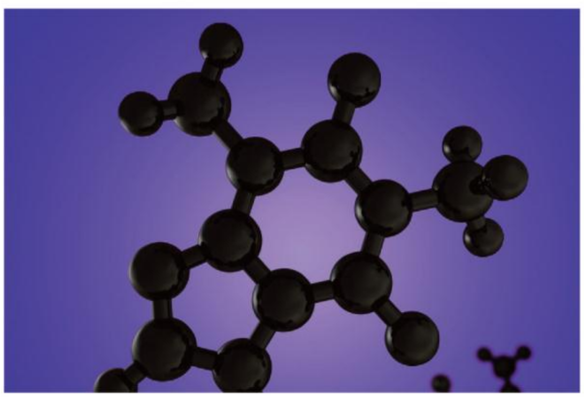
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Antimony in Juice and Bottled Water

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 test various foods for specific hazards.

The main objective of the antimony in juice and bottled water targeted survey was to generate baseline surveillance data on the levels of antimony in domestic and imported juice and bottled water available on the Canadian retail market.

Antimony is a naturally occurring metal and its levels in the environment have risen due to increased industrial uses. Since antimony is not known to fulfill a biological role in the human body, there is growing concern about its effects on humans[1]. Currently, no Canadian regulations exist for antimony in food although there is a Canadian drinking water quality guideline for antimony of 0.006 parts per million (ppm)[2]. Antimony trioxide, used in the manufacturing of polyethylene terephthalate (PET) plastic, is a suspected human carcinogen[3]. Previous studies have reported the leaching of antimony from packaging, particularly PET, into the food or beverage product.

In total, 359 samples (185 juices and 174 bottled waters) were collected from Canadian retail stores and analyzed for antimony. Eight of the 185 juice samples had detectable levels of antimony ranging from 0.0038 to 0.0572 ppm. Only one of the 174 bottled water samples had a detectable level of antimony at 0.0031 ppm. Given the documented leaching of antimony from PET plastic packaging materials in particular, the type of packaging (i.e., glass, plastic, metal can, Tetra Pak and cardboard (frozen)) was recorded for all samples. Detectable levels of antimony were found in juice samples packaged in glass, metal can, Tetra Pak and cardboard, while the bottled water sample was in plastic. This survey cannot distinguish between antimony originating from natural sources, environmental contamination and/or leaching from packaging materials.

All data generated were shared with Health Canada for use in performing human health risk assessments. The levels found were not considered to pose a concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the health concern.

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 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 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 (FSSC), a group of federal, provincial and territorial subject matter experts in the area of food safety.

The CFIA regularly monitors metal analytes, including antimony, in a variety of processed products under the National Chemical Residue Monitoring Program (NCRMP) and Children's Food Project. Targeted surveys focus mainly on products not monitored under these two programs. The purpose of this targeted survey was to establish baseline data on antimony levels in juices (ready-to-drink and concentrates) and bottled water in a range of packaging types, including plastic, glass bottles, Tetra-Pak, cardboard and cans, available at the Canadian retail level. The scope of this survey is complementary to

NCRMP and Children's Food Project monitoring of metals in processed products in that it includes additional commodities (i.e., juice types and bottled water) not routinely monitored. The antimony levels observed in juice sampled in this survey were compared with previous NCRMP and Children's Food Project data, as well as the 2008-2009 FSAP targeted survey on fruit juice concentrates[4].

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. Currently, no Canadian regulations exist for antimony levels in food although there is a Canadian drinking water quality guideline for antimony of 0.006 parts per million (ppm) (6 parts per billion (ppb))[2]. In addition, the *Food and Drug Regulations* specify that antimony cannot be present in titanium dioxide (an approved food additive that can be used as a colouring agent) at concentrations exceeding 50 ppm. Compliance with Canadian regulations was not evaluated for all samples in this survey as no maximum levels exist for antimony in food.

Internationally, a number of maximum levels have been established for antimony in water. The European Commission has set a maximum limit of 5 ppb antimony in natural mineral waters[5] and the United States has a maximum contaminant level for antimony in drinking water of 6 ppb[6]. The World Health Organization has set a 20 ppb guideline value for antimony in drinking water[7].

