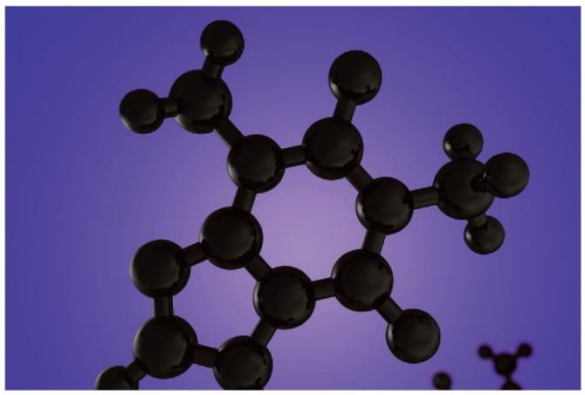
Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

# Food Safety Action Plan

## REPORT

2012-2014 Targeted Surveys

Chemistry



## *Antimony in Selected Foods*

Canada

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# Executive Summary

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

The main objectives of this targeted survey were to generate additional baseline surveillance data on the level of antimony in beverages, nut and seed butters, condiments, frozen/shelf-stable heat-and-serve meals, and processed fruit and vegetable products available on the Canadian retail market, and to compare the prevalence and levels of antimony to previous CFIA (FSAP, NCRMP and Children's Food Project) reports.

Antimony is a metal that can be found naturally in the earth's crust and is used widely in a variety of manufacturing processes including production of alloys, batteries, as fire retardants in plastics and textiles, as well as in paints and ceramics, and as enamels for plastics, metals and glass[1]. Specific to the food industry, antimony trioxide is used as a catalyst in the manufacturing of polyethylene terephthalate (PET) plastic. Based on inhalation studies in animals, antimony trioxide has been classified as a "possible human carcinogen" by the International Agency for Research on Cancer; however, there is insufficient scientific data to determine the potential carcinogenicity of antimony compounds by the oral route of exposure. Scientific studies have reported the migration of antimony from packaging, particularly PET plastic, into food or beverage products. Since antimony is not known to fulfill a biological role in the human body, there has been growing concern about the level of antimony exposure to humans from food packaging sources.

The 2012-2014 antimony survey focused on domestic and imported beverages, nut and seed butters, condiments, frozen/shelf-stable heat-and-serve meals, and processed fruits and vegetable products. A total of 1208 samples were collected from grocery and specialty stores in eleven Canadian cities between April 2012 and March 2014. The samples collected were packaged in various materials (i.e., plastic, glass, metal can, and Tetra Pak).

Currently, no maximum level, tolerance, or standard has been established by Health Canada for antimony in food. None of the samples analyzed in this survey were found to contain a detectable level of antimony. The results of this survey and previously published CFIA results indicates that antimony is rarely found in foods and when found, the levels are very low.

Given that none of the samples analyzed in this survey were positive for antimony, follow-up actions were not required.

# 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 preventive measures, and that there is a rapid response when/if these measures fail.

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.

Within the current regulatory framework, some commodities (such as meat products) traded internationally and interprovincially are regulated by specific Acts. These are referred to as federally registered commodities. 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. Targeted surveys are primarily directed towards non-federally registered commodities.

## 1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the possible occurrence of chemical residues, 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, a group of federal, provincial, and territorial subject matter experts in the area of food safety.

The CFIA regularly monitors a variety of metals, including antimony, in federally regulated commodities under the National Chemical Residue Monitoring Program (NCRMP) and the Children's Food Project (CFP). The scope of this survey is complementary to the NCRMP and CFP in that it includes additional commodities (beverages, ready-to-eat meals, nut and seed butters and condiments) not routinely monitored under those programs.

## 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 standards for chemical residues and contaminants in food sold in Canada. Certain standards for chemical contaminants in food appear in the Canadian Food and Drug Regulations (FDR), 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, which are available on Health Canada's website.

Currently in Canada, no maximum level, tolerance, or standard exists for antimony levels in food. There is a Canadian drinking water quality guideline for antimony of 0.006 parts per million (ppm)[2], and as well the standard for the permitted food colouring agent titanium dioxide, set out in section B.06.033 of the Food and Drug Regulations, specifies a limit on the amount of antimony (50 ppm) permitted in this colour.

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 a health concern. Actions may include further analysis, notification to the producer and importer, follow-up inspections, additional direct sampling, and recall of products.

# 2. Survey Details

## 2.1 Antimony

Antimony is a metal that is found in the earth's crust at low levels, and generally in combination with other elements. Antimony is used in the production of electronics, flame retardant materials, paint pigments, ceramic enamels, plastics, glass and pottery[2]. Antimony alloys are used in the manufacture of batteries, cable sheathing, plumbing solder, as well as in other industrial applications[2].

