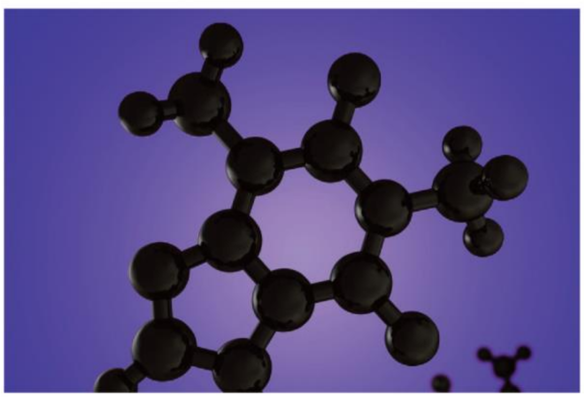
Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

# Food Safety Action Plan

## REPORT

2011-2013 Targeted Surveys

Chemistry



## *Perchlorate in Fresh Fruits and Vegetables, Fruit and Vegetable Juice, Dairy-based products and Infant Formulas*

TS-CHEM-11/13

Canada

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# Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As a part of the FSAP enhanced surveillance initiative, targeted surveys are used to provide data in order to evaluate various foods for specific hazards.

The main objectives of these perchlorate targeted surveys were to generate baseline surveillance data on the levels of perchlorate in fresh fruits and vegetables, fruit and vegetable juice, dairy-based products and infant formulas available on the Canadian retail market, and to compare the perchlorate levels in these surveys to the 2010-2011 FSAP survey on perchlorates, where feasible.

Perchlorate is a chemical that occurs naturally in the environment (e.g., in some nitrate and potash deposits or formed in the atmosphere). It is also an environmental contaminant resulting from industrial processing of rocket propellants, explosives, road flares, fireworks, and automotive airbags. Since perchlorate readily dissolves in water, it can be taken up and accumulated by plants and may also be transferred to animals through the consumption of perchlorate-contaminated feed or water.

Human exposure to perchlorate occurs primarily through ingestion of food and water. At sufficiently high doses, perchlorate can interfere with the uptake of iodide by the thyroid gland which is required to produce hormones essential for metabolism and growth.

Over the two years of surveys, a total of 1426 samples, including 881 fresh fruits and vegetables, 225 fruit and vegetable juices, 233 dairy-based products and 87 infant formulas, were collected from Canadian retail stores and analyzed for perchlorate. Six hundred and sixty-three of these samples were collected between April 2011 and March 2012 and 763 samples were collected between April 2012 and March 2013.

Six hundred thirty-seven of the 1426 samples (45%) did not contain a detectable level of perchlorate. Overall, 44% of fresh fruit, 74% of fresh vegetable, 23% of fruit and vegetable juice samples, 60% of dairy-based products, and 56% of infant formula samples analyzed were found to contain detectable levels of perchlorate ranging from 2 to 2400 parts per billion (ppb). Within the commodity types analyzed in these surveys, the highest average perchlorate levels were found in cucumbers (106 ppb), leafy green vegetables (65 ppb) and tomatoes (57 ppb).

The prevalence of perchlorate and the perchlorate levels in dairy-based products, fresh fruit and vegetable, juice and infant formula samples analyzed in these surveys were generally comparable with those reported in the previous CFIA survey, unpublished Health Canada data and the scientific literature.

As no maximum level, tolerance, or standard has been established by Health Canada for perchlorate in food, compliance with Canadian regulations was not evaluated in this survey. All data generated were shared with Health Canada for use in human health risk assessments. Health Canada's Bureau of Chemical Safety determined that the levels of

perchlorate found in these surveys were not expected to pose an unacceptable health risk and therefore no follow-up actions were needed.

# 1. Introduction

## 1.1 Food Safety Action Plan

In 2007, the Canadian government launched a five-year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen Canada's safety system for food, health, and consumer products. The FCSAP initiative unites multiple government partners in ensuring safe food for Canadians.

The Canadian Food Inspection Agency's (CFIA's) Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls and identify food importers and manufacturers. FSAP also looks to verify that the food industry is actively applying preventative measures, and that there is a rapid response if or when these measures fail.

Within FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess, and prioritize potential food safety hazards through risk mapping, information gathering, and testing of foods from the Canadian marketplace. Targeted surveys are one tool used to test for the presence and level of a particular hazard in specific foods.

