

**U.S. Food and Drug Administration**Department of
Health and
Human Services**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**[FDA Home Page](#) | [CFSAN Home](#) | [Search/Subject Index](#) | [Q & A](#) | [Help](#)**CFSAN/Office of Plant & Dairy Foods****September 20, 2003; Updated November 26, 2004; May 29, 2007 and February 7, 2008**

Perchlorate Questions and Answers

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Introduction

Perchlorate is a naturally occurring and manmade chemical. Naturally occurring

perchlorate, for example, is found in arid states in southwestern United States (U.S.), as well as in nitrate fertilizer deposits in Chile and potash ore found in U.S. and Canada. Perchlorate can also form naturally in the atmosphere, leading to trace levels of perchlorate in precipitation. Perchlorate is also an industrial chemical that is used as an oxidizing agent in rocket propellant, in fireworks and flares, and for other purposes. It has been detected in a variety of foods and in drinking water from some locations in the U.S.

In order to work toward development of an assessment of the potential risk of perchlorate, the Food and Drug Administration (FDA) started an initial exploratory survey in 2004 and expanded the exploratory survey in 2005 to better understand the occurrence and levels of perchlorate in a variety of foods from various locations. In 2005 and 2006, FDA conducted Total Diet Study (TDS) surveys to obtain perchlorate levels in TDS foods that are more comprehensive and nationally representative (see Question 6). The levels of perchlorate found in the foods are analyzed to better understand perchlorate exposure from food and to support action, if warranted, to protect the public health.

Based on the perchlorate data obtained from the exploratory and TDS surveys, the estimated average perchlorate intakes by the U.S. population were below the perchlorate reference dose (RfD) of 0.7 micrograms per kilogram body weight per day ($\mu\text{g}/\text{kg bw}/\text{day}$) recommended by the National Academy of Sciences and adopted by the U.S. Environmental Protection Agency (see questions 2, 8, and 13).

1. **What are the effects of perchlorate on the human body?**

Human exposure to high dosages (e.g., pharmacological) of perchlorate can interfere with iodide uptake into the thyroid gland, disrupting the functions of the thyroid and potentially leading to a reduction in the production of thyroid hormone. In fact, perchlorate has been used as a drug to treat hyperthyroidism (excess thyroid hormone production) and to diagnose disorders related to thyroid or iodine metabolism. In adults, the thyroid plays an important role in regulating metabolism. In fetuses and infants, thyroid hormones are critical for normal growth and development of the central nervous system. Therefore, pregnant women and their fetuses and newborns have the greatest potential for risk of adverse health effects following exposure to perchlorate.

Perchlorate-induced changes in thyroid function have not been demonstrated in studies of human groups intentionally exposed to levels of perchlorate below the therapeutic range, even at doses as high as 500 microgram per kilogram body weight per day ($\mu\text{g}/\text{kg bw}/\text{day}$). However, in a recent study by Blount *et al.* (Environmental Health Perspective 114:1865, 2006), the authors reported a statistically significant association between perchlorate exposure and changes in thyroid hormone levels in women with sub-optimal urine iodine levels (less than 100 microgram per liter ($\mu\text{g}/\text{L}$)) that may indicate iodine deficiency. The study analyzed cross-sectional data from the 2001-2002 National Health and Nutrition Examination Survey (NHANES) dataset. Thirty-six percent of the women tested had less than 100 $\mu\text{g}/\text{L}$ iodine in their urine. Blount *et al.* used the 100 $\mu\text{g}/\text{L}$ cut-off based on the World Health Organization (WHO) definition of sufficient iodine status.

Blount *et al.* have stated that the study should be affirmed with another large

population-based study that includes hundreds of women with low iodine levels as a vulnerable population group. The study will include measurement of other analytes that can be indicators of thyroid function, in addition to free T4 and thyroid stimulating hormone.

