

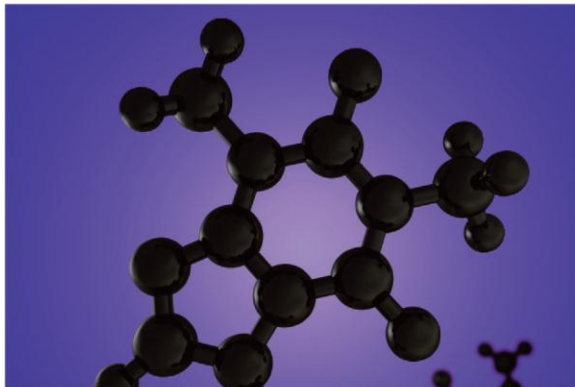


Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



***Perchlorate in Fresh Fruits and Vegetables, Dairy
Products and Infant Formulae***

Table of Contents

Executive Summary	2
1. Introduction.....	3
1.1 Food Safety Action Plan	3
1.2 Targeted Surveys	3
1.3 Acts and Regulations	4
2. Survey Details.....	4
2.1 Perchlorate	4
2.2 Rationale	5
2.3 Sample Distribution	5
2.4 Method Details.....	6
2.5 Limitations	7
3. Results and Discussion.....	7
3.1 Overview of Perchlorate Results	7
3.2 Fresh Fruits and Vegetables.....	9
3.3 Dairy Products	10
3.4 Infant Formula	11
4. Conclusions.....	12
5. References.....	13

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 test various foods for specific hazards.

The main objective of the perchlorate targeted survey was to generate baseline surveillance data on the levels of perchlorate in infant formulae, dairy products, and fresh fruits and vegetables available on the Canadian retail market.

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 originating from industrial processing of rocket propellants, explosives, road flares, fireworks, and car 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.

In total, 611 samples, including 433 fresh fruits and vegetables, 89 dairy products (milk, cheese and yogurt), and 89 infant formulae, were collected from Canadian retail stores and analyzed for perchlorate. 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.

Overall, 65% of fresh fruit and vegetable, 87% of dairy product, and 63% of infant formula samples analyzed were found to contain detectable levels of perchlorate in the range of 2 to 540 parts per billion (ppb). Within the commodity types analyzed in this survey, the highest average perchlorate levels were found in cucumbers (48.6 ppb) and tomatoes (44.9 ppb), cheese (5 ppb) and yogurt (4.9 ppb), and soy-based infant formula (16.7 ppb – tested as sold, not as consumed).

The perchlorate levels in dairy products and most fresh fruit and vegetable samples analyzed in this survey were consistent with those reported in the scientific literature. Average perchlorate levels detected in strawberry, cucumber, tomato, and infant formula samples were slightly higher than most of the levels reported in the scientific literature, although in some cases only limited data was available for comparison.

All data generated were shared with Health Canada for use in performing future human health risk assessments. The levels of perchlorate found in this survey were not expected to pose an unacceptable health concern. Additionally, the levels observed are not expected to represent a health concern over a lifetime exposure. No product recalls were warranted given the lack of health concern. As these contaminants are generally addressed under the principle of ALARA (As Low As Reasonably Achievable), appropriate follow-up actions such as notification of importer and continuation of the perchlorate targeted survey were initiated based on the results of this survey.

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 the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The Canadian Food Inspection Agency's (CFIA) Food Safety Action Plan (FSAP) is one element of the government's broader FCSAP initiative. The goal of the 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.

Within the FSAP there are 12 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. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are regulated solely by the *Food and Drugs Act* and *Regulations*, 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 in defined 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, 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 this targeted survey was to establish baseline data on perchlorate levels in infant formulae, dairy products (milk, cheese, and yogurt), and fresh fruits and vegetables, available at the Canadian retail level. The results of this survey were compared with ranges of perchlorate levels reported in 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 on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act and Regulations*.

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. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards. 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.

