



Perchlorate Contamination of Drinking Water: Regulatory Issues and Legislative Actions

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Summary

Perchlorate is the explosive component of solid rocket fuel, fireworks, road flares, and other products. Used heavily by the Department of Defense (DOD) and related industries, perchlorate also occurs naturally and is present in some organic fertilizer. This soluble, persistent compound has been detected in drinking water supplies, especially in California. It also has been found in milk and many foods. Because of this widespread occurrence, concern over the potential health risks of perchlorate exposure has increased, and some states, water utilities, and Members of Congress have urged the Environmental Protection Agency (EPA) to set a federal drinking water standard for this chemical. Regulatory issues have involved the health risk reduction benefits and the costs of federal regulation, including environmental cleanup and water treatment costs, both of which are driven by federal and state standards.

EPA has spent years assessing perchlorate's health effects and occurrence to determine whether a national standard is warranted. The Food and Drug Administration (FDA) has supported this effort by testing produce and other foods for the presence of perchlorate. Interagency disagreements over the risks of perchlorate exposure led several federal agencies to ask the National Research Council (NRC) to evaluate perchlorate's health effects and EPA's risk analyses. In 2005, the NRC issued its report, and EPA adopted the NRC's recommended reference dose (i.e., the expected safe dose) for perchlorate exposure. Subsequent studies raised more concerns about the potential effects of low-level exposures, particularly for infants in certain cases.

In October 2008, EPA made a preliminary determination not to regulate perchlorate in drinking water. Then, in early January 2009, the agency announced that it again would seek advice from the NRC before making a final determination. EPA also announced that it was replacing the preliminary remediation goal for perchlorate of 24.5 parts per billion (ppb) with an interim health advisory, which contains a value of 15 ppb.

In August 2009, the EPA Administrator announced that the agency would reevaluate the science regarding perchlorate's potential health effects, with particular emphasis on evaluating the effects of perchlorate exposure on infants and young children. The agency determined not to ask the NRC to conduct further review of issues related to perchlorate, having concluded that additional NRC review would unnecessarily delay the regulatory decision-making process. EPA intends to consider public comments before making a final regulatory determination. Legislation (H.R. 3206) has been introduced to require EPA to promulgate a drinking water standard for perchlorate. This report reviews perchlorate contamination issues and related developments.

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Background

Ammonium perchlorate is the key ingredient in solid fuel for rockets and missiles; other perchlorate salts are used to manufacture products such as fireworks, air bags, and road flares. Uncertainty about the health effects of perchlorate exposure has slowed efforts to establish drinking water and environmental cleanup standards. However, because of perchlorate's persistence in water and ability to affect thyroid function, concern has escalated with the detection of perchlorate in water in at least 33 states. In the absence of a federal standard, states have begun to adopt their own measures. Massachusetts set a drinking water standard of 2 parts per billion (ppb, or micrograms per liter [$\mu\text{g}/\text{L}$]) in 2006, and California adopted a 6 ppb standard in 2007. Several states have issued health goals or advisory levels ranging from 1 ppb in Maryland (advisory level) and New Mexico (drinking water screening level) to 17 ppb in Texas (residential protective cleanup level) and, also in Texas, 51 ppb (industrial cleanup level).

Occurrence

Perchlorate has been used heavily by the DOD and its contractors, and perchlorate contamination has been found near weapons and rocket fuel manufacturing facilities and disposal sites, research facilities, and military bases. Fireworks, road flares, construction sites, and other manufacturing activities and facilities also have been sources of contamination. Moreover, perchlorate occurs naturally (in West Texas, for example), is present in organic fertilizer imported from Chile, and can occur as a breakdown product of other products. It has been detected in drinking water sources, primarily in the Southwest and in scattered locations across the country. Contamination has been found most often in ground water, including some large aquifers in California.

In 1999, EPA required public water systems to monitor for perchlorate under the Unregulated Contaminant Monitoring Rule (UCMR) to determine the frequency and levels at which it is present in public water supplies nationwide. The UCMR required monitoring by all systems serving more than 10,000 persons and by a sample of smaller systems. Of 3,865 public water systems tested, perchlorate was detected at levels greater than or equal to 4 $\mu\text{g}/\text{L}$ (the minimum detection level of the test) in 160 (4.1%) systems in 26 states and two commonwealths, including 58 systems in California. In 14 systems, perchlorate levels exceeded EPA's preliminary remediation goal of 24.5 ppb. Approximately 1.9% (637) of a total of 34,331 samples collected by the systems had detections of perchlorate at levels of 4 $\mu\text{g}/\text{L}$ or greater. The average concentration of perchlorate for the samples with positive detections was 9.85 $\mu\text{g}/\text{L}$. California has required more comprehensive monitoring, and perchlorate has been detected at least twice in 241 active or standby sources of drinking water in that state since 2002.