Food and beverages may also be exposed to antimony as a result of its use in the production of some food packaging materials. Antimony trioxide, used in the manufacturing of polyethylene terephthalate (PET) plastic, is classified by the International Agency for Research on Cancer as possibly carcinogenic to humans[3]. The European Food Safety Authority has evaluated antimony trioxide and established a restriction on the level of antimony in food contact materials (e.g., PET plastic) at 0.04 mg/kg of food[8].

Elevated levels of antimony 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 Antimony

Antimony is a naturally occurring metal and its levels in the environment have risen due to increased industrial uses (e.g., flame retardants, batteries, pigments and ceramics/glass)[3,6]. Since antimony is not known to fulfill a biological role in the human body there is growing concern about its effects on humans[1]. Antimony can cause acute health effects such as nausea, vomiting and diarrhea and chronic exposure can lead to increased blood cholesterol and decreased blood sugar[9], as well as possible carcinogenic effects[3].

Dietary exposure to antimony may primarily be from the consumption of food products packaged with PET plastic materials. As mentioned above, antimony is widely used in the production of PET. Trace amounts of antimony are known to remain in the material and previous studies have reported that antimony leaches into bottled water and juice products from PET-based packaging[10,11,12]. A study comparing antimony levels in PET-based bottled water both before and after packaging found that average antimony levels were over ten times higher in bottled water than those in the source water[13].

Results of a survey conducted in Europe found that 19% of the juices analyzed contained antimony levels that exceeded the European drinking water guideline. The observed levels were attributed to leaching from the packaging material, antimony being present in the juice prior to packaging or a combination of the two[10]. Other studies have observed elevated leaching of antimony in juices and carbonated waters and some have attributed it to their acidic nature[9,10]. Other factors reported to affect the extent of leaching of antimony from the bottle into food were storage temperature and duration, sunlight exposure, as well as bottle quality (level of reuse) and the bottle size[9,14].

2.2 Rationale

According to Statistics Canada data from 2009, approximately 23.5 L of fruit juice is available for consumption per Canadian per year[15]. Fruit juices are highly consumed by toddlers (one to three years of age) at 168-200 grams fruit juice per day, or nearly three times the average consumption[16]. Bottled water is consumed by all age groups in Canada.

In 2006, 29% of Canadian households drank primarily bottled water as opposed to tap water[17]. The per capita annual consumption of bottled water in Canada was 66 L, and that volume had been steadily increasing over the last decade[18].

Given the high consumption of these beverages by Canadians, this targeted survey was designed to establish baseline data on antimony levels in juice and bottled water available to Canadians. It also enabled some comparison of antimony levels in juice with previous CFIA monitoring data. All data was shared with Health Canada for use in conducting human health risk assessments of antimony.

2.3 Sample Distribution

In this survey, a total of 359 samples of juice and bottled water were collected from grocery and specialty stores in four Canadian cities between October 2010 and March 2011. The samples included 185 juice and 174 bottled waters in various packaging types (i.e., glass, metal can, cardboard (frozen), plastic and Tetra Pak). The distribution of samples by packaging type is presented in Figure 1. As the specific type of plastic packaging (e.g., PET) was not recorded for each sample, all plastic containers were categorized together.

