

Issue Brief: Perchlorate

Perchlorate is a chemical that can be both naturally-occurring and man-made. It is widely used in industrial products such as fertilizer, rocket propellant, explosives, and fireworks. It also is one of the most studied and prevalent environmental pollutants in drinking water. Although it has been reported that human exposure to high dosages of perchlorate can lead to interference with the thyroid gland, in its "Perchlorate: Questions and Answers," the U.S. Food and Drug Administration (FDA) does not recommend consumers alter their diets to reduce perchlorate consumption. California's Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) also has decided against adding perchlorate to the Proposition 65 List.

Legal Framework

FDA has not established a general maximum action level for perchlorate in foods. Instead, FDA addresses perchlorate through its general food safety regulations. Under Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is adulterated if it contains an added poisonous or deleterious substance that may render it injurious to health while naturally occurring poisonous or deleterious substances are subjected a slightly different standard of "ordinarily render it injurious to health." ^{1/} Substances, such as perchlorate, that are partially present as environmental contamination from human actions are considered "added" substances. ^{2/}

Thyroid hormones are critical for normal growth and development of the nervous system of infants. FDA noted in the "Perchlorate: Questions and Answers" ^{3/} that a recent study reported a statistically significant association between perchlorate exposure and changes in thyroid hormone levels in women that may indicate iodine deficiency. ^{4/} However, FDA also conceded that effects on the thyroid have not been observed in humans exposed to lower doses of perchlorate. ^{5/} FDA has not independently evaluated the safety of perchlorate; it relies on the 0.7 µg/kg bw/day Reference Dose (RfD) established by the Environmental Protection Agency (EPA) in

^{1/} 21 U.S.C. § 342(a)(1).

^{2/} See *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980). Specifically, the court held that "where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an added substance and so considered under the "may render injurious to health" standard of the Act (FFDCA)."

^{3/} See FDA's "Perchlorate: Questions and Answers," <http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077572.htm>.

^{4/} Blount, Benjamin C., et al. "Urinary perchlorate and thyroid hormone levels in adolescent and adult men and women living in the United States." *Environmental health perspectives* (2006): 1865-1871.

^{5/} See *supra* note 3.

2005. 6/ The EPA RfD leveraged the recommendations from the 2005 National Academies of Sciences report "Health Implication of Perchlorate Ingestion" and was based on inhibition of iodine uptake – a precursor to an adverse effect – not on thyroid hormone levels *per se*. 7/ To more accurately and more efficiently measure the perchlorate levels in foods, FDA has developed an ion chromatography-tandem mass spectrometry (IC-MS/MS) method for determining perchlorate in selected food with a limit of detection from 0.3 parts per billion (ppb) for fruits and fruit juices to 1 ppb for milk and grain products. 8/

Additionally, FDA has included perchlorate testing in its Total Diet Study (TDS) program, which is designed to monitor the U.S. food supply for chemical contaminants, nutritional elements, and toxic elements. Recently, FDA published a study reporting that, based on perchlorate analyzed in TDS samples, the estimated lower bound to upper bound average perchlorate intakes by the 14 age-gender subgroups ranged from 0.08 to 0.39 µg/kg bw/day—all lower than the 0.7 µg/kg bw/day RfD established by EPA. 9/ Notably, according to the FDA's report, infants and children demonstrated the highest estimated intakes of perchlorate on a body weight basis.

At the State level, under California's Proposition 65, which was adopted as a voter initiative in 1986 and is not preempted by federal law, a company may not expose a consumer in California to a chemical known to the state of California to cause cancer or reproductive harm without first providing an adequate warning, unless the company can show that the exposure poses no significant risk under conditions specified in the law. The law has a "bounty hunter" provision which allows private litigants to file lawsuits against companies to enforce the warning requirement. In August, 2005, California's OEHHA decided against adding perchlorate to the Proposition 65 List. 10/ In its decision, OEHHA concluded that the current evidence is not sufficient to establish that perchlorate can be "clearly shown" to cause reproductive toxicity. 11/ However, OEHHA also noted that when ingested at significant levels, perchlorate can disrupt the proper functioning of the thyroid gland; there is evidence that impairment of thyroid function in pregnant women may result in delayed development and decreased learning capability of the fetus. 12/

6/ See EPA's Integrated Risk Information System:

<http://www.epa.gov/iris/subst/1007.htm>

7/ "Health Implication of Perchlorate Ingestion." 2005. National Research Council of the National Academies: <http://www.nap.edu/openbook.php?isbn=0309095689>

8/ FDA's "Rapid Determination of Perchlorate Anion in Foods by Ion Chromatography-Tandem Mass Spectrometry" (April 12, 2005)

<http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm077793.htm>

9/ Murray, Clarence William, et al. "US Food and Drug Administration's Total Diet Study: dietary intake of perchlorate and iodine." *Journal of Exposure Science and Environmental Epidemiology* 18.6 (2008): 571-580.