In 2005, EPA reported perchlorate contamination had been found at 65 DOD facilities, 7 other federal facilities, and 37 private sites.¹ All sampling results combined (i.e., soil, public and private drinking water wells, groundwater monitoring wells, and surface water), the Government Accountability Office reported that perchlorate had been detected at 395 sites.²

¹ EPA, Federal Facilities Restoration and Reuse, *Known Perchlorate Releases in the U.S.*, March 25, 2005, at http://www.epa.gov/fedfac/documents/perchlorate_links.htm#occurrences.

² U.S. Government Accountability Office, *Perchlorate: A System to Track Sampling and Cleanup Results is Needed*, GAO-05-462, May 2005, pp. 29-44.

Monitoring also has been conducted to assess the presence of perchlorate in foods. In 2004, the Food and Drug Administration (FDA) tested 500 samples of foods, including vegetables, milk, and bottled water for perchlorate. Samples were taken in areas where water was thought to be contaminated. The FDA found perchlorate in roughly 90% of lettuce samples (average levels ranged from 11.9 ppb to 7.7 ppb for lettuces), and in 101 of 104 bottled milk samples (with an average level of 5.7 ppb). To assess the presence of perchlorate in a wider range of foods, the FDA began testing all samples in its Total Diet Study in 2005.³ Perchlorate was detected in 625 of 1065 (50%) of samples, and in 211 of the 285 (74%) foods tested.⁴ In most cases, perchlorate levels were in the low single digits; however, levels were higher in some foods (e.g., shrimp, tomatoes, spinach, and bacon). The study found that 2-year-olds have the highest total perchlorate intake per kilogram body weight per day, followed by infants (6 to 12 months of age) and children 6 to 10 years of age. The widespread detection of perchlorate in food is relevant to EPA's standard-setting efforts, because EPA considers non-water exposures when determining whether to establish a standard for a contaminant, and at what level to set a standard.

Health Concerns

Perchlorate is not known to cause cancer. It is known to disrupt the uptake of iodine in the thyroid, and health effects associated with perchlorate exposure are expected to parallel those caused by iodine deficiency. Iodine deficiency decreases the production of thyroid hormones, which help regulate the body's metabolism and growth. A key concern is that impairment of thyroid function in pregnant women can affect fetuses and nursing infants and can result in delayed development and decreased learning capacity. Several human studies have indicated that thyroid changes occur in humans at significantly higher levels of perchlorate than the amounts typically observed in water supplies.⁵ However, a 2006 study by the Centers for Disease Control and Prevention (CDC) of a representative sample of the U.S. population found that environmental exposures to perchlorate have an effect on thyroid hormone levels in women with iodine deficiency. (No effect was found in men.) Fully 36% of the 1,111 women in this study were found to be iodine deficient, and the median level of urinary perchlorate measured in the women was 2.9 ppb.⁶

EPA Assessment of Perchlorate for Regulation

Over the past decade, EPA has evaluated perchlorate to determine whether a federal drinking water standard is needed. Under the Safe Drinking Water Act (SDWA, §1412(b)(1)), EPA must regulate a contaminant if the Administrator determines that the contaminant (1) may have an adverse health effect, (2) occurs in public water systems at a frequency and level of public health concern, and (3), in the sole judgment of the Administrator, regulation of the contaminant

³ The FDA test results are available online at <http://www.cfsan.fda.gov/~dms/clo4dat2.html>.

⁴ Clarence W. Murray et al., "U.S. Food and Drug Administration's Total Diet Study: Dietary Intake of Perchlorate and Iodine," *Journal of Exposure Science and Environmental Epidemiology* (2008), 1-10.

⁵ Michael A. Kelsh et al., "Primary Congenital Hypothyroidism, Newborn Thyroid Function, and Environmental Perchlorate Exposure Among Residents of a Southern California Community," *Journal of Occupational Environmental Medicine*, 2003, p. 1117.