Within the current regulatory framework, some commodities (such as meat and fish products) traded internationally and interprovincially are regulated by specific Acts. These are referred to as federally registered commodities, which are monitored as a part of the CFIA's core activities. Under the current regulatory framework, the non-federally registered commodities encompass 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act and Regulations* (FDAR). Targeted surveys are primarily directed towards the 70% of domestic and imported foods that are regulated solely by the *FDAR* and the *Consumer Packaging and Labelling Act and Regulations* (CPLAR), and are generally referred to as non-federally registered commodities.

## 1.2 Targeted Surveys

Targeted surveys are pilot surveys used to gather information regarding the potential occurrence of chemical residues, food additives, contaminants, and/or natural toxins in defined food commodities. The surveys are designed to answer specific questions; therefore, unlike monitoring activities, testing of a particular chemical hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of chemical hazards and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all chemical hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, and/or a risk-based model developed by the Food Safety Science Committee (FSSC), a group of federal, provincial and territorial subject matter experts in the area of food safety. The Committee ranked perchlorate in fresh fruits and vegetables, milk and milk products as a priority.

The purpose of these targeted surveys was to establish baseline data on perchlorate levels in fresh fruits and vegetables, fruit and vegetable juice, dairy-based products and infant formulas available on the Canadian retail market. The results of this survey were compared with previous FSAP data, the scientific literature and with unpublished data from Health Canada, where feasible.

## 1.3 Acts and Regulations

The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing restrictions/Canadian laws and regulations on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act and Regulations* (FDAR).

Health Canada establishes the health-based maximum levels for chemical residues and contaminants in food sold in Canada. Certain maximum levels for chemical contaminants in food appear in the *Canadian Food and Drug Regulations*, where they are referred to as tolerances. Tolerances are established as a risk management tool and generally only for foods that significantly contribute to the total dietary exposure of the food contaminant in question. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards. However, all foods sold in Canada must comply with the provisions in Section 4(1)(a) of the *Food and Drug Act*, which prohibits the sale of a food that contains a poisonous or harmful substance.

Currently, no maximum level, tolerance, or standard has been established by Health Canada for perchlorate levels in food and therefore, compliance with Canadian regulations was not evaluated in this survey. Similarly, regulations for perchlorate in food have not been established internationally.

In the absence of tolerances or standards, elevated levels of perchlorate in specific foods may be assessed by Health Canada on a case-by-case basis using the most current scientific data available. If Health Canada's Bureau of Chemical Safety identifies a potential safety concern, the CFIA can conduct follow-up actions. Follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include further analysis, notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

# 2. Survey Details

## 2.1 Perchlorate

Perchlorate is a chemical that occurs naturally in the environment (e.g., in some nitrate fertilizers and potash deposits, and in the atmosphere)[1]. It is also considered an environmental contaminant that is industrially produced, originating from the inappropriate storage or disposal of perchlorate used in the production of rocket propellants, explosives, road flares, fireworks, automotive airbags and some fertilizers[2,3,4,5].

Since perchlorate readily dissolves in water, it can accumulate in groundwater and surface waters in areas where products containing perchlorate are manufactured or used, or on land previously treated with perchlorate-containing fertilizers. Perchlorate can then be taken up and accumulated by plants, particularly the leafy portions part of several food crops. As such, through the consumption of perchlorate-contaminated feed or water, perchlorate may also accumulate in animal meat and milk[6].

Human exposure to perchlorate occurs primarily through ingestion of food and water[7]. At sufficiently high doses, perchlorate can interfere with the uptake of iodide by the thyroid gland[7]. This can affect the production of thyroid hormones, which have a role in regulating many metabolic and developmental functions in humans[7]. The most sensitive subpopulations are pregnant women and their unborn children, newborns and individuals with thyroid conditions or iodine deficiencies[3].

## 2.2 Rationale

Studies have indicated that plants can absorb perchlorate from the soil and water, and elevated perchlorate levels have been found in leafy greens as well as various other fruits and vegetables, most notably citrus, tomatoes, and melons[8,9,10].

Perchlorate has been detected in dairy products[5,10] resulting from the ingestion of perchlorate-contaminated water or feed by dairy cattle. Perchlorate has also been found in milk-based and soy-based infant formula[11,12]. Dairy products are highly consumed by young children in particular, and results of the U.S. Food and Drug Administration's Total Diet Survey found that infants and children had the highest estimated intakes of perchlorate due to higher food and water consumption relative to body weight[3].