2. Has a safe level for perchlorate in water and food been established?

In 2003, the Environmental Protection Agency (EPA), the Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautics and Space Administration (NASA) asked the National Academy of Sciences (NAS) to review EPA's draft health assessment for perchlorate. In January 2005, the NAS Committee to Assess the Health Implications of Perchlorate Ingestion released its study report (see "[Health Implications of Perchlorate Ingestion](#)" [EXIT disclaimer >](#)) that recommended a perchlorate reference dose (RfD) of 0.7 microgram per kilogram body weight per day ($\mu\text{g}/\text{kg}$ bw/d). The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects over a lifetime. The RfD for perchlorate includes a 10-fold uncertainty factor. In addition, the NAS used a non adverse end point, inhibition of iodine uptake, to derive the reference dose. Inhibition of iodine uptake is a precursor that can lead to hypothyroidism, the adverse effect considered by the NAS committee. As a result, the reference dose was considered conservative and health protective by the NAS committee. The NAS also considered pregnant women and their fetuses to be the most sensitive populations to the health effects of perchlorate and emphasized the importance of ensuring that all pregnant women have adequate iodine intake.

In February 2005, the Environmental Protection Agency (EPA) adopted the NAS recommended RfD of 0.7 $\mu\text{g}/\text{kg}$ bw/day for perchlorate (see "[EPA Sets Reference Dose for Perchlorate](#)"), which focuses on protecting the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodine deficiency. If all exposure is assumed to come from drinking water, the RfD translates to a drinking water equivalent level (DWEL) of 24.5 parts per billion (ppb) based on two (2) liters of drinking water consumption per day by adults. However, because EPA's RfD is relevant to assessing total intake, information on total exposure from both water and food is needed to evaluate the impact of perchlorate on populations, including sensitive subgroups.

3. The EPA's drinking water equivalent level for perchlorate is 24.5 parts per billion (ppb). Is this the standard for perchlorate in bottled water?

No. FDA has not established a standard (i.e., an allowable level) for perchlorate in bottled water. In February 2005, EPA adopted the NAS recommended RfD of 0.7 $\mu\text{g}/\text{kg}$ bw/day for perchlorate (see "[EPA Sets Reference Dose for Perchlorate](#)"), which focuses on protecting the most sensitive population, the fetuses of pregnant women who might have hypothyroidism or iodine deficiency. If all perchlorate exposure is assumed to come from drinking water, the RfD translates to a drinking water equivalent level (DWEL) of 24.5 ppb based on two (2) liters of drinking water consumption per day by adults. EPA has not yet determined whether a drinking

water standard (i.e., a maximum contaminant level or MCL) is warranted for perchlorate.

EPA has been gathering and evaluating information on the perchlorate health effects and occurrence in public water systems to determine whether or not a drinking water standard presents a meaningful opportunity to reduce risk for those persons served by public water systems. Understanding overall exposure to perchlorate, including the potential contribution from food, is important to making a decision about regulating perchlorate in drinking water. EPA is working with FDA, as well as other federal agencies and states to better understand perchlorate exposure and the impact on EPA's policies.

Under the Federal Food, Drug, and Cosmetic Act, if EPA establishes an MCL for perchlorate in public drinking water, FDA is required to establish an allowable level for perchlorate under the quality standard regulations for bottled water or make a finding that such a regulation is not necessary to protect the public health because the contaminant is found in water in public water systems but not in water used for bottled drinking water.

4. In some areas of California, perchlorate has been found in tap water. Do bottled water manufacturers test for perchlorate?

FDA has not established a standard for perchlorate in bottled water, and FDA's current bottled water regulations do not require bottled water manufacturers to test for perchlorate. If EPA establishes a standard for perchlorate in public drinking water, FDA will consider establishing a quality standard for perchlorate in bottled water. If FDA establishes such a standard, bottlers will be required to test for perchlorate.

The bottled water industry is aware of the potential for perchlorate contamination in source waters for bottling and some bottlers may voluntarily test for perchlorate. Consumers should contact bottled water producers for more information.