⁶ Benjamin C. Blount, James L. Pirkle, et al., "Urinary Perchlorate and Thyroid Hormone Levels in Adolescent and Adult Men and Women Living in the United States," Centers for Disease Control and Prevention, in *Environmental Health Perspectives*, December 2006, p. 1865.

presents a meaningful opportunity for reducing health risks. In 1997, when a sensitive detection method became available for perchlorate and detections increased, scientific information was limited. In 1998, EPA placed perchlorate on the list of contaminants that were candidates for regulation, but concluded that information was insufficient to determine whether perchlorate should be regulated under the SDWA. EPA listed perchlorate as a priority for further research on health effects and treatment technologies and for collecting occurrence data. In 1999, EPA required water systems to monitor for perchlorate under the Unregulated Contaminant Monitoring Rule to determine the frequency and levels at which it is present in public water supplies nationwide. In January 2007, EPA reported that it had collected sufficient occurrence data, and that further monitoring was not needed for the agency to make a regulatory determination (72 *Fed. Reg.* 367, January 4, 2007).

Perchlorate Risk Assessment

In 1992, and again in 1995, EPA issued draft reference doses (RfDs) for perchlorate exposure. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure that is not expected to cause any adverse, non-cancer health effects during a lifetime. In developing an RfD, EPA incorporates factors to account for sensitive subpopulations, study duration, inter- and intraspecies variability, and data gaps. The draft RfDs range of 0.0001 to 0.0005 milligrams per kilogram (mg/kg) body weight per day translated to a drinking water equivalent level of 4 ppb-18 ppb. EPA takes the RfD into account when setting a drinking water standard; it also considers costs, the capabilities of monitoring and treatment technologies, and other sources of perchlorate exposure, such as food.

EPA's 1999 draft risk characterization resulted in a human risk benchmark of 0.0009 mg/kg per day (with a 100-fold uncertainty factor), which converted to a drinking water equivalent level of 32 ppb. However, EPA determined that the available health effects and toxicity database was inadequate for risk assessment. In 1999, EPA issued an *Interim Assessment Guidance for Perchlorate*, which recommended that EPA risk managers use the earlier reference dose range and drinking water equivalent level (DWEL) of 4-18 ppb for perchlorate-related assessment activities at hazardous waste sites.

In 2002, EPA prepared a draft risk assessment that concluded that the potential human health risks of perchlorate exposures include effects on the developing nervous system and thyroid tumors, based on rat studies that observed benign tumors and adverse effects in fetal brain development. The document included a draft RfD of 0.00003 mg/kg per day, which translated to a drinking water equivalent level of 1 ppb. This document was controversial, both for its implications for cleanup costs and for science policy reasons. (For example, some peer reviewers expressed concern over EPA's risk assessment methodology and reliance on rat studies.) DOD, water suppliers, and other commentators expressed concern that the draft RfD could lead to unnecessarily stringent and costly cleanups of perchlorate releases at federal facilities and in water supplies. In 2002, a federal interagency perchlorate working group convened to discuss perchlorate risk assessment, research and regulatory issues, and related agency concerns. Working group members included DOD, EPA, the Department of Energy, the National Aeronautics and Space Administration, the Office of Science and Technology Policy, the Council on Environmental Quality, and the Office of Management and Budget.

NRC Perchlorate Study

To resolve some of the uncertainty and debate over perchlorate's health effects and the 2002 draft risk assessment, the interagency working group asked the National Research Council (NRC) to review the available science for perchlorate and EPA's draft assessment. The NRC was asked to comment and make recommendations. The NRC Committee to Assess the Health Implications of Perchlorate Ingestion issued its review in January 2005 and suggested several changes to EPA's draft risk assessment. The committee concluded that because of key differences between rats and humans, studies in rats were of limited use for quantitatively assessing human health risk associated with perchlorate exposure. Although the committee agreed that thyroid tumors found in a few rats were likely perchlorate treatment-related, it concluded that perchlorate exposure is unlikely to lead to thyroid tumors in humans. The committee noted that, unlike rats, humans have multiple mechanisms to compensate for iodide deficiency and thyroid disorders. Also, the NRC found flaws in the design and methods used in the rat studies. The committee concluded that the animal data selected by EPA should not be used as the basis of the risk assessment.

The committee also reviewed EPA's risk assessment model. It agreed that EPA's model for perchlorate toxicity represented a possible early sequence of events after exposure, but it did not think that the model accurately represented possible outcomes after changes in thyroid hormone production. Further, the committee disagreed with EPA's definition of a change in thyroid hormone level as an adverse effect. Rather, the NRC defined transient changes in serum thyroid hormone as biochemical events that might precede adverse effects, and identified hypothyroidism as the first adverse effect.