Given that fruits and vegetables, dairy-based products and infant formulas are staples of the Canadian diet, this targeted survey was designed to establish baseline data on perchlorate levels in these products available at the Canadian retail level. All data were shared with Health Canada for use in conducting human health risk assessments of perchlorate.

## 2.3 Sample Distribution

In these surveys, a total of 663 samples were collected between April 2011 and March 2012 and 763 samples were collected between April 2012 and March 2013 from grocery and specialty stores in 11 Canadian cities. The samples included 881 fresh fruit and vegetable samples, 225 fruit and vegetable juice samples, 233 dairy-based products, and 87 infant formulas. The general distribution of samples by product type and sampling year is presented in Table 1.

**Table 1. Distribution of samples by product type**

| Product Type | Sample Type | | Number of samples | | |
|---|---|---|---|---|---|
| | | | **2011-2012** | **2012-2013** | **Total** |
| Fresh Fruits and Vegetables | Fruits | Blueberry | - | 22 | 22 |
| | | Cantaloupe | - | 22 | 22 |
| | | Grapefruit | - | 25 | 25 |
| | | Lemon | - | 25 | 25 |
| | | Orange | 44 | 48 | 92 |
| | | Strawberry | 38 | 48 | 86 |
| | | Watermelon | 37 | 47 | 84 |
| | **Fruits Total** | | **119** | **237** | **356** |
| | Vegetables | Cucumber | 45 | 50 | 95 |
| | | Leafy greens* | 200 | 142 | 342 |
| | | Tomato | 40 | 48 | 88 |
| | **Vegetables Total** | | **285** | **240** | **525** |
| **Fresh Fruits and Vegetables Total** | | | **404** | **477** | **881** |
| Fruit and Vegetable Juice | Fruit Juice | Apple | 13 | 15 | 28 |
| | | Grape | 13 | 14 | 27 |
| | | Orange | 14 | 17 | 31 |
| | | Other/Mixed | 7 | 66 | 73 |
| | Fruit/Vegetable Juice | | - | 8 | 8 |
| | Vegetable Juice | Carrot | 2 | 10 | 12 |
| | | Other/Mixed | 7 | 66 | 73 |
| | | Tomato | 8 | 11 | 19 |
| **Fruit and Vegetable Juice Total** | | | **78** | **147** | **225** |
| Dairy-based Products | Creams | | 8 | 9 | 17 |
| | Desserts | | 39 | 71 | 110 |
| | Dips, dressings & sauces | | 47 | 59 | 106 |
| **Dairy-based Products Total** | | | **94** | **139** | **233** |
| Infant Formula | Dairy-based Formula | | 68 | - | 68 |
| | Soy-based Formula | | 19 | - | 19 |
| **Infant Formula Total** | | | **87** | - | **87** |
| **Total** | | | **663** | **763** | **1426** |

*Leafy Greens includes lettuce, radicchio, chard, mixed baby greens, kale and spinach.

The 663 samples collected in 2011-2012 included 100 domestic products, 324 imported products (from 14 countries), and 239 samples of unspecified origin for which country of origin could not be determined from the product label or available sample information. The 763 samples collected in 2012-2013 included 194 domestic products, 536 imported products (from 18 countries), and 33 samples of unspecified origin. It is important to note that the products sampled often contained the statement “imported for Company A in Country Y” or “manufactured for Company B in Country Z”. Although the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of “Product of”, “Prepared in”, “Made in”, “Processed in”, and “Manufactured by” were considered as being from a specific country of origin.

## 2.4 Method Details

Samples were analyzed for perchlorate by an ISO 17025 accredited laboratory under contract with the Government of Canada. The laboratory used ion chromatography-tandem mass spectrometry to analyze perchlorate levels in the samples. The method has limits of detection (LOD) in the range of 0.27 ppb to 1.25 ppb.

All samples, including infant formulas, were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable).