10/ See "Scientific Panel Decides Against Adding Perchlorate to Proposition 65 List of Toxic Chemicals":

http://www.oehha.org/public_info/press/perchlorateP65press.html

11/ See *id.*

12/ *Id.*

Recent Developments

- Recently, the Natural Resources Defense Council (NRDC) along with other groups have petitioned FDA to prohibit the use of perchlorates in food contact applications. ^{13/} Specifically, they are requesting that: (1) FDA revoke its 2005 approval of “threshold of regulation” (TOR) No. 2005-006 allowing as much as 1.2% sodium perchlorate monohydrate in dry food packaging; (2) FDA promulgate a new 21 CFR § 189.301 prohibiting the use of perchlorate as a conductivity enhancer in the manufacture of antistatic agents to be used in food contact articles; and (3) FDA remove potassium perchlorate as an allowed additive in sealing gaskets for food containers in existing 21 CFR § 177.1210.
- EPA decided to regulate perchlorate contaminants in drinking water under the Safe Drinking Water Act (SDWA) in 2011. ^{14/} Specifically, EPA has determined that perchlorate meets SDWA’s criteria for regulating a contaminant – perchlorate’s potential to cause adverse health effects, perchlorate is known to occur in public water system with a frequency and at levels of public health concern, and regulation of perchlorate may present a meaningful opportunity for health risk reduction. EPA is in the process of developing a national primary drinking water regulation for perchlorate.
- In December, 2012, California’s OEHHA issued a peer-reviewed draft that would establish 1 ppb as the state’s new “public health goal” for perchlorate when finalized. ^{15/} The state’s public health goal is not legally binding but serves as the starting point for lowering the legal limit for this type of contaminant. The existing public health goal for perchlorate in California is 6 ppb. The existing public health goal for perchlorate in Massachusetts is 2 ppb. ^{16/}
- In October 2013, two Non-Governmental Organizations (NGOs) (i.e., the Environmental Working Group and the Keep A Breast Foundation) released a guide to educate consumers about some of the most problematic hormone-altering chemicals to which people are routinely exposed. ^{17/} The so-called “Dirty Dozen List of Endocrine Disruptors” includes perchlorate and other chemicals such as BPA and phthalates. Notably, instead of providing a list of foods that might contain perchlorate, these NGOs simply recommend consumers get enough iodine in their diets to compensate for perchlorate consumption

^{13/} “Food additive petition seeking food additive regulation prohibiting the use of perchlorate as a conductivity enhancer in the manufacturer of antistatic agents in contact with dry food and as additive to sealing gaskets for food containers.” Oct. 15, 2014. - http://docs.nrdc.org/health/files/hea_14101601a.pdf.

^{14/} Additional Background on EPA’s Regulation of Perchlorate is available at: <http://water.epa.gov/drink/contaminants/unregulated/perchlorate.cfm>

^{15/} OEHHA, *Public Health Goal for Perchlorate in Drinking Water* (December, 2012), <http://www.oehha.org/water/phg/pdf/120612Perchloratedraft.pdf>; Also see: http://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/Perchlorate.shtml. Accessed Oct. 30, 2014.

^{16/} Agency for Toxic Substances and Disease Registry’s 2008 Toxicological Profile For Perchlorates Table 8-1. Regulations and Guidelines Applicable to Perchlorates (p. 213): <http://www.atsdr.cdc.gov/toxprofiles/tp162-p.pdf>; <http://www.atsdr.cdc.gov/toxprofiles/tp162-c8.pdf> (Accessed Oct 30, 2014)

^{17/} The Environmental Working Group and the Keep A Breast Foundation, *Dirty Dozen List of Endocrine Disruptors - 12 Hormone-Altering Chemicals and How to Avoid Them* (October 2013): <http://www.ewg.org/research/dirty-dozen-list-endocrine-disruptors>

because perchlorate is so widely-present in foods that total avoidance might not be possible.