Because of research gaps regarding perchlorate's potential effects following changes in thyroid hormone production, the committee made the recommendation that EPA use a *nonadverse effect* (i.e., the inhibition of iodide uptake by the thyroid in humans) rather than an adverse effect as the basis for the risk assessment. The committee explained that "[i]nhibition of iodide uptake is a more reliable and valid measure, it has been unequivocally demonstrated in humans exposed to perchlorate, and it is the key event that precedes all thyroid-mediated effects of perchlorate exposure."⁷ Based on the use of this point of departure, the reliance on human studies, and the use of an uncertainty factor of 10 (for intraspecies differences), the NRC's recommendations led to an RfD of 0.0007 mg/kg per day. The committee concluded that this RfD should protect the most sensitive population (i.e., the fetuses of pregnant women who might have hypothyroidism or iodide deficiency) and noted that the RfD was supported by clinical studies, occupational and environmental epidemiologic studies, and studies of long-term perchlorate administration to patients with hyperthyroidism. In addition, the NRC identified data gaps and research needs. The committee has received some criticism for the extent to which it relied on a small, short-term human study, and debate over perchlorate's health risks has continued.

EPA's Response and Subsequent Actions

In 2005, EPA adopted the NRC recommended reference dose of 0.0007 mg/kg per day, which translates to a drinking water equivalent level of 24.5 ppb. The DWEL is the concentration of a contaminant in water that is expected to have no adverse effects; it is intended to include a margin

⁷ National Research Council, *Health Implications of Perchlorate Ingestion*, Committee to Assess the Health Implications of Perchlorate Ingestion, National Academy of Sciences, 2005, p. 9.

of safety to protect the fetuses of pregnant women who might have a preexisting thyroid condition or insufficient iodide intake. Notably, EPA based the DWEL on the assumption that all exposure would come from drinking water. If EPA were to develop a drinking water standard for perchlorate, it would lower the DWEL to account for other sources of exposure, particularly food.

In January 2006, EPA's Superfund office issued guidance adopting the NRC reference dose and the DWEL of 24.5 ppb as the recommended value to be considered as the preliminary remediation goal (PRG) to guide perchlorate assessment and cleanup at Superfund sites. In March, EPA's Children's Health Protection Advisory Committee (CHPAC) wrote to the EPA Administrator that the PRG did not protect infants, who are highly susceptible to neurodevelopmental toxicity and may be more exposed than fetuses to perchlorate. The CHPAC noted that perchlorate is concentrated in breast milk and that nursing infants could receive daily doses greater than the RfD if the mother is exposed to 24.5 ppb perchlorate in tap water. The committee recommended that the Superfund office lower the PRG and that the Office of Water develop a standard for perchlorate and, in the interim, issue a drinking water health advisory that takes into account early life exposures.

In October 2008, EPA announced a preliminary determination not to regulate perchlorate, noting that less than 1% of water systems have perchlorate levels above the health reference level. EPA concluded that perchlorate failed to meet two of SDWA's regulatory criteria (i.e., that a contaminant occur frequently at levels of health concern, and that establishing a national drinking water standard would provide a "meaningful opportunity for health risk reduction"). In response, EPA's Science Advisory Board's (SAB's) Drinking Water Committee argued that, given perchlorate's occurrence and well-documented toxicity, EPA must have a compelling basis to support a determination not to regulate. The SAB requested more time to review the new model EPA relied on, and to comment on the preliminary determination.

On January 8, 2009, EPA announced that it would seek further advice from the NRC before making a final determination on whether or not to set a drinking water standard for perchlorate. EPA also announced that it was replacing the perchlorate preliminary remediation goal of 24.5 ppb with an interim health advisory, which contains a value of 15 ppb.⁸ Health advisories are nonregulatory, but can be useful to state and local officials in addressing drinking water contamination and making cleanup decisions for Superfund sites. EPA based the 15 ppb level on the reference dose recommended by the NRC. The agency explained that it calculated the advisory level to protect the most sensitive population that was identified by the NRC perchlorate committee (the fetuses of pregnant women), and took into account exposures from food as well as water. This approach does not appear to address a key concern of EPA's Children's Health Protection Advisory Committee which identified nursing infants as potentially more exposed than fetuses. The evaluation of impacts to infants and young children is one of the scientific issues that EPA wanted the NRC to evaluate. EPA also was considering asking the NRC to evaluate recent studies, EPA's use of models, and its derivation of the 15 ppb health reference level.