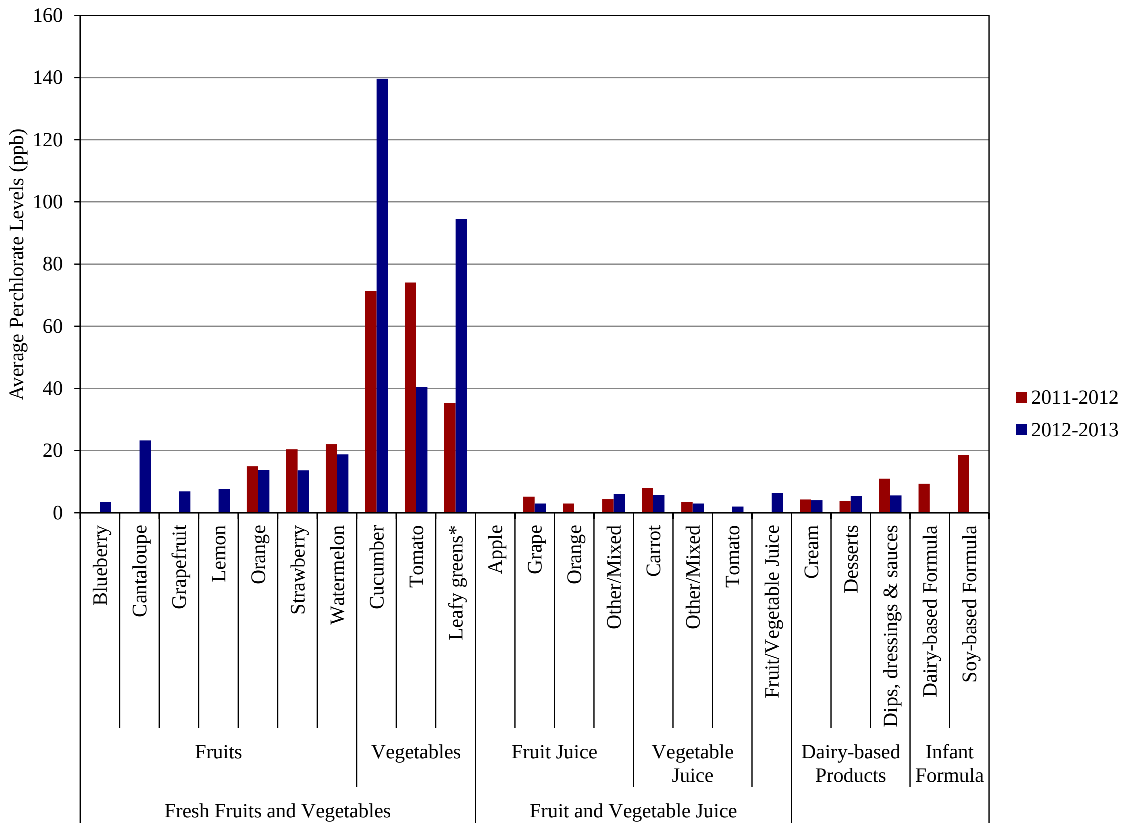
## 2.5 Limitations

The current targeted surveys were designed to provide a snapshot of the levels of perchlorate in fresh fruits and vegetables, fruit and vegetable juice, dairy-based products and infant formulas in various packaging types available for sale in Canada, and had the potential to highlight commodities that warrant further investigation. The limited sample sizes analyzed represent a small fraction of the products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results. Regional differences, impact of product shelf-life, packaging and storage conditions, or cost of the commodity on the open market were not examined in this survey.

# 3. Results and Discussion

## 3.1 Overview of Perchlorate Survey Results

A total of 663 and 763 samples, obtained from Canadian retail, were tested in the 2011-2012 and 2012-13 targeted surveys, respectively. It should be noted that the average perchlorate results discussed below were calculated using only those samples for which perchlorate was detected (i.e., average of the positive results only). A summary of the average detected perchlorate levels of survey samples is presented in Figure 1. The highest average levels of perchlorate were found in selected vegetables (cucumber, leafy greens, and tomato). More detailed results by product type are presented in the following sections.




*Leafy Greens includes lettuce, radicchio, chard, mixed baby greens, kale and spinach.

**Figure 1. Summary of average detectable perchlorate levels in food samples.**

## 3.2 Fresh Fruits and Vegetables

In these surveys, 881 samples of fresh fruit and vegetables were analyzed. The results of the two surveys were relatively consistent (Figure 2). In general, 44% of fresh fruit and 74% of fresh vegetable samples analyzed were found to contain detectable levels of perchlorate (i.e., positive results).) The detected perchlorate levels in fresh fruit and vegetable samples ranged from 2 ppb (various fruits and vegetables) to 2400 ppb in leafy green vegetables (spinach), with the highest average levels found in cucumbers (106 ppb, averaged over both survey years), leafy green vegetable (65 ppb, averaged over both survey years and tomatoes (57 ppb, averaged over both survey years) (Figure 1). The levels of perchlorate found in fresh fruit and vegetable samples in these surveys were assessed by Health Canada’s Bureau of Chemical Safety and were not expected to pose an unacceptable health risk.

