



**Testimony**  
**Committee on Energy and Commerce**  
**Subcommittee on Environment and**  
**Hazardous Materials**  
**United States House of Representatives**

**FDA's Role in Measuring and**  
**Assessing Perchlorate Levels in**  
**Food and Beverages**

*Statement of*

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Mr. Chairman and Members of the Subcommittee, I am Dr. Robert E. Brackett, Director of the Center for Food Safety and Applied Nutrition (CFSAN). Thank you for the opportunity to testify about the actions taken by the U.S. Food and Drug Administration (FDA) to measure and assess the presence of perchlorate in food and beverages.

We at FDA take our responsibility to protect the nation's food supply very seriously. To better understand the potential for food to provide an exposure pathway for perchlorate, we began in 2004 to sample and analyze a variety of foods to determine the occurrence of perchlorate and to estimate resulting human exposure through consumption of those foods. This information will be used to help determine whether additional action might be needed to protect the public health. The following statement will describe our past, ongoing, and planned data collection and analyses.

## **Background**

Perchlorate is an industrial chemical contaminant that is used as a propellant in rockets, in fireworks and flares, and for other purposes. Perchlorate has also been found to occur naturally, and there is preliminary evidence that it can be generated under certain climatic conditions. The relative contribution to perchlorate levels in food of man-made versus natural perchlorate is not known. Perchlorate at high doses (e.g., therapeutic, pharmacologic) can interfere with iodide uptake into the thyroid gland, interfering with thyroid hormone production.

Sustained inhibition of iodide uptake can lead to hypothyroidism, which can lead to metabolic problems in adults and abnormal development *in utero* and in infancy.

There is a potential for perchlorate contamination in food, most likely through the use of contaminated irrigation water, processing water, and, with respect to bottled water, which is a “food” regulated by FDA, source waters for bottling. However, we do not know the relative contribution of any particular source of perchlorate to that found in foods. Recognizing this potential for perchlorate contamination in food, FDA in 2004 and 2005 conducted exploratory surveys to investigate the occurrence of perchlorate in certain foods and is using the data collected in these surveys to develop preliminary assessments of human exposure to perchlorate through food. In addition, we added perchlorate as a chemical that we analyzed as part of our 2005/2006 Total Diet Study, which is a long-running FDA program using well-established sampling methods and exposure models. We have additional investigations planned. These studies, described more fully below, will allow us to characterize exposure to perchlorate from food, and may be used as scientific support for any action by FDA that might be needed to protect the public health.

### **Detection of Perchlorate in Foods**

As a first step in our investigation of perchlorate in foods, FDA developed a rapid and scientifically accurate method to measure the presence of perchlorate in

foods. This method, a sensitive and specific ion chromatography-tandem mass spectrometry (IC-MS/MS) method, was first developed for use on a limited number of foods, including lettuce, milk, and bottled water. The method is described on the FDA Web site at [www.cfsan.fda.gov/~dms/clo4meth.html](http://www.cfsan.fda.gov/~dms/clo4meth.html) and it has been published.<sup>i</sup> The method was updated during fiscal year 2005 for determining perchlorate in grain products, fruits and fruit juices, fish, and shrimp. The smallest amounts of perchlorate this method can quantify are 1 part per billion (ppb) for produce, including fruits and fruit juices; 3 ppb for milk, grain products, fish, and shrimp; and 0.5 ppb for bottled water.

### **Fiscal Year 2004 Perchlorate Survey and Preliminary Exposure Assessment**

In December 2003, FDA began an initial exploratory survey to investigate perchlorate levels in various foods, particularly in produce and bottled water. The initial survey called for a total of 500 samples of domestic origin to be collected and analyzed by the FDA. The first collection of data, which spanned from December 2003 until August 2004, involved two phases. For the first phase of the survey, 150 samples of lettuce and 50 samples of bottled water were collected and analyzed for perchlorate. The second phase of the survey, conducted beginning in August 2004, called for collection and analysis of 120 milk, 55 tomato, 45 carrot, 45 cantaloupe, and 35 spinach samples.

In November 2004, FDA posted on its Web site the initial set of perchlorate data collected from December 2003 to August 2004 to inform the public of FDA's progress and share its initial exploratory data. The data included perchlorate levels found in lettuce, bottled water, and milk samples collected as part of the exploratory survey issued in December 2003

(<http://www.cfsan.fda.gov/~dms/c1o4data.html>). FDA also posted Perchlorate Questions and Answers to explain and provide context to the survey data (<http://www.cfsan.fda.gov/~dms/clo4qa.html>). Some additional samples, also collected in 2004 but not analyzed until 2005, were later posted at this site.

The values for perchlorate found in the foods sampled in 2004 were similar to those reported by other researchers external to FDA. These data confirmed that we should continue to investigate the occurrence of perchlorate in a greater variety of foods and in other regions of the country, which we proceeded to do in 2005, as discussed below. It is important to note that the results we obtained are preliminary and do not reflect the distribution of perchlorate in the U.S. food supply. The sampling methodology used was not intended to be representative; rather, it was specifically targeted at foods that we anticipated to contain higher levels of perchlorate due to where the food was grown and its high water content.