In August 2009, the EPA Administrator announced that the agency would reevaluate the science regarding perchlorate's potential health effects, with particular emphasis on evaluating the effects of perchlorate exposure on infants and young children. The agency determined not to ask the

⁸ Health advisories establish nonenforceable concentrations of contaminants in drinking water at which no adverse health effects are expected to occur over specific timeframes. Advisories include information on health effects, occurrence, exposure, monitoring methods, and treatment technologies. EPA's Interim Drinking Water Health Advisory for Perchlorate is available at, <http://www.epa.gov/safewater/contaminants/unregulated/perchlorate.html>.

NRC to conduct further review of issues related to perchlorate, having concluded that additional NRC review would unnecessarily delay the regulatory decision-making process. Instead, EPA published a *Supplemental Request for Comments* notice in the Federal Register, seeking public comment on additional ways to analyze data related to the regulatory determination for perchlorate. EPA noted its intent to consider a broader range of alternatives for interpreting the available data on the level of health concern, the frequency of occurrence of perchlorate in drinking water, and the opportunity for health risk reduction through a national drinking water standard. EPA is reevaluating perchlorate exposure to sensitive life stages including infants and developing children, expanding the previous emphasis on pregnant women and their developing fetuses as the most sensitive subpopulations. EPA intends to take public comments into account before making a final regulatory determination. The agency's announcement noted that the final decision may be a determination to regulate.⁹

DOD Perchlorate Actions

DOD is responsible for some large releases of perchlorate into the environment and has allotted significant resources to address this problem. DOD has spent more than \$114 million on research activities regarding perchlorate treatment technologies, detection methods, toxicity studies, and substitutes. Additional funds have been spent on cleanup.

Although remediation has proceeded at some sites, cleanups typically are driven by drinking water standards or other established cleanup standards. With no federal standard, cleanup goals and responsibilities have been ambiguous outside of California and Massachusetts where standards have been set. In 2006, after EPA established a DWEL for perchlorate and issued cleanup guidance based on the DWEL, DOD adopted a policy setting 24 ppb as the level of concern to be used in managing perchlorate releases (unless a more stringent federal or state standard exists). The policy applies broadly to DOD installations and former military lands, and directs the services to test for perchlorate when it is reasonably expected that a release has occurred. Under the policy, if perchlorate levels exceed 24 ppb, a site-specific risk assessment must be conducted; if the assessment indicates that the perchlorate could result in adverse health effects, then the site must be prioritized for risk management. DOD uses a relative risk site evaluation framework to help prioritize environmental restoration work and to allocate resources among sites.¹⁰ EPA has withdrawn the 2006 perchlorate remediation guidance and recommends that its Regional offices now consider using the interim health advisory level of 15 ppb for cleanup. The DOD may follow suit and adopt the new level for managing perchlorate releases.

Legislative Actions

Several perchlorate bills were considered, but none were enacted during the 110th Congress. Responding to EPA's 2007 decision not to require further monitoring for perchlorate as an unregulated contaminant, S. 24 was introduced to require community water systems to test for perchlorate and disclose its presence in annual consumer reports. S. 150 and H.R. 1747 would

⁹ For more information see EPA's perchlorate website, <http://www.epa.gov/safewater/contaminants/unregulated/perchlorate.html>.

¹⁰ Links to Department of Defense perchlorate information, policies, and other resources are available through http://www.epa.gov/fedfac/documents/perchlorate_links.htm#state_adv.

have required EPA to set a standard for perchlorate. The Senate Environment and Public Works Committee reported S. 24 (S.Rept. 110-483) and S. 150 (S.Rept. 110-484). Additionally, H.Con.Res. 347 expressed the sense of Congress that the CDC and FDA should take action to educate the public on the importance of adequate iodine intake. (Iodine is protective against perchlorate exposure.)

In the 111th Congress, legislation has been introduced concerning regulation of perchlorate under the Safe Drinking Water Act and the cleanup of perchlorate contamination of ground water and public drinking water supplies. H.R. 3206 would require EPA to propose a drinking water regulation for perchlorate within 12 months of enactment of the legislation, and to promulgate a final regulation no later than 18 months after publishing the proposed rule. The report accompanying the House-passed Department of Defense Appropriations Act, 2010 (H.R. 3326, H.Rept. 111-230), includes \$2 million for the cleanup of perchlorate contaminated wells. H.R. 102 would authorize additional appropriations for the San Gabriel Basin Restoration Fund, and would establish a 35% non-federal matching requirement for the recipient water districts after a specified amount of federal funds had been appropriated.

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