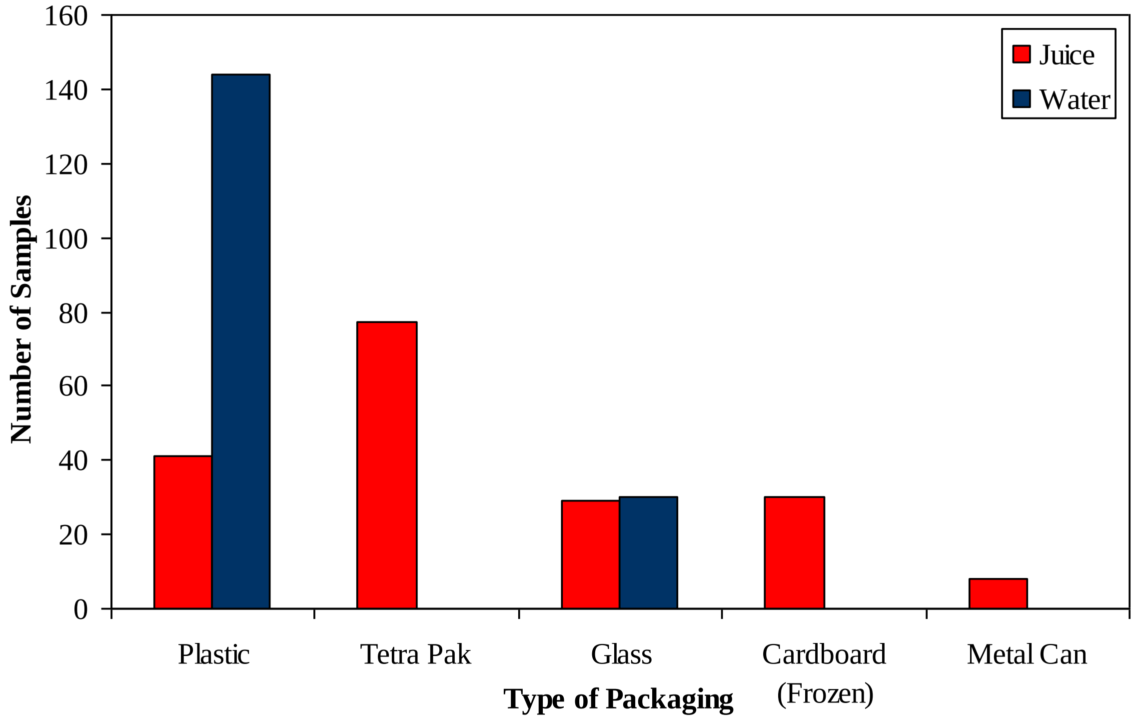
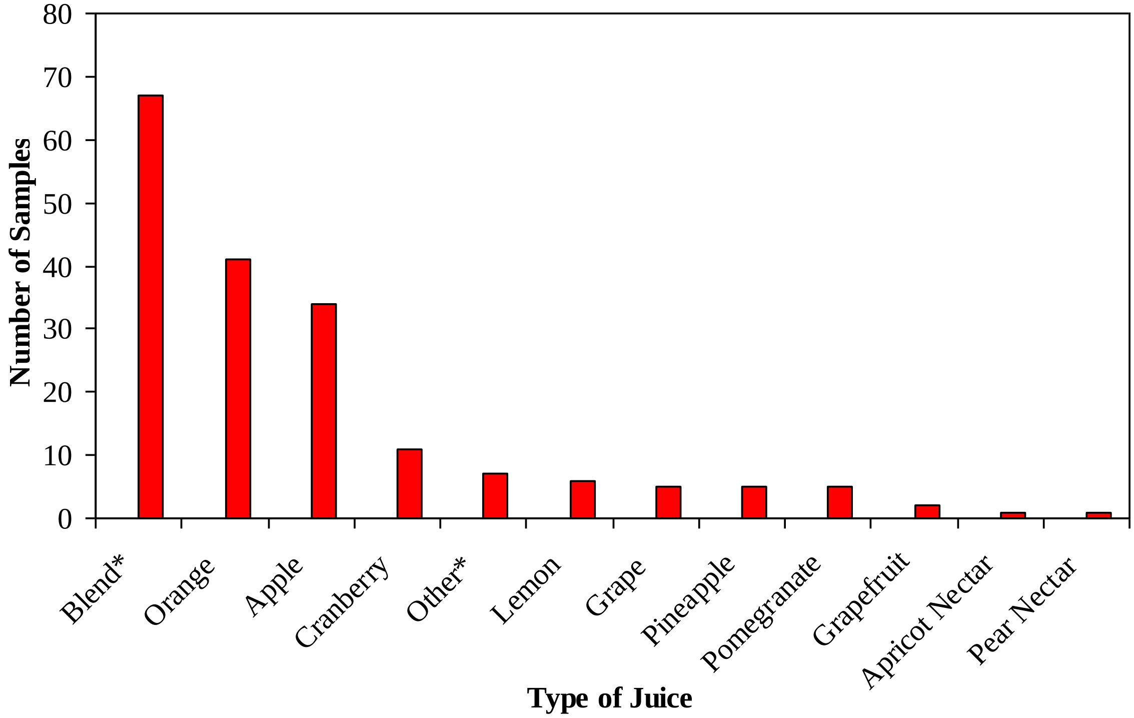


Figure 1. Distribution of juice and bottled water samples by packaging type.