5. Has FDA developed a method to detect perchlorate in foods?

Yes. FDA has developed a rapid, sensitive, and specific ion chromatography-tandem mass spectrometry (IC-MS/MS) method for determining perchlorate in selected foods. The smallest amount of perchlorate that this method can detect, or the limit of detection (LOD), is 0.30 ppb for fruits, fruit juices, and vegetables; 1.00 ppb for milk, grain products, fish, and shrimp; and 0.20 ppb for bottled water. An article, entitled "[Rapid Determination of Perchlorate Anion in Foods by Ion Chromatography-Tandem Mass Spectrometry](#)," describing FDA's method has been published in the September 15, 2004 issue of the scientific journal *Analytical Chemistry* (Analytical Chemistry. 2004, 76, 5518-5522).

FDA's 2005/2006 Total Diet Study Surveys

6. What is FDA's Total Diet Study?

FDA's Total Diet Study (TDS) is the Agency's ongoing market basket survey in which 285 core foods (TDS foods) in the U.S. food supply are collected and analyzed to determine levels of various contaminants and nutrients in those foods. The foods collected in the TDS (referred to as the TDS food list) represent the major components of the diet of the U.S. population. The food list is based on results of national food consumption surveys and is updated from time to time to reflect changes in food consumption patterns.

Four market baskets are generally collected each year, one in each of four geographic regions of the U.S. (i.e., West, North Central, South, and Northeast). For each market basket, samples of each TDS food are collected from grocery stores and fast food restaurants in three cities within the region, prepared table-ready, and composited for analysis. Therefore, each data point for a contaminant or a nutrient represents the analytical result for a composite of three samples of the TDS food. For more information on the TDS, see [Total Diet Study](#).

7. Did FDA test TDS foods for perchlorate and iodine?

Yes. For perchlorate, 54 out of 57 TDS baby foods were analyzed in four market baskets collected in FY05; the remaining three baby foods were analyzed in three market baskets because they were not available for analysis in the fourth market basket for FY05. The other 228 TDS foods were collected and analyzed in FY06; of those, 128 were analyzed for four market baskets and 100 were analyzed for two market baskets. The complete set of perchlorate data obtained from [FY05 and FY06 TDS](#) surveys is available on FDA's website. For iodine, 285 TDS foods from five markets baskets collected in FY03 and FY04 were analyzed (iodine results are available at [Total Diet Study](#)).

On January 2, 2008, FDA published a study entitled "U.S. Food and Drug Administration's Total Diet Study: Dietary Intake of Perchlorate and Iodine" in the *Journal of Exposure Science and Environmental Epidemiology*. This study reports on the estimated average dietary intakes of perchlorate and iodine based on analytical results for perchlorate from FDA's TDS samples collected in FY 05/06 and for iodine from TDS samples collected in FY03/04.

8. What were the estimates of the dietary intake of perchlorate from the "U.S. Food and Drug Administration's Total Diet Study: Dietary Intake of Perchlorate and Iodine" study?

The estimated lower bound to upper bound average perchlorate intakes by the 14 age-gender subgroups (see below) range from 0.08 to 0.39 $\mu\text{g}/\text{kg}$ bw/day, all below the RfD of 0.7 $\mu\text{g}/\text{kg}$ bw/day recommended by the National Academy of Sciences and adopted by the U.S. Environmental Protection Agency.

The 14 age-gender subgroups consist of infants (6-11 months), children (2 years), children (6 years), children (10 years), teenage girls (14-16 years), teenage boys (14-16 years), women (25-30 years), men (25-30 years), women (40-45 years), men (40-45 years), women (60-65 years), men (60-65 years), women (70 + years), and men (70 + years). Children 2 years of age, with estimated average intakes ranging from

0.35 to 0.39 $\mu\text{g}/\text{kg}$ bw/day, have the highest total perchlorate intake per kilogram body weight per day, but are below the RfD of 0.7 $\mu\text{g}/\text{kg}$ bw/day recommended by the National Academy of Sciences and adopted by the U.S. Environmental Protection Agency. Total average intake ranges for infants 6-11 months, children 6, and children 10 years of age are estimated to be 0.26 to 0.29 $\mu\text{g}/\text{kg}$ bw/day, 0.25 to 0.28 $\mu\text{g}/\text{kg}$ bw/day, and 0.17 to 0.20 $\mu\text{g}/\text{kg}$ bw/day, respectively. The estimated total average intakes by the other age-gender subgroups ranged from 0.08 to 0.14 $\mu\text{g}/\text{kg}$ bw/day.