Although there is currently no enforceable national drinking water standard for perchlorate either in Canada or in the United States, various states have implemented guidelines for perchlorate in drinking water¹. Furthermore, in 2011, the US Environmental Protection Agency launched a process to propose a national drinking water regulation for perchlorate². In rare cases where perchlorate contamination of drinking water supplies in Canada has occurred, Health Canada recommends a drinking water guidance value of 6 parts per billion (ppb), based on a review of existing health risk assessments from other agencies¹.

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. 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 or formed in the atmosphere)³. It is also considered an environmental contaminant that is industrially produced and originates from the inappropriate storage or disposal of perchlorate used in the production of rocket propellants, explosives, road flares, fireworks, car airbags and some fertilizers^{4,5,6,7}.

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 as compared to the fruit or the seed part of several food crops. As such, it may also be transferred to animals (and their milk) through the consumption of perchlorate-contaminated feed or water⁸.

Human exposure to perchlorate occurs primarily through ingestion⁹. At sufficiently high doses, perchlorate can interfere with the uptake of iodide by the thyroid gland⁹. This can affect the production of thyroid hormones, which have a role in regulating many metabolic and developmental functions in humans⁹. Pregnant women and their unborn children, newborns and individuals with thyroid conditions or iodine deficiencies are the groups most sensitive to perchlorate exposure⁵.

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^{10,11,12}.

Perchlorate has been detected in dairy products^{7,12} related to the ingestion of perchlorate-contaminated water or feed by dairy cattle. Perchlorate has also been found in milk-based and soy-based infant formula^{13,14}. 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 generally greater food and water consumption relative to body weight⁵.

Given that fruits and vegetables, dairy products and infant formulae 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 this survey, a total of 611 samples were collected from grocery and specialty stores in 11 Canadian cities between July 2010 and March 2011. The samples included 433 fruit and vegetable samples, 89 dairy products (skim to homogenized and chocolate fluid milk, plain and flavoured yogurt, and soft to hard cheeses), and 89 infant formulae (dairy- and soy-based, powdered, ready-to-serve and concentrate). The general distribution of samples by product type is presented in Table 1.

Table 1. Distribution of samples by product type.

Product Type	Sample Type	Number of Samples
Infant Formula	Dairy-based	74
	Soy-based	15
Infant Formula Total		89
Dairy Products	Cheese	23
	Yogourt	24
	Milk	42
Dairy Products Total		89
Fresh Fruits and Vegetables	Cantaloupe	16
	Strawberry	19
	Cucumber	22
	Green Bean	23
	Orange	23
	Broccoli	24
	Celery	24
	Watermelon	24
	Grape	29
	Carrot	40
	Tomato	55
	Leafy Green*	134
	Fresh Fruits and Vegetables Total	
Total		611

*Leafy Green includes lettuce, arugula, cabbage, chicory, dandelion, radicchio, chard, collard greens, kale and spinach.

The 611 samples collected included 216 domestic products, 353 imported products (from 18 countries), and 42 samples of unverifiable origin for which country of origin could not be determined from the product label or sample information. It is important to note that the products sampled often contained the statement “processed in Country X”, “imported for Company A in Country Y” or “manufactured for Company B in Country Z”. Although the labelling is accurate, it does not unambiguously identify the origin of the product ingredients. Only those products labelled with a clear statement of “Product of Country A” were considered as being from a specific country of origin.

2.4 Method Details

Samples were analyzed for perchlorate by a laboratory under contract with the Government of Canada. Contracted laboratories are accredited to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories (or its equivalent) by the Standards Council of Canada. The laboratory was required to use analytical methods that met or exceeded the requirements and limits of detection of the equivalent CFIA method. 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 to 1.25 ppb, depending on the food, and a limit of quantitation (LOQ) of 2 ppb.