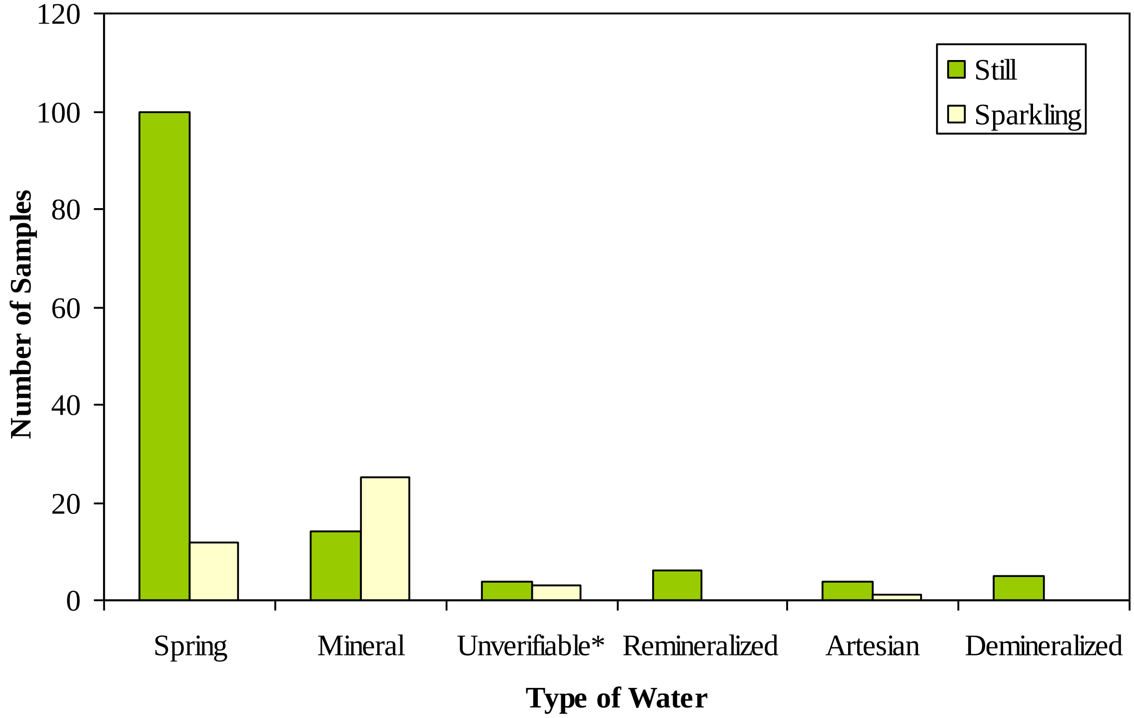
The distribution of juice samples by type is shown in Figure 2. Juice samples included pure fruit juices, drinks and cocktails.



* Blend refers to juice derived from a mixture of fruits. Other refers to other single fruit juices (e.g., blueberry).

Figure 2. Distribution of juice samples by type.