9. What were the estimates of the dietary intake of iodine from the "U.S. Food and Drug Administration's Total Diet Study: Dietary Intake of Perchlorate and Iodine" study?

Because human exposure to high dosages of perchlorate can interfere with iodide uptake into the thyroid gland, it is important to consider the levels of iodine in the body. The estimated average iodine intakes by the 14 age-gender subgroups show a range from 138 to 353 $\mu\text{g}/\text{person}/\text{day}$. The estimated average iodine intakes for infants, 6-11 months exceeded their adequate intake (AI) of 135 $\mu\text{g}/\text{person}/\text{day}$. The estimated average iodine intakes by all other 13 children and adult age-gender subgroups exceeded their relevant estimated average requirements (EARs) of 65 $\mu\text{g}/\text{person}/\text{day}$ for children 2 and 6 years, 73 $\mu\text{g}/\text{person}/\text{day}$ for children 10 years, and 95 $\mu\text{g}/\text{person}/\text{day}$ for the remaining 10 age-gender subgroups.

The EARs are defined by NAS as the nutrient intake levels estimated to meet the requirements of half the healthy individuals within a particular age group. An AI is set by NAS when there is insufficient evidence to determine an EAR and defined as the recommended average daily intake level of a nutrient that is assumed to be adequate for a group of apparently healthy individuals.

10. What is FDA recommending to consumers?

FDA is not recommending any changes to infants' and children's diets and eating habits based on current perchlorate data. FDA continues to recommend a healthy eating plan, consistent with the Dietary Guidelines for Americans, that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; and is low in saturated fats, trans fats, cholesterol, salt (sodium) and added sugars. Additionally, adequate intake of iodine has previously been recognized as important for healthy thyroid function .

FDA's 2004/2005 Exploratory Surveys

11. How did FDA conduct the exploratory surveys for perchlorate in 2004 and 2005?

During Fiscal Year 2004 (FY04), FDA conducted an initial exploratory survey that involved the collection and analysis of samples of domestic origin (i.e., bottled water, milk, lettuce, tomatoes, carrots, spinach, cantaloupe). Produce samples (lettuce, tomatoes, carrots, spinach, and cantaloupe) were collected particularly from

regions (i.e., Southern California and Arizona) where water sources were known to be contaminated with perchlorate, based on a study report of detecting perchlorate in winter lettuce grown in Southern California or Arizona (Environmental Working Group. [Suspect Salads: Toxic rocket fuel found in samples of winter lettuce. 2003. !\[\]\(d84e7ea36f695d92cb39ec32c307ac93_img.jpg\)](#)). Bottled water and milk samples were collected from throughout the country. Bottled water was selected for the survey to obtain an initial assessment of perchlorate occurrence in source waters for bottling, while milk was sampled as a follow up to a Texas Tech University study that found perchlorate in a small number of milk samples from Texas (Kirk et al., Perchlorate in Milk. Environ. Sci. Technol. 2003, 37:4979-4981). Produce samples (lettuce, tomatoes, carrots, spinach, and cantaloupe) were selected for the survey based on their high water content, relatively high consumption, and early indications of perchlorate uptake by plants (when irrigated with perchlorate-containing water or when grown in soil that naturally contains perchlorate or that has been previously exposed to perchlorate-containing water or fertilizer).

For FY05, FDA expanded the exploratory survey. In addition to collecting further samples of tomatoes, carrots, spinach, and cantaloupe, FDA collected samples of other high water content foods, including fruits and fruit juices such as apples, oranges, and grapes; vegetables such as cucumbers, green beans, and greens; and seafood such as aquaculture fish and shrimp. In addition, grain products such as wheat flour, cornmeal, and rice were sampled as a follow up to a Texas Tech University study report that found perchlorate in wheat heads (Jackson et al., Perchlorate Accumulation in Forage and Edible Vegetation. J. Agric. Food Chem. 2005, 53:369-373). The FY05 samples collected by FDA consisted of domestic products grown in a broader range of locations within the U.S. (i.e., Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Mississippi, Missouri, Montana, Nebraska, New Jersey, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Washington) to determine if perchlorate occurs in foods from wider regions of the United States, and not only from regions where water sources were known to be contaminated with perchlorate. In FY05, FDA also collected and analyzed a limited number of imported products commonly entering the U.S. market (e.g., produce from Mexico, grapes from Chile, aquaculture salmon from Canada, shrimp from Southeast Asia) that were available for sampling during FY05.