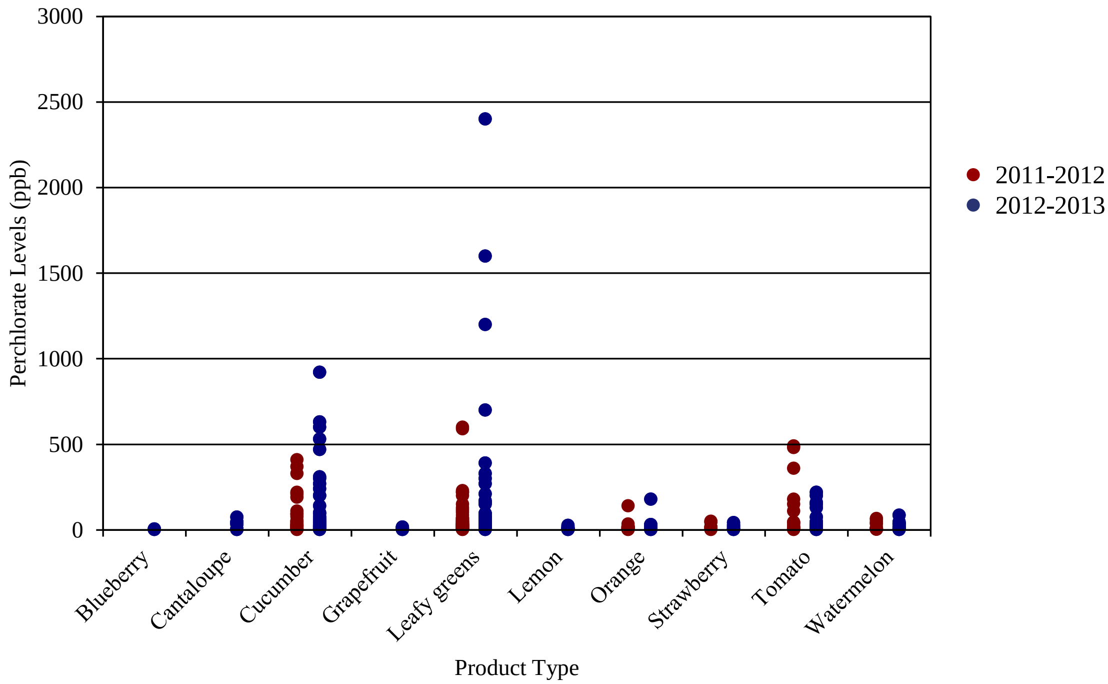



**Figure 2. Summary of perchlorate levels found in fresh fruit and vegetable samples.**

In general, the results of the current FSAP surveys are consistent with the results of the previous 2010-11 FSAP perchlorate targeted survey[13] and with other published studies [14,15,16] except for cucumbers and lemons. Table 2 presents a comparison of the perchlorate levels in fruit and vegetables in the current surveys with the previous 2010-2011 FSAP survey[13] and the scientific literature, where feasible. Blueberries, lemons and grapefruit were not analyzed in the previous FSAP survey, and, to our knowledge, no other published data on the perchlorate levels in blueberries is available. The average and maximum perchlorate levels for cantaloupes, oranges and strawberry are higher in the current surveys than in the 2010-2011 FSAP surveys. As noted in other scientific studies, perchlorate levels are highly variable, even for the same fruit or vegetable[3,8,9,14,15]. The observed variation in perchlorate levels in fresh fruits and vegetables may be related to factors such as the uptake of perchlorate by the plant, growth rate, geographic location, level and length of exposure to perchlorate due to the presence of perchlorate in the water or soil, irrigation with water containing perchlorate and/or the use of fertilizer containing perchlorate[3,5,9].