All samples, including infant formulae, were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable). For infant formula samples found to contain perchlorate, the approximate preparation (dilution) factors were applied as per the manufacturer's instructions to enable a more appropriate comparison with published "as consumed" infant formula data.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of perchlorate in fresh fruits and vegetables, dairy products and infant formulae 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. Country of origin was assigned for all but 42 samples based on accompanying sample documentation or as indicated on the label. 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 Results

The 2010-2011 perchlorate targeted survey consisted of testing 611 samples obtained from Canadian retail. A summary of the percentage of survey samples with perchlorate detected is presented in Figure 1. Eighty percent or more of the leafy green, cucumber, orange, soy-based infant formula, milk, and yogurt samples tested had detectable levels of perchlorate.

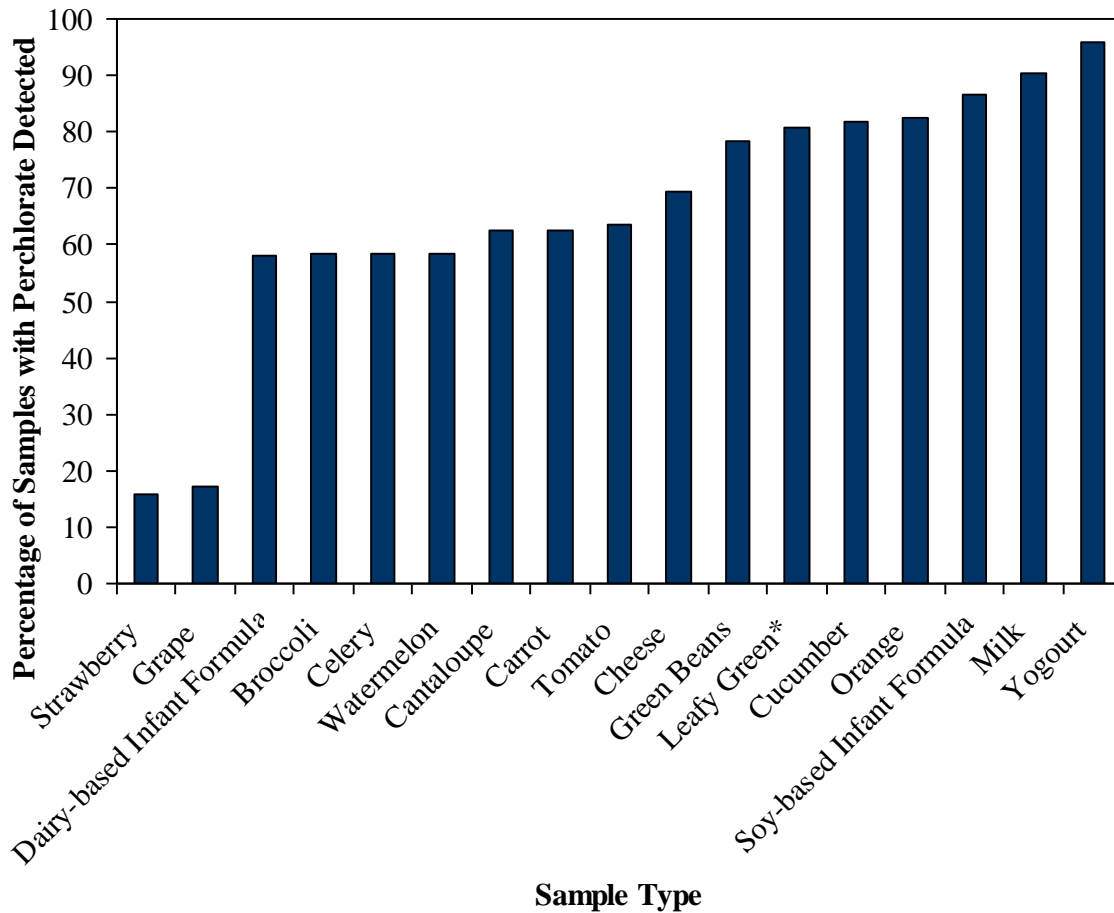


Figure 1. Summary of percentage of samples with perchlorate detected (arranged in increasing order).