We want to stress that the 2004 preliminary perchlorate exposure assessment was based on perchlorate data collected in 2004 for a small number of food types and a small number of samples within a food type. Additionally, these

samples came from areas where there was known perchlorate occurrence, thus they are not representative of samples throughout the U.S. Because of these limitations, it would not be appropriate to consider the 2004 preliminary exposure assessment to be a reflection of the actual perchlorate exposure of the U.S. population.

### **Fiscal Year 2005 Perchlorate Survey and Updated Preliminary Exposure Assessment**

In February 2005, FDA issued a second perchlorate survey assignment to obtain information on the distribution of perchlorate in a wider variety of foods. This survey called for a total of 450 samples, domestic and imported, to be collected in two phases during fiscal year 2005. The first phase consisted of collection of additional samples of tomatoes, carrots, spinach, and cantaloupe, and collection of a wider variety of foods that included fruits and fruit juices such as apples, oranges, and grapes; vegetables such as broccoli; and grain products such as cornmeal and oatmeal. The second phase consisted of the collection of additional types of fruits, vegetables and grain products, as well as aquaculture fish.

As part of a separate survey assignment issued in December 2004, FDA collected and analyzed for perchlorate content in 105 farm milk samples, 105 associated feed samples, and 105 water samples from dairy farms in top milk producing states to determine potential sources of contamination at the farm

level. In addition, FDA collected and analyzed a total of 228 baby food samples, including a few infant formula samples, obtained from four market baskets (57 samples per market basket) under the FDA's Total Diet Study (TDS) survey program (described in more detail below). Separately, we also collected and analyzed a total of 21 samples of different types of infant formula and have plans to collect and analyze an additional 40 infant formula samples in 2007.

FDA has compiled the preliminary results of the mean perchlorate exposure assessment for the general population (all persons aged 2 and above), based on FY 2004/2005 exploratory survey data for 27 types of food and beverages (milk, fruit and fruit juices, vegetables, grain products, and seafood (aquaculture fish and shrimp)). The analysis of these preliminary results has been reviewed by three external government experts and has been shared with the Interagency Working Group. When finalized, we plan to release the updated exploratory exposure assessment. It is important to reiterate that this preliminary exposure assessment is based on non-representative food data and is not necessarily a reflection of perchlorate exposure to the U.S. population. We expect to have representative exposure estimates following the analysis of the total diet study which is described below.

### **Total Diet Study**

FDA's Total Diet Study (TDS), sometimes called the market basket study, is an ongoing program to determine the levels of various contaminants and nutrients in

foods. Using data obtained through the TDS program, dietary intakes of the analyzed substances by the U.S. population can be estimated. Since its inception in 1961 as a program to monitor for radioactive contamination of foods, the TDS has grown to encompass additional substances, including pesticide residues, industrial chemicals, and toxic and nutrient elements.

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. Currently, there are about 280 foods collected and analyzed in the TDS. A unique aspect of the TDS is that foods are prepared as they would be consumed (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of the dietary intake of these analyzed substances.

In FY 2005 and 2006, FDA analyzed samples from the TDS survey for perchlorate to obtain information on the distribution of the contaminant in a wide variety of foods. FDA plans to publish, in late 2007, an assessment of the exposure to perchlorate from food, based on the levels in TDS foods collected and analyzed during FY 2005/2006. Because of the size of the dataset and the design of this study, these data will provide a robust estimate of the exposure of U.S. consumers to perchlorate through food consumption than the updated preliminary exposure assessment, based on the 2004/2005 targeted sampling.

## **Additional Steps**

In FY 2007, FDA is continuing to test samples of specific food types collected through additional targeted surveys (e.g., infant formulas, sweet potatoes, celery, green peppers, grapes, apples, oranges, apple juice, whole wheat bread, aquaculture catfish, aquaculture salmon, and shrimp). Information on the distribution of perchlorate in a wider variety of foods obtained from these surveys will further enhance FDA's assessment of the dietary exposure of U.S. consumers to perchlorate. FDA will continue to inform the public of its findings as more knowledge is gained.

FDA continues to work with the U.S. Department of Agriculture (USDA) and the EPA to determine the occurrence of perchlorate in foods for continuing assessment of the dietary exposure to perchlorate. FDA is aware that other data on perchlorate levels in foods are under development and welcomes external research that can assist us in describing the distribution of perchlorate in foods and in developing exposure estimates.

## **Recommendations for Consumers**

Consumers should not view the low levels of perchlorate in the foods tested as an indicator of the "risk" of eating certain foods, particularly when many of the foods are important components of a nutritious and balanced diet. Some of these food items are also important sources of iodine. Until more is known concerning perchlorates occurrence in foods, FDA continues to recommend that

consumers eat a balanced diet, choosing a variety of foods that are low in *trans* fat and saturated fat, and rich in high-fiber grains, fruits, and vegetables.

Thank you for the opportunity to provide this information and discuss these important public health issues with you.

## Endnotes

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<sup>i</sup> Krynitsky, A.J., R.A. Nieman, and D.A. Nortrup. 2004. Determination of Perchlorate Anion in Foods by Ion Chromatography-Tandem Mass Spectrometry. *Anal. Chem.* 76:5518-5522.