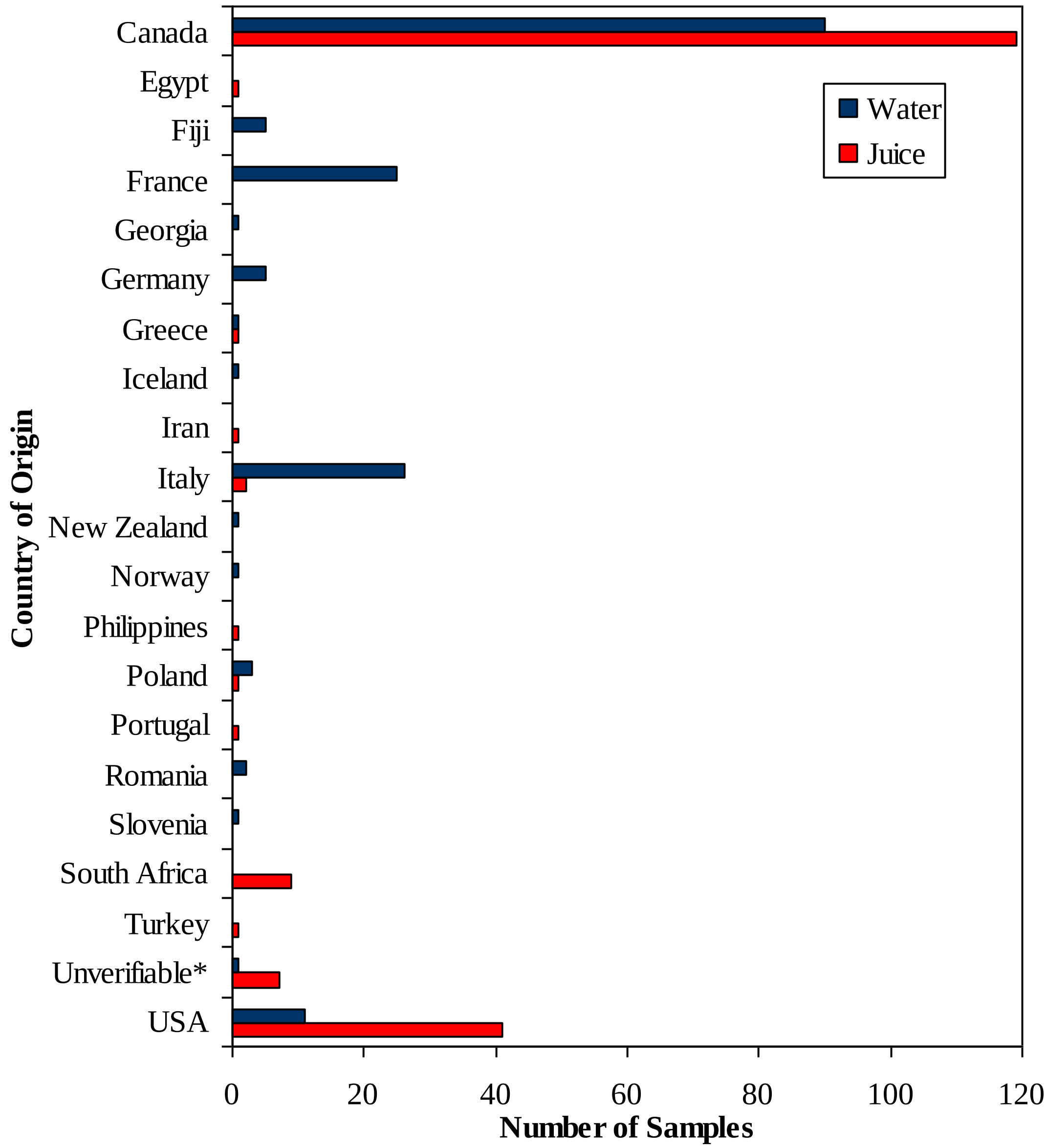
A total of 174 bottled water samples were collected and analyzed, including sparkling and still, flavoured and unflavoured spring and mineral, artesian, purified (i.e., demineralized and remineralized) and water of unverifiable type. The distribution of water samples by type is shown in Figure 3.



* Unverifiable refers to samples for which type of water (e.g., mineral, spring) could not be determined based on the label or sample description. Four of the seven unverifiable water samples were flavoured.

Figure 3. Distribution of water samples by type.

The distribution of juice and bottled water samples by country of origin (as recorded by the sampler or indicated on the label) is presented in Figure 4 to provide a general sense of the origin of products sampled. It is important to note, however, that some of the samples considered imported or as originating in Canada may include, for example, products prepared for a Canadian company without further clarification of the country of origin. Determination of country of origin is further complicated by the fact that ingredients are often sourced from different countries. Samples originated from at least 20 countries. The majority of juice samples were of domestic and US origin while the bottled water samples were primarily from Canada, France and Italy.



*Unverifiable refers to those samples for which country of origin could not be determined from the label or sample information.

Figure 4. Distribution of juice and bottled water samples by country of origin.

2.4 Method Details

Juice and bottled water samples in the antimony targeted survey were analyzed for metals 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 used microwave digestion and inductively coupled plasma mass spectroscopy to analyze and confirm metal residues in the samples. While the focus of this survey was antimony, the method also analyzed for 19 other metals. The method has a limit of detection (LOD) for antimony of 0.003 ppm and a limit of quantitation (LOQ) of 0.01 ppm.

2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of antimony in juice and bottled water in various packaging types available for sale in Canada and had the potential to highlight commodities that warranted further investigation. This survey cannot distinguish between antimony originating from natural sources, environmental contamination and/or leaching from packaging materials. In addition, the level of antimony in the packaging material cannot be analyzed with the validated method. 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. Country of origin was assigned for all but eight samples (designated "Unverifiable" in Figure 4) based on information provided by the sampler or indicated on the label.

3. Results and Discussion

The levels of antimony detected in samples in this survey are presented and discussed below. The results of the 19 other metals tested in this survey will not be presented or discussed.