*Leafy Green includes lettuce, arugula, cabbage, chicory, dandelion, radicchio, chard, collard greens, kale and spinach.

The distribution of average perchlorate levels among sample types tested in this survey is presented in Figure 2. Cucumbers (48.6 ppb) and tomatoes (44.9 ppb) had the highest and cantaloupe (2.2 ppb) and celery (2.5 ppb) had the lowest average perchlorate levels in this survey. It is important to note that the number of samples for each sample type varied considerably from 15 soy-based infant formula samples to 134 leafy green samples (see Table 1). On average, fresh fruit and vegetable samples analyzed in this survey contained the highest average perchlorate level (20 ppb), followed by infant formulae (6.6 ppb) and dairy products (4.8 ppb).

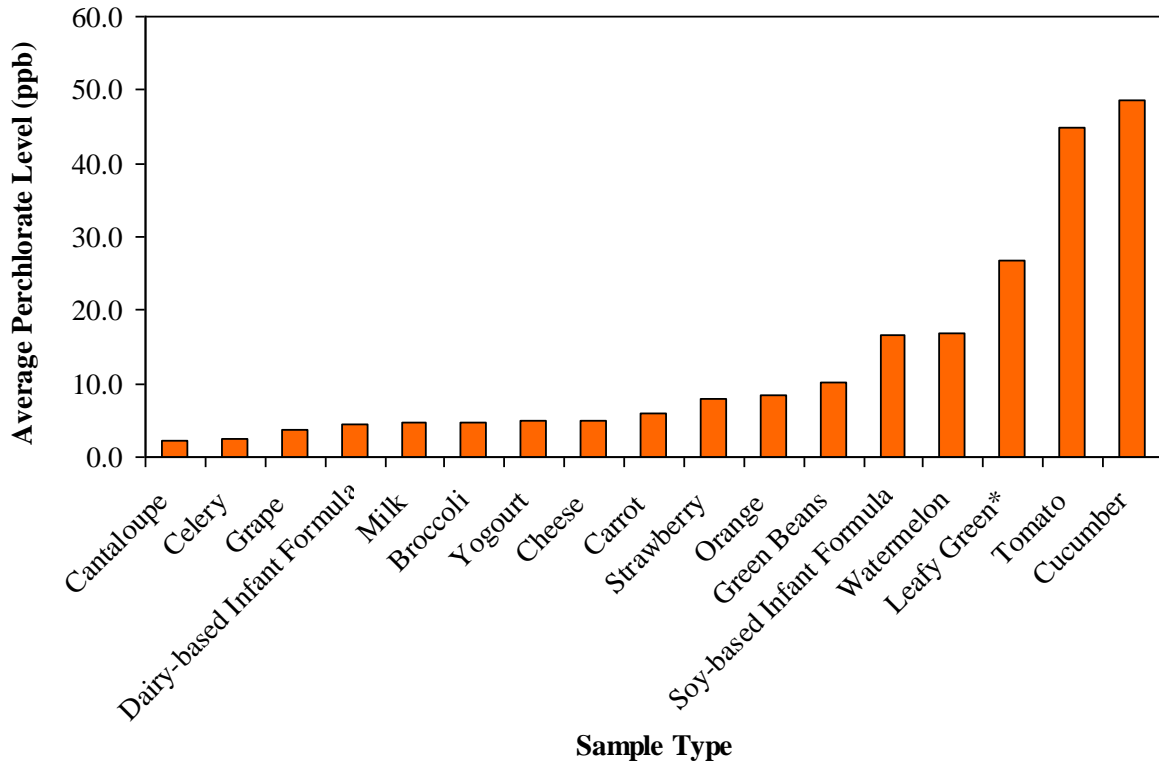


Figure 2. Distribution of average perchlorate levels (arranged in increasing average perchlorate level).

