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Perchlorate Contamination of Drinking Water: Regulatory Issues and Legislative Actions

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Summary

Perchlorate is the key ingredient of solid rocket fuel and has been used mainly by the Department of Defense (DOD), the National Aeronautics and Space Administration (NASA), and related industries. It also occurs naturally. This highly soluble, persistent compound has been disposed of on the ground for decades, and it has been detected in sources of drinking water for more than 11 million people. It also has been found in milk and vegetables. Thus, concern has grown regarding the potential health risks of exposure to perchlorate. The Environmental Protection Agency's (EPA's) efforts to make a determination whether to regulate perchlorate in drinking water have been slowed by uncertainties about the health effects of exposure at low levels, and because of the need for more research on occurrence and treatment technologies. Related issues involve environmental cleanup and water treatment costs, which will depend on the level at which a standard is set. Because of scientific uncertainties and interagency disagreement about the health risks of perchlorate exposure, several federal agencies asked the National Research Council (NRC) of the National Academy of Sciences to assess perchlorate's health effects and EPA's draft risk assessment. The NRC issued its report in January 2005, and EPA adopted the NRC's recommended safe level, or reference dose, for perchlorate exposure. This report will be updated.

Background

Ammonium perchlorate is widely used in solid propellant for rockets and missiles, and other perchlorate salts are used to manufacture various products including fireworks, air bags, and road flares. Uncertainty over perchlorate's health effects has slowed federal and state efforts to establish drinking water standards and environmental cleanup standards for this compound. However, given perchlorate's persistence in water, concern has escalated with its detection in the groundwater or surface water in at least 33 states. No federal or state drinking water standard has been established for perchlorate, but efforts are underway, and several states have issued public health goals or advisory levels.

Occurrence. Perchlorate has been used heavily by DOD and its contractors, and perchlorate contamination of water has been found most often near weapons and rocket fuel manufacturing facilities and disposal sites, research facilities, and military bases.[1] Fireworks and other manufacturing facilities and construction sites also have been sources of contamination. Perchlorate also occurs naturally, as it does in West Texas, and is present in organic fertilizer imported from Chile, which has been used on some crops. Regulators were aware of contamination in California and Nevada in the 1980s; however, before 1997, perchlorate could not be detected at concentrations below 400 parts per billion (ppb). In 1997, a new analytical method lowered the detection limit to 4 ppb, prompting several states to test for perchlorate. Within two years, it had been detected in the drinking water sources for more than 11 million people in the Southwest and in the surface or ground water in scattered locations across the United States.[2] Contamination has been found most often in ground water; however, perchlorate is present at low levels in the Colorado River, a major source of drinking water and irrigation water for California, Nevada, and Arizona.[3] Perchlorate also has been detected in dairy milk in various states, especially California and Texas; one source of this perchlorate is thought to have been the water used to irrigate the alfalfa crops eaten by dairy cows.

In 1999, EPA required drinking water monitoring for perchlorate under the Unregulated Contaminant Monitoring Rule (UCMR) to determine the frequency and levels at which perchlorate is present in public water supplies nationwide. The regulation required monitoring by all water systems serving more than 10,000 persons and by a representative sample of smaller systems. Some 3,700 water systems have been tested, and perchlorate has been reported in 153 systems in 26 states and two commonwealths.[4] Of the 153 systems, 14 had perchlorate levels above 24.5 ppb.[5] The agency also reported perchlorate contamination at 65 DOD facilities, 7 other federal facilities, and 37 private sites. In sampling done by California water systems, perchlorate has been detected at least twice in 276 sources of drinking water that supply 77 public water systems.[6]

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[1] U.S. Army Center for Health Promotion and Preventive Medicine, Directorate of Environmental Health Engineering, *Perchlorate in Drinking Water,* Aberdeen Proving Ground, MD. This document notes that perchlorate has a short shelf life as an effective propellant and must be replaced periodically within the DOD's missile and rocket inventory. Also, detonation of rockets, missiles, and fireworks, and the use of road flares, leave perchlorate residuals in the affected areas.

[2] U.S. Environmental Protection Agency, *Region 9 Perchlorate Update,* June 1999, p. 1.

[3] A key source of perchlorate in the Colorado River has been a Kerr McGee plant in Nevada, where perchlorate production began in 1951. Since 1997, Nevada and EPA have worked with Kerr McGee to control the source of releases. From January 2004 through June 2005, only 3 of the monthly samples had detectable levels of perchlorate. U.S. EPA, Region 9, *Perchlorate Monitoring Results: Henderson, Nevada to the Lower Colorado River,* June 2005.

[4] U.S. Environmental Protection Agency, *Federal Facilities Restoration and Reuse: Known Perchlorate Releases in the U.S. — March 25, 2005,* available at [http://www.epa.gov/fedfac/documents/perchlorate_links.htm#occurrences], visited Jan. 31, 2006.

