) or Hispanics (28%) to be very confident in the safety of their drinking water. Six out of 10 people living in households making more than $100,000 a year are very confident in the safety of their water, while less than 4 in 10 people making less than $50,000 a year are very confident in the safety of their water [14]. A study showed that bottled water costs 2000 times as much as tap water, and Americans have continued to buy it through both good and bad economic times, with the U.S. more than tripling its bottled water consumption since 1999 [15].

In summary, while it is not possible to know precisely what percentage of people would drink tap water if they trusted the federal government to ensure that their water was clean, it is probable that many of them are purchasing costly water filters and bottled water because of their lack of trust. Many of these people cannot afford to spend this money without cutting back on other necessities, such as food or medicine. Therefore, when people become aware that the federal government does not have a drinking water regulation for a chemical such as perchlorate, it adds to a general distrust of the government to provide a basic and necessary service, and may create economic hardship among people who can least afford it.

States

The lack of a federal drinking water regulation has led to the states setting a patchwork of standards and guidelines for perchlorate [16]:

Two states have set their own drinking water standards for perchlorate:

- Massachusetts: 2 µg/L
- California: 6 µg/L (proposal to lower it to 1 µg/L)

Five states have set public health goals for perchlorate in drinking water:

- Arizona: 14 µg/L
- New York: 5 µg/L
- Maryland: 1 µg/L
- New Mexico: 1 µg/L
- New Hampshire: 1 µg/L

Three states have set enforceable action levels (if an enforceable action level is exceeded, the water treatment company must take appropriate action to reduce the concentration in water below the action level) for perchlorate in drinking water:

- New York: 18 µg/L
- Nevada: 18 µg/L
- Texas: 4 µg/L

Although the states cited above have set different regulations or guidelines for perchlorate, the actual values are very close considering their levels of uncertainty; they range from 1 µg/L to 18 µg/L which is a very small difference, considering the measurement is taking place at the parts-per-billion range.

The lack of a federal drinking water standard means that states must make difficult decisions when perchlorate is detected in drinking water. Most states and companies greatly prefer having one federal regulation with its clear requirements. For states that detect perchlorate in drinking water and do not have their own regulation or guideline, they have the option to not do anything, to set their own standard or guideline (as the states above have done) and remove the perchlorate to that level, to remove the perchlorate to the health advisory level suggested by EPA, or to take other action, such as notifying consumers.

Department of Defense (DOD)

About 3 million people who live and work on military instillations across the country receive drinking water from a DOD public water system. About two-thirds of these people drink DOD-treated water and about one-third drink non-DOD-treated water, i.e. drinking water from DOD systems that have been privatized or obtain treated drinking water from a local water utility. DOD's public water systems, like all public water systems, are required to comply with legally enforceable drinking water regulations that are issued by the EPA under the SDWA [2].

Due to perchlorate's use in rocket and missile fuel, it has been detected in water supplies at and near military facilities across the country. Since there is not an enforceable drinking water standard for perchlorate, DOD has not been required to monitor for or to clean-up water containing perchlorate. However, following EPA's

issuance of an interim health advisory for perchlorate in 2008, DOD issued a policy in 2009 directing DOD-owned drinking water systems that were already testing for inorganic contaminants to also test for perchlorate [2].

However, currently DOD is no longer testing for perchlorate unless there is a state requirement to do so. DOD stated that "previous testing indicated that DOD was not a primary source of perchlorate in drinking water and that known releases of perchlorate did not currently pose a threat to drinking water". According to DOD, "once EPA has issued a final regulation, DOD is committed to complying with it" [2].

Potential solutions

The following are several solutions to streamline the regulatory process for drinking water contaminants:

Amend the Safe Drinking Water Act

The SDWA was first enacted in 1974 and has been amended numerous times since then (see Table 2). However, only two of these amendments (1986 and 1996) concerned the process for regulating contaminants in drinking water. Amending the Safe Drinking Water Act may not seem to be a practical suggestion due to the length of time it takes for Congress to act on issues. However, this suggestion consists of amending one small section of the law, not rewriting the entire law. As noted in Table 2, the Safe Drinking Water Act has already been amended 12 times since 1974 [3], so this would not be a unique undertaking.

The 1974 law gave EPA substantial discretion as to its regulation of drinking water contaminants. The first major amendments were enacted in 1986 and were intended to increase the pace at which EPA regulated contaminants. From 1974 to 1986, EPA had regulated just one additional contaminant beyond the 22 standards previously developed by the Public Health Service. The 1986 amendments required EPA to issue regulations for 83 specified contaminants by June 1989 and 25 more contaminants every three years after that.