As presented in Figure 4, most of the juice samples (119 of 185) were of domestic origin. Only eight juice samples (4%) contained detectable levels of antimony (Table 1). Antimony levels detected in juice samples in this survey ranged from 0.0038 ppm to 0.0572 ppm.

Table 1. Summary of antimony levels detected in juice and bottled water samples.

Type of Packaging	Commodity	Level of Antimony (ppm)
Glass	Grape Juice	0.0572
Metal Can	Pineapple Juice	0.0551
Tetra Pak	Orange Juice	0.0415
	Juice Blend	0.014
	Pineapple Juice	0.0063
	Juice Blend	0.0058
	Juice Blend	0.0042
Cardboard (Frozen)	Orange Juice Concentrate	0.0038
Plastic	Flavoured Spring Water	0.0031

Antimony levels found were considered in terms of the packaging type and type of juice. The samples in which antimony was detected were as follows, listed in order of decreasing concentration: grape juice packaged in glass; pineapple juice in a metal can; orange juice; pineapple juice and three juice blends in Tetra Pak packaging; and frozen orange juice concentrate in cardboard packaging. It has been proposed that the citric acid present in some juices helps to extract antimony from packaging[10], which may partly account for the higher levels found in some juices compared to water in this survey. Antimony may also be used in the manufacture of glass[13] and the leaching of antimony from glass containers has been documented[19]. It should be noted that other samples of juice/packaging combinations identical to those in which antimony was found (e.g. orange juice in Tetra Pak) did not have detectable levels of antimony.

The antimony levels measured in five of the juice samples in the current survey were higher than the Canadian drinking water guideline of 6 ppb (0.006 ppm) as well as levels reported in the scientific literature for bottled beverages[20]. Comparison with the drinking water guideline is not directly relevant given the different consumption patterns of water and juice; however, it is included as a point of reference. The antimony observed in these samples may be due to the juice or water itself, leaching from the packaging, exposure to antimony prior to bottling, or a variety of other factors (production process, storage conditions, acidity of the juice, etc.).

Of the 174 bottled water samples collected and analyzed (30 packaged in glass and 144 in plastic), only one bottled water sample (flavoured spring water in plastic) contained detectable levels of antimony (Table 1). However, the level of antimony detected was below the Canadian drinking water guideline.

Results of the present survey were compared with those of the 2008-2009 FSAP targeted survey on metals in fruit juice concentrates[4]. Of the 186 samples analyzed in the 2008-2009 survey, nine had detectable levels of antimony ranging from 0.034 ppm to 0.239 ppm. Six of these juice concentrate samples were grape, two were cranberry and one was lemon. The highest level observed was in a grape juice concentrate sample. It is important to note that the levels detected represented the concentrated product rather than the diluted form, which would be consumed. Taking into account approximate dilution factors, the two highest antimony levels observed in the current survey are similar to those reported for the juice concentrate samples analyzed in 2008-2009.

The positive samples in the current survey had higher levels of antimony than the majority of juices analyzed for metals under the NCRMP (2009-2010) and the Children's Food Project (2009 to 2011). Nine of 67 ready-to-serve juices analyzed under the Children's Food Project contained detectable levels of antimony below the Canadian drinking water guideline. Only one (lemon juice) sample of 19 juice samples tested under the NCRMP had a detectable level of antimony at 0.04 ppm.

4. Conclusions

The present survey generated baseline surveillance data on the levels of antimony in domestic and imported juice and bottled water, in a variety of packaging types, available on the Canadian retail market. No Canadian maximum levels have been established for antimony in food although there is a Canadian drinking water quality guideline for antimony.

In total, eight of the 185 juice and one of the 174 bottled water samples had detectable levels of antimony. Five of the eight juice samples contained levels of antimony (0.0063 ppm to 0.0572 ppm) above the Canadian drinking water guideline of 0.006 ppm. The samples with the highest detectable levels of antimony were packaged in glass, metal can and Tetra Pak. Lower levels of antimony were also detected in single samples packaged in cardboard (frozen) and plastic.

Overall, the levels of antimony detected in several juice samples analyzed in this survey were higher than those reported in the scientific literature. This may, in part, be due to contamination of the product prior to bottling, introduction during production, specific type of packaging, storage conditions, acidity of the juice, etc.

All data generated were shared with Health Canada for use in performing human health risk assessments. The levels found were not considered to pose a concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the health concern.

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