**Table 2. Comparison of perchlorate levels in fruits and vegetables in the current FSAP surveys with the previous FSAP survey and scientific literature**

| Study | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| **Cantaloupe** | | | | | | |
| CFIA | 2012-2013 | 22 | 11 (50) | 2 | 74 | 23 |
| | 2010-2011 | 16 | 10 (62) | 2 | 7 | 2 |
| FDA[14] | 2006 | 48 | 48 (100) | 0.52 | 713 | 28.6 |
| **Cucumber** | | | | | | |
| CFIA | 2012-2013 | 50 | 41 (82) | 2 | 920 | 140 |
| | 2011-2012 | 45 | 37 (82) | 2 | 410 | 71 |
| | 2010-2011 | 22 | 18 (82) | 3 | 430 | 49 |
| FDA[14] | 2006 | 19 | 16 (84) | 0.3 | 24.2 | 7.6 |
| **Grapefruit** | | | | | | |
| CFIA | 2012-2013 | 25 | 11 (44) | 2 | 17 | 7 |
| Sanchez[16*] | 2006 | 4 | 4 (100) | 17 | 149 | 80 |
| **Leafy Greens** | | | | | | |
| CFIA | 2012-2013 | 142 | 105 (74) | 2 | 2400 | 95 |
| | 2011-2012 | 200 | 150 (75) | 2 | 600 | 35 |
| | 2010-2011 | 134 | 108 (80) | 2 | 540 | 27 |
| FDA[14] | 2006 | 174 | 165 (95) | 0.4 | 927 | 33.9 |
| **Lemon** | | | | | | |
| CFIA | 2012-2013 | 25 | 16 (64) | 2 | 26 | 8 |
| Sanchez[16*] | 2006 | 5 | 5 (100) | 29 | 261 | 115 |
| **Orange** | | | | | | |
| CFIA | 2012-2013 | 48 | 35 (73) | 2 | 180 | 14 |
| | 2011-2012 | 44 | 28 (64) | 2 | 140 | 15 |
| | 2010-2011 | 23 | 19 (83) | 2 | 72 | 8 |
| FDA[14] | 2006 | 10 | 5 (50) | 1.29 | 28.3 | 6.63 |
| Sanchez[16*] | 2006 | 12 | 12 (100) | 89 | 731 | 199 |
| **Strawberry** | | | | | | |
| CFIA | 2012-2013 | 48 | 9 (19) | 2 | 43 | 14 |
| | 2011-2012 | 38 | 7 (18) | 2 | 51 | 20 |
| | 2010-2011 | 19 | 3 (16) | 2 | 87 | 8 |
| FDA[14] | 2006 | 19 | 15 (79) | 0.8 | 11.3 | 2.63 |
| **Tomato** | | | | | | |
| CFIA | 2012-2013 | 48 | 30 (63) | 2 | 220 | 40 |
| | 2011-2012 | 40 | 28 (70) | 2 | 490 | 74 |
| | 2010-2011 | 55 | 35 (64) | 2 | 360 | 45 |
| FDA[14] | 2006 | 73 | 54 (74) | 0.37 | 286 | 18.4 |

*Note: The Sanchez study examined only the peels of the citrus fruit while the FSAP survey looked at the whole fruit.

## 3.3 Fruit and Vegetable Juice

In the 2011-2012 and 2012-13 surveys, a total of 225 juice samples were analyzed. The samples included fruit juices (single fruit or blends), vegetable juices (single vegetable or blends), as well as fruit and vegetable juice blends. Overall, 23% of juice samples analyzed were found to contain detectable levels of perchlorate. Perchlorate levels found in juice samples ranged from 2 ppb to 20 ppb (see Table 3). Although, carrot juice had the highest number of positive samples (100%), the average perchlorate level found in carrot juice was similar to those found in other types of juice. The levels of perchlorate found in juice samples in these surveys were assessed by Health Canada's Bureau of Chemical Safety and were not expected to pose an unacceptable health risk.

**Table 3. Summary of minimum, maximum and average perchlorate levels found in fruit and vegetable juice samples**

| Type of Juice | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| **Fruit Juice** | | | | | | |
| Apple | 2011-2012 | 13 | 0 (0) | - | - | - |
| | 2012-2013 | 15 | 0 (0) | - | - | - |
| Grape | 2011-2012 | 13 | 5 (38) | 2 | 11 | 5 |
| | 2012-2013 | 14 | 2 (14) | 2 | 4 | 3 |
| Orange | 2011-2012 | 14 | 3 (21) | 3 | 3 | 3 |
| | 2012-2013 | 17 | 0 (0) | - | - | - |
| Other/ Mixed | 2011-2012 | 7 | 3 (43) | 2 | 7 | 4 |
| | 2012-2013 | 66 | 13 (20) | 2 | 20 | 6 |
| **Vegetable Juice** | | | | | | |
| Carrot | 2011-2012 | 2 | 2 (100) | 5 | 11 | 8 |
| | 2012-2013 | 10 | 10 (100) | 4 | 8 | 6 |
| Tomato | 2011-2012 | 8 | 0 (0) | - | - | - |
| | 2012-2013 | 22 | 2 (18) | 2 | 2 | 2 |
| Other/ Mixed | 2011-2012 | 21 | 4 (19) | 3 | 4 | 4 |
| | 2012-2013 | 6 | 1 (17) | - | 3 | - |
| **Vegetable/Fruit Juice** | | | | | | |
| Mixed | 2012-2013 | 8 | 6 (75) | 2 | 20 | 6 |