- In March 2009, a study published in the *Journal of Exposure Science and Environmental Epidemiology* by scientists at the Centers for Disease Control and Prevention (CDC), raised new safety concerns with perchlorate in infant formula. ^{18/} Specifically, the authors found that bovine milk-based infant formula with lactose had a significantly higher perchlorate concentration than soy, lactose-free, and elemental infant formulas. ^{19/} The study commented that the perchlorate RfD may be exceeded when certain bovine milk-based infant formulas are ingested and/or when the formulas are reconstituted with perchlorate-contaminated water. ^{20/}

Issues to Watch

- FDA will continue testing additional foods for perchlorates. The agency might also reassess the cumulative dietary exposure for perchlorate intake in light of the 2009 study published by scientists at CDC and any EPA action regarding perchlorate in drinking water.
- Given perchlorate's application in industrial chemicals such as fertilizer and rocket propellant and the fact that pregnant women, fetuses, and newborns have the greatest potential for risk of adverse health effects following exposure to perchlorate, there may be new "social media campaigns" against the presence of perchlorate in food. The Environmental Working Group, an NGO, has been particularly active in this area.
- The California's OEHHA decided not to add perchlorate to Proposition 65 in 2008. Should the agency choose to revisit this issue, the 2009 study published by CDC scientists might tip the scale and help OEHHA establish that perchlorate can be "clearly shown" to cause reproductive toxicity.

International Perspective

- European Union (EU): The use of certain nitrate fertilizer containing high levels of perchlorate is an important contributor to the presence of perchlorate in fruits and vegetables. The European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM Panel) issued a Scientific Opinion which concludes that the chronic dietary exposure to perchlorate is of potential concern, in particular for the high consumers in the younger age groups of the population with mild to moderate iodine deficiency. The CONTAM Panel established a tolerable daily intake of 0.3 µg/kg body weight per day, based on the inhibition of thyroid iodine uptake in healthy adults. The Panel noted that a single acute exposure to perchlorate

^{18/} Schier, Joshua G., et al. "Perchlorate exposure from infant formula and comparisons with the perchlorate reference dose." *Journal of Exposure Science and Environmental Epidemiology* 20.3 (2010): 281-287.

^{19/} See *id.*

^{20/} *Id.*

at levels found in food and water is unlikely to cause adverse effects on human health, including the more vulnerable groups of the population, and concluded that the establishment of an acute reference dose for perchlorate is not warranted. ^{21/} EU's Standing Committee on the Food Chain and Animal Health will now consider an appropriate provisional harmonized enforcement approach in view of EFSA's scientific opinion. ^{22/}

- Canada: There is currently no enforceable national drinking water standard for perchlorate in Canada. ^{23/} Health Canada recommends a drinking water guidance value of 6 ppb. More research is required to examine levels of perchlorate in water supplies (ground and surface waters) and foodstuffs, as well as the possible linkages between exposure to perchlorate and potential health effects. Sampling programs are planned or underway to determine the extent of perchlorate contamination in Canadian water and food supplies. Health Canada will continue to work with its partners, including the provinces and territories and international agencies, to assess the situation and ensure the safety of Canada's drinking water and food supplies.
- Codex: The Joint WHO/FAO Expert Committee on Food Additives and Contaminants (JECFA) in 2010 reviewed the safety of perchlorate. ^{24/} The Committee established a Provisional Maximum Tolerable Daily Intake (PMTDI) of 10 µg/kg bw for perchlorate. The estimated dietary exposures of 0.7 µg/kg bw per day (highest) and 0.1 µg/kg bw per day (mean), including both food and drinking-water, are well below the PMTDI. The Committee considered that these estimated dietary exposures were not of health concern.

AFFI Action Items

- AFFI will continue to monitor FDA, EPA, and OEHHA regulatory developments, as well as new safety studies regarding perchlorate's adverse health effects.

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^{21/} EFSA, *Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables*, Oct. 17, 2014. <http://www.efsa.europa.eu/en/efsajournal/pub/3869.htm>.

^{22/} SUMMARY REPORT OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH HELD IN BRUSSELS ON 01 JULY 2013: http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/sum_01072013_en.pdf (Accessed Oct 30, 2014)

^{23/} Perchlorate and Human Health: <http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/perchlorate-eng.php> (Accessed Oct. 30, 2014)

^{24/} 2010 JECFA evaluation of perchlorate: http://www.who.int/foodsafety/chem/summary72_rev.pdf; <http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=5885>