[5] U.S. Government Accountability Office. *Perchlorate: A System to Track Sampling and Cleanup Results is Needed*. GAO-05-462. May 2005. p. 3.

[6] California Department of Health Services, *Perchlorate in California Drinking Water:* (continued...)

Health Effects. Perchlorate is known to disrupt the uptake of iodine in the thyroid, and health effects associated with perchlorate exposure are expected to be similar to those caused by iodine deficiency.[7] 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 infants and can result in delayed development and decreased learning capability. Various human studies indicate that thyroid changes occur in humans at significantly higher concentrations of perchlorate than the amounts typically observed in water supplies.[8] Studies have not directly measured the impact of perchlorate on human metabolism and growth. (Health effects studies are discussed further in section below on EPA regulation of perchlorate.)

Federal Responses to Perchlorate Contamination

Various federal, state, tribal, and local government agencies have been examining issues related to perchlorate contamination for nearly a decade. A federal interagency perchlorate working group was convened in 2002, to discuss perchlorate risk assessment, research, and regulatory issues. Members of this group include DOD; NASA; EPA; the Department of Energy; and, within the Executive Office of the President, the Office of Science and Technology Policy, the Council on Environmental Quality, and the Office of Management and Budget. DOD, EPA, and the Food and Drug Administration are among the federal agencies that have been assessing perchlorate contamination and occurrence.

EPA Regulation of Perchlorate. EPA has taken steps toward establishing a drinking water standard for perchlorate, but has not yet made a determination to regulate perchlorate. In 1997, when a better detection method became available for perchlorate and water monitoring increased, scientific information for perchlorate was extremely limited. In 1998, EPA placed perchlorate on the list of contaminants that are candidates for regulation, but concluded that information was insufficient at that time to make a determination as to whether perchlorate should be regulated under the Safe Drinking Water Act (SDWA). The agency listed perchlorate as a priority for further research on health effects and treatment technologies, and as a priority for collecting occurrence data.

Perchlorate Risk Assessment. In 1992, and again in 1995, EPA issued draft reference doses (RfDs) for perchlorate exposure that would be expected to protect against any health threats. An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure that is likely to be without appreciable risk of adverse

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[6] (...continued)
Monitoring Update for Active and Standby Sources, Jan. 19, 2006.For detailed results, see [http://dhs.ca.gov/ps/ddwem/chemicals/perchl/monitoringupdate.htm], visited Jan. 30, 2006.

[7] California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, *Public Health Goal for Perchlorate*, March 2004, pp. 1-2. In 2004, California published a final public health goal (PHG) of 6 ppb for perchlorate. A PHG is set at a level determined to pose no significant risk to individuals, including sensitive groups. California officials will use the public health goal to establish an enforceable drinking water standard, which must be set as close to the goal as is economically and technologically feasible.

[8] 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.

non-cancer 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 resulting draft RfD range of 0.0001 to 0.0005 milligrams per kilogram (mg/kg) body weight per day would be equivalent to a drinking water level of 4 ppb-18 ppb. EPA takes the RfD into consideration when setting a drinking water standard. The agency also must consider cost, the capabilities of monitoring and treatment technologies, and other sources of perchlorate exposure, such as food.

EPA continued to assess perchlorate risks, and its 1999 draft risk characterization resulted in a human risk benchmark of 0.0009 mg/kg per day (with a 100-fold uncertainty factor), which would convert 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 standing reference dose range of 4-18 ppb for perchlorate-related assessment activities.

In 2002, EPA completed a draft risk assessment for perchlorate that concluded that the potential human health risks of perchlorate exposures include effects on the developing nervous systems 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 draft document was controversial, both for its implications for cleanup costs and for science policy reasons. For example, some expert peer reviewers expressed concern over EPA's use of a new risk assessment approach and reliance on certain rat studies.

NRC Perchlorate Study. To resolve some of the uncertainty and debate over perchlorate's health effects and EPA's 2002 draft risk assessment, the interagency perchlorate working group asked the National Research Council 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. Based on its scientific findings, this independent expert committee suggested several changes to EPA's draft risk assessment. The committee determined that, because of major differences between rats and humans, studies in rats are 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, and that hypothyroidism occurs only if daily iodide intake is less than about 10%-20% of average U.S. intake. 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 thought that EPA's model for perchlorate toxicity represented the possible early sequence of events after exposure, but did not think that the model provided an accurate representation of possible outcomes after changes in thyroid hormone production. Also, 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 unusual 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."[9] Based on the use of this conservative point of departure, the reliance on human studies, and the use of an uncertainty factor of 10 (for intraspecies differences), the NRC's recommendations lead 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 is supported by clinical studies, occupational and environmental epidemiologic studies, and studies of long-term perchlorate administration to patients with hyperthyroidism.[10] The NRC also called for additional research, and controversy over perchlorate's potential health risks continues.