Table 4 presents a comparison of the perchlorate levels in juices in the current surveys with the results published by the US FDA. To our knowledge, additional perchlorate data for juices have not been published. The current FSAP survey and the FDA both reported very low perchlorate levels in juice approaching the method limit of detection[14].

**Table 4. Comparison of perchlorate levels in juices in the current FSAP surveys with the scientific literature**

| Study | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| **Apple Juice** | | | | | | |
| CFIA | 2012-2013 | 13 | 0 (0) | - | - | - |
| FDA[14] | 2006 | 11 | 11 (100) | 1.28 | 3.45 | 2.15 |
| **Orange Juice** | | | | | | |
| CFIA | 2012-2013 | 17 | 0 (0) | - | - | - |
| FDA[14] | 2006 | 5 | 5 (100) | 2.27 | 3.15 | 2.59 |

## 3.4 Dairy-based Products

In the two current FSAP surveys, a total of 233 dairy-based samples were analyzed. The products included cream, desserts (cheesecake and other cream or cheese-based goods), dips, dressings and cream-based sauces. Overall, 60% of dairy-based product samples analyzed were found to contain detectable levels of perchlorate. Perchlorate levels detected in dairy samples ranged from 2 ppb to 49 ppb (Table 5). Average perchlorate levels were similar for the cream, desserts, and dips/dressings/sauces category. The high rate of detection of perchlorate in dairy-based products is not unexpected given that dairy cattle may potentially consume water and feed containing trace amounts of perchlorate, which subsequently transfers to the milk[17]. The levels of perchlorate found in dairy-based product samples in these surveys were assessed by Health Canada's Bureau of Chemical Safety and were not expected to pose an unacceptable health risk.

**Table 5. Summary of minimum, maximum and average perchlorate levels found in dairy-based product samples**

| Study | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| Cream | 2011-2012 | 8 | 7 (88) | 3 | 6 | 4 |
| | 2012-2013 | 9 | 9 (100) | 3 | 7 | 4 |
| Desserts | 2011-2012 | 39 | 34 (87) | 2 | 9 | 4 |
| | 2012-2013 | 71 | 53 (75) | 2 | 46 | 5 |
| Dips, Dressings & Sauces | 2011-2012 | 47 | 25 (53) | 2 | 49 | 11 |
| | 2012-2013 | 59 | 12 (20) | 2 | 28 | 6 |

The data shown in Table 6 compares of the perchlorate levels in dairy products in the current surveys with milk results reported in scientific literature and unpublished data from Health Canada[3,10,15,18]. Direct comparison of the perchlorate levels in the dairy products listed in Table 5, above, to milk is not fully applicable, but the levels observed in this survey were similar to those seen in milk products examined in the scientific literature and by Health Canada. The proportion of positive samples in this study was lower than in the other survey results reported in Table 6.

**Table 6. Comparison of perchlorate levels in dairy products in the current FSAP survey with scientific literature and unpublished data from Health Canada**

| Study | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| CFIA | 2011-2013 | 233 | 140 (60) | 2 | 49 | 6 |
| FDA[14] | 2006 | 180 | 180 (100) | N/A | N/A | 5 |
| Health Canada[18] | 2006 | 110 | 110 (100) | 2.37 | 7.62 | 5.75 |
| Kirk[10] | 2003 | 7 | 7 (100) | 1.75 | 6.30 | 3.98 |
| Sanchez[15] | 2003-2006 | 41 | 41 (100) | 0.9 | 11.0 | 5.8 |

*N/A not available

## 3.5 Infant Formula

Eighty-seven samples of powdered, liquid ready-to-serve, and liquid concentrate infant formula (68 dairy-based and 19 soy-based) were analyzed in the 2011-2012 survey (3 domestic, 67 imported, 17 of unspecified origin). Taking into account the preparation directions on the concentrated products, it would be expected that the concentration of perchlorate in the product as consumed would be comparable to concentrations in ready-to-serve products. The levels of perchlorate found in infant formula samples in this survey were assessed by Health Canada's Bureau of Chemical Safety and were not expected to pose an unacceptable health risk.