12. Has FDA informed the public of the perchlorate levels that have been found in foods from the exploratory surveys?

Yes. The complete set of perchlorate data obtained from the [FY04 and FY05 exploratory surveys](#) is available on FDA's website.

13. What was the exposure estimate based on the exploratory surveys and how did it compare to EPA's RfD?

FDA's preliminary perchlorate exposure assessment (see "[Preliminary Estimation of Perchlorate Dietary Exposure Based on FDA 2004/2005 Exploratory Data](#)") suggested that perchlorate levels found in the 27 foods and beverages (milk, fruits and fruit juices, vegetables, grain products, aquaculture fish and shrimp) are not

likely to present a public health risk. Based on perchlorate data obtained from FDA's FY04 and FY05 exploratory surveys, the estimated total mean population (all persons aged 2 and above) perchlorate exposure from the 27 foods and beverages was determined to be 0.053 µg/kg bw/day, which is below the RfD of 0.7 µg/kg bw/day, the daily exposure level over a lifetime that is not expected to cause adverse health effects, recommended by NAS and adopted by EPA. FDA's preliminary exposure estimate was similar to the geometric mean perchlorate dose of 0.066 µg/kg bw/day for the U.S. population (males and females aged 20 years and older) estimated by Blount *et al.* in 2006 (Perchlorate Exposure of the US Population, 2001-2002. *J Expo Sci Environ Epidemiol* (2006), 1-8).

14. Did the perchlorate levels in the 27 foods and beverages analyzed from the exploratory surveys provide an accurate measure of exposure to perchlorate?

There are uncertainties associated with the conclusions of FDA's preliminary exposure assessment because the perchlorate levels in the 27 foods and beverages were exploratory data and consumption of the 27 foods and beverages represented only about 32 percent of the total diet for the U.S. population, ages 2 years and older and 42 percent of the total diet for children, 2-5 years.

At the time FDA conducted the preliminary exposure assessment based on 2004/2005 exploratory perchlorate data, it did not have any information on the distribution of perchlorate in foods that constitute the remaining 68 percent of the total diet for U.S. population, ages 2 years and older and 58 percent of the total diet for children, 2-5 years. Therefore, the true average intake of perchlorate could be higher than the average intake based on FDA's exploratory perchlorate data for the 27 foods and beverages. Sampling of additional food types to increase representation of the total U.S. diet and collection of food types from wider regions of the country would better characterize perchlorate distribution in the U.S. food supply that could provide a more precise assessment of the scope of perchlorate exposure and the public health implications for food with more reasonable certainty.

Therefore, FDA conducted a more comprehensive and nationally representative exposure assessment based on perchlorate data obtained from FY05 and FY06 Total Diet Study surveys (see questions 6-10 above).

FDA's Next Steps

15. What are FDA's next steps?

FDA is continuing to test additional food types for perchlorate. In FY07, FDA tested additional samples of individual food products collected through additional surveys, and during FY 08, additional TDS samples will be analyzed for perchlorate. Information on the distribution of perchlorate in a wider variety of foods obtained from these surveys will further enhance FDA's ability to assess the dietary exposure of U.S. consumers to perchlorate.

FDA will continue to inform the public of its findings as additional data is collected.

Other steps may include developing and fostering public/private partnerships to gather scientific and technological information and data for assessing the human exposure to perchlorate.

FDA is continuing to work with the Interagency Working Group on Perchlorate, composed of other federal agencies, including USDA and EPA, to evaluate the potential risk associated with perchlorate exposure.

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