Table 2: History of Safe Drinking Water Act [3]

Year	Act and Amendments	Public Law Number
1974	Safe Drinking Water Act of 1974	P.L. 93-523
1977	Safe Drinking Water Act Amendments of 1977	P.L. 95-190
1979	Safe Drinking Water Act Amendments	P.L. 96-6396
1980	Safe Drinking Water Act Amendments	P.L. 96-502
1986	Safe Drinking Water Act Amendments of 1986	P.L. 99-339
1988	Lead Contamination Control Act of 1988	P.L. 100-572
1996	Safe Drinking Water Act Amendments of 1996	P.L. 104-182
2002	Public Health Security and Bioterrorism Preparedness and Response Act of 2002	P.L. 107-188
2011	Reduction of Lead in Drinking Water Act	P.L. 111-380
2013	Community Fire Safety Act of 2013	P.L. 113-64
2015	Drinking Water Protection Act	P.L.114-45
2015	Grassroots Rural and Small Community Water Systems Assistance Act	P.L. 114-98
2016	Water Infrastructure Improvements for the Nation Act	P.L. 114-322

After concern that these amendments were unworkable, Congress amended the SDWA in 1996 and revoked the requirement that EPA regulate 25 new contaminants every three years and created a risk-based approach for selecting contaminants for regulations. For setting regulations, EPA is currently operating under these 1996 amendments. However, EPA has not regulated any new contaminants using this process since 1996.

Suggestions

The following are several suggestions for amending the SDWA to streamline the process:

1. **Revise the contaminant selection process:**

- Remove the last two criteria for selecting contaminants for drinking water regulations (i.e., that the contaminant is known to occur or there is a high chance that the contaminant will occur in public water systems often enough and at levels of public health concern and that regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems) but keep the first criterion that "the contaminant may have adverse health effects". This criterion is workable and can be carried out in a timely fashion.
- Change the requirement that every 5 years, EPA is required to make a regulatory determination as to whether to regulate five contaminants included on the CCL. This regulatory determination is not workable and does not lead to practical decisions as to which chemicals to regulate. One suggestion is to require EPA to consult with the water industry to decide

which chemicals to next regulate. Many times, one type of water treatment removes multiple contaminants and the decision as to which contaminants to regulate should include this consideration.

2. **Revise the standard setting process:**

- Remove the two-step process of first setting the MCLG and then setting the MCL as close to the MCLG as feasible. This process is extremely time-consuming and a more practical process where health, technology, costs, and analytical methods are all considered in one step should be considered.

Change EPA's process for setting MCLGs

The SDWA does not mandate the process that EPA must use to set the MCLGs. The only requirement is that the "MCLG is a non-enforceable health goal set at a level at which no known or anticipated health effects occur".

The risk-based process that EPA uses to set the MCLGs is extremely time-consuming. One option is the use of computational toxicology to set the MCLG. EPA's Computational Toxicology Chemicals Dashboard evaluates thousands of chemicals based on their chemical structure and results from short-term studies. The purpose is to "help scientists and decision-makers quickly and efficiently evaluate thousands of chemicals." [17].

Another option is for EPA to use one of the approaches that have been set forth in the literature for grouping contaminants based on toxicity and setting health levels for groups of contaminants [18, 19]. Although none of these approaches have specifically addressed drinking water contaminants, they could easily be used to set the MCLGs.

Regulatory Reform

Regulatory reform is a buzzword that has come to encompass many aspects of regulatory change, including eliminating existing regulations or substantially changing the regulatory process. This section will touch on a few regulatory reform ideas that could be useful in making changes to setting drinking water regulations.

Increase Transparency

Increasing transparency in the rulemaking process is one aspect of regulatory reform that has been embraced by individuals on all sides of the political spectrum. One part of the regulatory process that many people are not aware of are scientific reviews by panels or boards. In the case of perchlorate, the scientific reviews added years onto the process (see Section 'Role of scientific review in perchlorate regulation'). Increasing transparency would involve publicizing all steps of the rulemaking process in a more organized fashion.

For more than 35 years, federal agencies have been required to notify the public about upcoming regulatory actions in the Unified Agenda of Federal Regulatory and Deregulatory Actions. The regulatory actions in the Unified Agenda are those that the agency is expected to act on within the next 12 months. Agency entries are organized by agency, and each entry is associated with one of five rulemaking stages, including "proposed rule stage" and "final rule stage" [20].

The Unified Agenda of Spring 2019 actions [21] includes EPA's proposed rule for perchlorate [3] with a link to a page that contains the basics of the rule (legal authority, legal deadline, timetable). However, there is no way to tell from looking at the Agenda that EPA has been working on the perchlorate rule for more than 20 years. One option to increase transparency would be a companion to the Unified Agenda that lists all the previous steps in the rulemaking process and the time period for each step. This should include scientific reviews, including the dates they began and ended and the Agency's responses to the reviews and timetable. This would help greatly in monitoring the rulemaking process. In addition, with a companion to the Unified Agenda, there would be a process to identify rules that have been in development for over five years. These rules could be reevaluated as to their continuing need and the Agency could identify how it is going to accelerate the process to complete within the next 12 months.