EPA's Response. EPA has adopted the NRC recommended reference dose of 0.0007 mg/kg per day, which translates to a drinking water equivalent level (DWEL) of 24.5 ppb. The DWEL is the concentration of a contaminant in water that is expected to have no adverse effect; it includes a margin of safety to protect the fetuses of pregnant women who might have a preexisting thyroid condition or insufficient iodide intake. It is based on the assumption that all exposure would come from drinking water. If EPA were to develop a drinking water standard for perchlorate, it would adjust the DWEL to account for other sources of exposure. In January 2006, EPA's Superfund office issued new guidance adopting the new reference dose and its corresponding DWEL of 24.5 ppb as the recommended value "to be considered" and the preliminary remediation goal, respectively, to guide perchlorate assessment and cleanup under the Superfund program.

Department of Defense. The DOD, which has the greatest number of identified sites with perchlorate contamination, has been under state and congressional pressure to identify and remediate perchlorate contamination. In 2003, DOD adopted a perchlorate sampling policy that included sampling on Base Realignment and Closure (BRAC) properties, but DOD was criticized by Members of Congress, communities, and states for not evaluating other DOD sites. In 2004, DOD and the California EPA adopted a procedure to prioritize perchlorate sampling efforts at DOD facilities in California. The procedure is intended to help the state and DOD identify and prioritize the investigation of military sites where perchlorate has likely been released near drinking water sources.

Overall, DOD has tested 800 sites at 101 facilities and spent at least $60 million on perchlorate related activities, including $40 million on developing treatment technologies, $8.5 million on health and toxicity studies, and $8 million on pollution prevention.[11]

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

[10] Ibid. p. 10.

[11] U.S. Department of Defense, *Perchlorate in the Southwestern United States*, July 2005, p. vii. (The conference report for DOD FY2004 appropriations, P.L. 108-87, had called for this study.
(continued...)

Cleanup is proceeding at several sites; however, DOD's general policy is to remediate sites to meet drinking water standards or other established cleanup standards. In the absence of a perchlorate standard, this approach has been problematic for communities that have found perchlorate in their drinking water. A key issue for DOD has concerned the potential perchlorate cleanup cost, which will depend largely on any standards set by EPA or a state. Both DOD and public water suppliers that may need to treat their water to meet standards are interested in seeing that a standard is set at a level that assures public health protection, but is not so strict that added costs would be incurred without providing further public health benefits. EPA's new Superfund guidance and preliminary cleanup goal may help inform DOD cleanup decisions at perchlorate contaminated sites.

Food and Drug Administration. In 2004, FDA collected 500 samples of foods, including vegetables, milk, and bottled water to assess the presence of perchlorate. Samples were taken in areas where water sources were 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 in 4 states), and in 101 of 104 bottled milk samples (with an average level of 5.7 ppb across 14 states).[12] FDA's research is relevant to EPA's standard-setting efforts, because EPA would take into account exposures to perchlorate from food and other sources when setting a drinking water standard. If other exposure sources are significant, EPA would set a stricter standard to account for those exposures.

Congressional Actions

The 109th Congress has targeted some funding for perchlorate cleanup in conference reports for the DOD and EPA FY2006 appropriation acts (P.L. 109-148 and P.L. 109-54, respectively). In the conference report for the Department of Health and Human Services FY2006 appropriations act (P.L. 109-149), conferees encouraged the National Institute for Environmental Health Sciences to support studies on the long-term health effects of perchlorate. The conference report for FDA's FY2006 funding act (P.L. 109-97) affirms a Senate directive for FDA to continue conducting perchlorate surveys of food and bottled water and to report back to Congress. In addition, the House has passed two bills to address perchlorate contaminated groundwater in California: H.R. 186 would authorize the Secretary of the Interior to make grants to the Santa Clara Valley Water District for groundwater remediation projects, and H.R. 18 would authorize such grants for water authorities within the Santa Anna River watershed. H.R. 3053 also would authorize funding for perchlorate remediation in Santa Clarita, whereas H.R. 213 would require EPA to issue a perchlorate drinking water standard in 2007. Enactments in the 108th Congress include the defense authorization acts for FY2004 (P.L. 108-136) and FY2005 (P.L. 108-375) that respectively required DOD to provide for a health study on exposure to perchlorate in drinking water and included a "Sense of Congress" that DOD should develop a plan to remediate contamination, continue remediating sites that pose a serious health threat, and evaluate sites in the absence of a drinking water standard.

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[11] (...continued)
The conference report to the Military Construction Appropriations Act for FY2004 [P.L. 108-132]. In July 2004, DOD submitted a report to Congress identifying sources of, and remediation plans for, perchlorate on BRAC properties as required by P.L. 108-132.)

[12] U.S. Food and Drug Administration, *Exploratory Data on Perchlorate in Food*, Nov. 2004.