*Leafy Green includes lettuce, arugula, cabbage, chicory, dandelion, radicchio, chard, collard greens, kale and spinach.

More detailed results by product type are presented in the following sections.

3.2 Fresh Fruits and Vegetables

In this survey, 433 fresh fruit and vegetable samples (146 domestic, 285 imported, 2 of unverifiable origin) were analyzed. In general, 65% of fresh fruit and vegetable samples analyzed were found to contain detectable levels of perchlorate (i.e., positive) (Table 2). Oranges (83%), cucumbers (82%), and leafy greens (81%) were the sample types with the greatest percentage of positive samples (Table 2). Perchlorate levels in fresh fruit and vegetable samples in this survey ranged from not detected (in all types of fruit and vegetable) to 540 ppb in leafy greens (kale), with the highest average levels found in cucumbers (48.6 ppb) and tomatoes (44.9 ppb) (Table 2).

Table 2. Summary of minimum, maximum and average perchlorate levels found in fresh fruit and vegetable samples (arranged in increasing average perchlorate level).

Sample Type	Number of Samples	Number of Positive Samples	Percentage of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Cantaloupe	16	10	63	ND	7.0	2.2
Celery	24	14	58	ND	11.0	2.5
Grape	29	5	17	ND	40.0	3.8
Broccoli	24	14	58	ND	49.0	4.8
Carrot	40	25	63	ND	72.0	6.1
Strawberry	19	3	16	ND	87.0	7.9
Orange	23	19	83	ND	72.0	8.5
Green Beans	23	18	78	ND	120.0	10.1
Watermelon	24	14	58	ND	110.0	16.8
Leafy Green*	134	108	81	ND	540.0	26.7
Tomato	55	35	64	ND	360.0	44.9
Cucumber	22	18	82	ND	430.0	48.6

ND = not detected

*Leafy Green includes lettuce, arugula, cabbage, chicory, dandelion, radicchio, chard, collard greens, kale and spinach.

Average perchlorate levels in the current survey were in good agreement with those reported in the literature for cantaloupe, carrots, oranges, grapes, broccoli, celery, green beans, watermelon, dark leafy greens and lettuce (including other leafy greens)^{5,11,15,16}.

As noted in other studies, the perchlorate levels for cucumbers and tomatoes showed considerable variability^{5,11}. Similar results were observed in this survey, where perchlorate levels for tomatoes and cucumbers were in agreement with some levels reported in the literature but not consistent across studies^{5,8,11,15}. While the range of perchlorate levels for strawberry samples tested in this survey was higher than that reported by the U.S. Food and Drug Administration (not detected to 11.3 ppb, 19 samples)¹⁵, only three of the 19 samples tested in this survey contained perchlorate and there was limited data available for comparison. 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^{5,7,11}. The levels of perchlorate found in fresh fruit and vegetable samples in this survey were not expected to pose an unacceptable health risk.

3.3 Dairy Products

Eighty-nine samples of dairy products (42 domestic fluid milk, 24 domestic yogurt and 23 cheese samples (4 domestic, 19 imported)) were analyzed in this survey. Fluid milk included skim to homogenized and chocolate milk, yogurt included plain and flavoured yogurt, and cheese included a range of soft to hard cheeses. Overall, 87% of dairy

product samples analyzed were found to contain detectable levels of perchlorate (i.e., positive). Perchlorate levels in dairy samples in this survey ranged from not detected to 24 ppb (Table 3). Average perchlorate levels in this survey were similar for milk, yogurt, and cheese. The high rate of detection of perchlorate in dairy 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.

Table 3. Summary of minimum, maximum and average perchlorate levels found in dairy product samples (arranged in increasing average perchlorate level).