Negotiated Rulemaking

In 1990, Congress enacted the Negotiated Rulemaking Act (Neg Reg Act) "to establish a negotiated rulemaking committee to develop and negotiate a proposed agency rule whenever the head of the agency determines that the use of the negotiated rulemaking procedure is in the public interest." The Act states that "Negotiated rulemaking can increase the acceptability and improve the substance of rules, making it less likely that the affected parties will resist enforcement or challenge such rules in court. It may also shorten the amount of time needed to issue final rules" [22].

EPA has used Neg Reg for rulemaking on several occasions, but not for drinking water regulations. This option could be used for setting drinking water regulations, but it would need to include all the major stakeholders involved in drinking water, i.e. the water works industry, state governments, and environmental groups. An agreement negotiated by a skilled mediator may be possible.

Conclusions

Perchlorate was first detected in drinking water supplies across the U.S. in the 1990s. Since 1998, EPA has been evaluating perchlorate for regulation in drinking water, a process that included two major scientific reviews, two contradictory regulatory determinations, and a court case that resulted in EPA issuing a proposed rule for perchlorate in 2019. EPA has proposed health reference levels for perchlorate of 15 µg/L in 2008; 4 µg/L in 2011; and 56 µg/L in 2019. Scientifically, these values do not differ greatly, considering the amount of uncertainty in the calculations and the fact that the measurement is taking place at the parts-per-billion range. The 20-year journey to set a drinking water regulation for perchlorate demonstrates the limits to the use of science in the regulatory process and environmental policy.

References

1. ATSDR (Agency for Toxic Substances and Disease Registry). Toxicological Profile for Perchlorates. U.S. Dept. of Health and Human Services, Public Health Service. 2008.
2. GAO (Government Accountability Office). Drinking Water: DOD has acted on some emerging contaminants but should improve internal reporting on regulatory compliance. GAO-18-78: 2017.
3. Congressional Research Service. Safe Drinking Water Act (SDWA): A Summary of the Act and its Major Requirements. 2017.
4. EPA (Environmental Protection Agency). National Primary Drinking Water Regulations: Perchlorate, Proposed Rule, Request for Comment. Federal Register. 2019;84(123):30524-30569.
5. EPA (Environmental Protection Agency). Perchlorate Peer Review Workshop Report. Prepared for Office of Solid Waste, U.S. EPA; Prepared by Center for Environmental Analysis, Research Triangle Institute, Research Triangle Park, NC. 1999.
6. NRC (National Research Council). Health Implications of Perchlorate Ingestion. National Academies Press. 2005.
7. EPA. (Environmental Protection Agency). Integrated Risk Information System on Perchlorate and Perchlorate Salts. 2005.
8. EPA (Environmental Protection Agency). Drinking Water: Preliminary Regulatory Determination on Perchlorate, Notice. Federal Register. 2008;73(198):60262-60282.
9. U.S. Senate Committee on Environment and Public Works. Full Committee Hearing entitled, "Perchlorate and TCE in Water". 2008.
10. EPA (Environmental Protection Agency). Drinking Water: Regulatory Determination on Perchlorate, Regulatory Determination. Federal Register. 2011;76(29):7762-7767.
11. Greer MA, Goodman G, Pleus RC, Greer SE. Health effects assessment for environmental perchlorate contamination: the dose response for inhibition of thyroidal radioiodide uptake in humans. Environ Health Perspect. 2002;110(9):927-937.
12. 104th Congress, 2nd session. The Safe Drinking Water Act as Amended by the Safe Drinking Water Act of 1996, Public Law 104-182. 1996.
13. WQA (Water Quality Association). Water Quality Association survey: concerns over contaminants. 2017.
14. Waterpolls.org. Americans avoid drinking from tap, oppose smaller federal role in water safety. 2016.
15. Business Insider. Bottled water costs 2000 times as much as tap water. 2013.
16. WQA (Water Quality Association). Technical Fact Sheet: Perchlorate. 2013.
17. EPA (Environmental Protection Agency). CompTox Chemicals Dashboard. 2019.
18. Dolan DG, Naumann BD, Sargent EV, Maier A, Dourson M. Application of the threshold of toxicological concern concept to pharmaceutical manufacturing operations. Regul Toxicol Pharmacol. 2005;43(1):1-9.
19. Munro IC, Renwick AG, Danielwska-Nikiel B. The threshold of toxicological concern (TTC) in risk assessment. Toxicol Lett. 2008;180(2):151-156. doi: 10.1016/j.toxlet.2008.05.006
20. Administrative Conference of the United States. The Unified Agenda: Promoting Regulatory Transparency, Planning, and Public Participation. 2019.
21. U.S. GSA (General Services Administration). Spring 2019 Unified Agenda of Regulatory and Deregulatory Actions. 2019.
22. 101st Congress. S.303 - Negotiated Rulemaking Act of 1990: 1989-1990.