Overall, 56% of infant formula samples analyzed contained detectable levels of perchlorate. Perchlorate levels found in infant formula samples ranged from 2 ppb to 35 ppb. Although, the maximum amount observed in soy-based formula (35 ppb) was similar to that found in dairy based formula (33 ppb), soy-based infant formula samples were found to contain a greater percentage of positive samples (13/18 samples or 72%) compared to dairy-based samples (36/68 or 53%). The average perchlorate level was also higher in soy-based infant formulas (19 ppb) than in dairy-based infant formulas (9 ppb).

**Table 7. Comparison of perchlorate levels in infant formula in the current FSAP surveys with the previous FSAP survey and scientific literature**

| Study | Year | Number of Samples | Number (%) of Positive Samples | Minimum (ppb) | Maximum (ppb) | Average (ppb) |
|---|---|---|---|---|---|---|
| **Dairy-Based Infant Formula** | | | | | | |
| CFIA | 2011-2012 | 68 | 36 (53) | - | 33 | 9 |
| | 2010-2011 | 74 | 43 (58) | 2 | 22 | 4 |
| Pearce[12] | 2007 | 14 | 14 (100) | 0.2 | 4.1 | 1.7 |
| Schier[11] | 2010 | 15 | 15 (100) | 0.68 | 5.05 | 1.72 |
| **Soy-Based Infant Formula** | | | | | | |
| CFIA | 2012-2013 | 18 | 13 (72) | - | 35 | 19 |
| | 2010-2011 | 15 | 13 (87) | - | 50 | 17 |
| Pearce[12] | 2007 | 3 | 3 (100) | 0.3 | 0.6 | 0.4 |
| Schier[11] | 2010 | 15 | 15 (100) | 0.10 | 0.44 | 0.21 |

Table 7 presents a comparison of the perchlorate levels in infant formulas in the current surveys with the previous FSAP survey and the scientific literature. The positive rate, maximum and average perchlorate levels are very similar to the previous FSAP survey results. There was no information in the scientific literature on the levels of perchlorate in powdered and liquid concentrate infant formula (as sold). However, some studies on perchlorate levels in infant formula as consumed have been published.

Results from this survey and those from the literature were not directly comparable because all of the samples in this survey were tested as sold and not necessarily as consumed. Ready-to-serve formulas require no preparation prior to consumption. For liquid concentrate formulas, the formula is typically mixed with an equal amount of water (dilution factor of 0.5). For powdered formulas, the specific manufacturer’s instructions vary but in general, one part infant powdered formula is mixed with 7 parts of water (dilution factor of 0.125)[19,20]. As expected, the ready-to serve formulas had the lowest average and maximum perchlorate levels, liquid concentrates had intermediate levels, and powdered formulas had the highest levels. When the manufacturer’s recommended preparation instructions are taken into consideration, the results from the survey samples were in good agreement with those reported in the literature[11,12]. However, the average perchlorate level for soy-based formula samples in the current survey was still higher than that for soy-based samples reported in other studies[11,12]. It is not known why the perchlorate levels were higher in soy-based formulas were higher than in diary-based formulas.

# 4. Conclusions

The 2011-2012 and 2012-2013 FSAP targeted surveys generated baseline surveillance data on the levels of perchlorate in fresh fruits and vegetables, fruits and vegetable juice, dairy-based products, and infant formulas available on the Canadian retail market. Overall, 23% of fruit and vegetable juice samples, 44% of fresh fruit, 56% of infant formula, 60% of dairy-based products, and 74% of fresh vegetable samples analyzed contained detectable levels of perchlorate; detected levels ranged from 2 ppb to 2400 ppb. The prevalence of perchlorate and the perchlorate levels in these surveys were generally comparable to those reported in the previous 2010-2011 CFIA survey, unpublished Health Canada data and the scientific literature.

As no Canadian regulations have been established for perchlorate in food, compliance with a numerical standard was not evaluated in this survey. All data generated were shared with Health Canada's Bureau of Chemical Safety for review and use in performing human health risk assessments. Health Canada determined that the levels of perchlorate in the subject surveys did not pose an unacceptable health concern and therefore no follow-up actions were needed.

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