Sample Type	Number of Samples	Number of Positive Samples	Percentage of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Milk	42	38	90	ND	9.0	4.6
Yogourt	24	23	96	ND	12.0	4.9
Cheese	23	16	70	ND	24.0	5.0

ND = not detected

The average perchlorate levels found in the dairy samples in this survey were similar to those reported for milk in the scientific literature and unpublished data from Health Canada^{5,12,16}. The levels of perchlorate found in dairy products in this survey were not expected to pose an unacceptable health risk.

3.4 Infant Formula

Eighty-nine samples of imported powdered, liquid, and concentrate infant formula (74 dairy-based and 15 soy-based) were analyzed in this survey. Overall, 63% of infant formula samples analyzed were found to contain detectable levels of perchlorate (i.e., positive). Perchlorate levels in infant formula samples in this survey ranged from not detected (in both dairy-based and soy-based) to 50 ppb (in soy-based) (Table 4). The highest average level was detected in soy-based infant formula (16.7 ppb) (Table 4). Soy-based infant formula samples were found to contain a greater percentage of positive samples (87%) compared to dairy-based samples (58%), although the number of samples analyzed was much smaller.

Table 4. Summary of minimum, maximum and average perchlorate levels found in infant formula samples, tested “as sold” (arranged in increasing average perchlorate level).

Sample Type	Number of Samples	Number of Positive Samples	Percentage of Positive Samples	Minimum (ppb)	Maximum (ppb)	Average (ppb)
Dairy-based	74	43	58	ND	22.0	4.5
Soy-based	15	13	87	ND	50.0	16.7

ND = not detected

A limited number of studies have reported on the levels of perchlorate in liquid (0.2 to 4.1 ppb)¹⁴ and reconstituted powdered dairy-based, soy-based and elemental (0.03 to 5.05 ppb)¹³ infant formula. Results from this survey and those from the literature are not directly comparable given that the samples in this survey were tested as sold and not necessarily as consumed. For a more relevant comparison of the current survey data to the ready-to-consume data in the published studies^{13,14}, the approximate preparation (dilution) factors, as per the manufacturer's instructions, were applied to survey samples with detected levels of perchlorate. When dilution factors were applied, average perchlorate levels for all samples in the current survey were in good agreement or only slightly higher than those reported in the literature^{13,14}. 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^{13,14}. The levels of perchlorate found in infant formula samples in this survey were not expected to pose an unacceptable health risk.

4. Conclusions

The present survey generated baseline surveillance data on the levels of perchlorate in fresh fruits and vegetables, dairy products and infant formulae available on the Canadian retail market. As no Canadian regulations have been established for perchlorate in food, compliance with a numerical standard was not evaluated in this survey.

Overall, 65% of fresh fruit and vegetable, 87% of dairy product and 63% of infant formula samples analyzed were found to contain detectable levels of perchlorate. On average, fresh fruit and vegetable samples analyzed in this survey contained the highest average perchlorate level (20 ppb), followed by infant formula (6.6 ppb) and dairy products (4.8 ppb). Within the commodity types analyzed in this survey, the highest average perchlorate levels were found in cucumbers (48.6 ppb) and tomatoes (44.9 ppb), cheese (5.0 ppb) and yogurt (4.9 ppb), and soy-based infant formulae (16.7 ppb, tested as sold, not as consumed).

The perchlorate levels in dairy products and most fresh fruit and vegetable samples analyzed in this survey were consistent with those reported in the scientific literature. Average perchlorate levels detected in strawberry, cucumber, tomato and infant formula samples were slightly higher than most of the levels reported in the scientific literature, although in some cases only limited data was available for comparison.

All data generated were shared with Health Canada for use in performing future human health risk assessments. The levels of perchlorate found in this survey were not expected to pose an unacceptable health concern. Additionally, the levels observed are not expected to represent a health concern over a lifetime exposure. No product recalls were warranted given the lack of health concern. As these contaminants are generally addressed under the principle of ALARA (As Low As Reasonably Achievable), appropriate follow-up actions such as notification of importer and continuation of the perchlorate targeted survey were initiated based on the results of this survey.

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