Antimony exposure at high levels can cause acute health effects such as abdominal pain, nausea, vomiting and diarrhoea[2]. Chronic inhalation exposure to antimony is associated with respiratory effects (e.g., inflammation of lungs, chronic bronchitis/ emphysema) and cardiovascular effects (e.g., increased blood pressure, heart muscle damage)[3]. In animal studies, long-term oral exposure to antimony potassium tartrate can lead to increased blood cholesterol and decreased blood sugar[4]. Based on inhalation studies in animals antimony trioxide has been classified as a possible human carcinogen by the International Agency for Research on Cancer[5], however there is insufficient scientific data to determine the potential carcinogenicity of antimony compounds by the oral route of exposure. Dietary exposure to antimony may come from the consumption of food products packaged with PET plastic materials. PET is a polymer widely used for the production of food packaging and films. As previously mentioned, antimony is sometimes used in the production of PET. Trace amounts of antimony are known to remain in the PET material, and studies have reported that antimony may migrate into bottled water and juice products from PET-based packaging[6,7,8]. One academic study compared antimony levels in PET-based bottled water as well as in source water from the same region where the bottled waters originated. They reported that there was a noted difference in the concentrations of antimony observed in the water bottled in PET in comparison to the source water[9].

Results of a survey conducted in Europe found that 19% of the juices analyzed contained antimony levels that exceeded the European drinking water guideline[6]. 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[6]. Studies have reported elevated migration of antimony from packaging in juices and carbonated waters, and some have attributed the elevated antimony level to the acidic nature of the beverage[7]. Other factors reported to affect the extent of leaching of antimony from the PET bottle into food were storage temperature and duration, sunlight exposure, acidity or alkalinity, as well as bottle quality (level of reuse) and the bottle size[7,8,9].

Antimony is classified as a priority pollutant/contaminant by the US Environmental Protection Agency (EPA)[10], and the European Commission (EC) has set a maximum concentration limit of 0.0050 ppm for natural mineral waters[11]. 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 bottles) at 0.04 ppm of food[12].

## 2.2 Rationale

Based on the findings of elevated levels of antimony in juices in Europe and given the lack of Canadian specific data on levels of antimony in foods packaged in PET containers, a survey examining these specific commodities was considered timely. Beverages (i.e. bottled water, juices, sports drinks, and soft drinks), nut and seed butters, condiments, frozen/ shelf-stable ready-to-eat meals, and processed fruit and vegetable products were targeted in this survey, as these products are highly consumed by Canadians of all ages and are often packaged in PET plastics, which is a known source of antimony.

There have been two previous FSAP targeted surveys that focused on antimony in selected foods[13,14]. This survey was designed with an extended range and amount of commodities (wider variety of beverages, condiments, and processed fruits and vegetable products). The data gathered was shared with Health Canada for use in conducting human health risk assessments.

## 2.3 Sample Distribution

A total of 1208 samples were collected from grocery and specialty stores in eleven Canadian cities between April 2012 and March 2014. Survey samples collected included 591 beverages, 190 condiments, 176 frozen and shelf-stable meals, 169 nut and seed butters, and 82 processed fruit and vegetable products (see details in Table 1).

The sum of the survey samples included 255 domestic products, 421 imported products (from 30 different countries), and 532 products of unspecified origin. In general, an unspecified country of origin refers to those samples for which the 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 “imported for Company A in Country Y” or “manufactured for Company B in Country Z”, and though the labeling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labeled 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.

**Table 1. Detailed description of product types and associated samples collected in the 2012-14 Antimony Survey**

| Product Type | Sample Type | Number of Samples | Details |
|---|---|---|---|
| **Beverages** | Juices | 250 | Apple, orange, cranberry, grape, blueberry, tomato, lemon, lime, prune, pomegranate, peach, grapefruit, carrot, vegetable blend, fruit blend, cocktails, drinks, nectars and smoothies |
| | Soft Drinks | 117 | Cola, lemon/lime, ginger-ale, orange, grapefruit and other soda flavours etc. |
| | Sports Drinks | 118 | Energy drinks, electrolyte and vitamin beverages |
| | Bottled Waters | 106 | Mineral/spring, carbonated or still, flavoured, any other type of water (demineralized, artesian etc.) |
| **Nut and Seed Butters** | Nut Butters | 132 | Peanut, almond, cashew, soy |
| | Seed Butters | 37 | Tahini and sunflower seed butter |
| **Ready-To-Eat (RTE) Meals** | Pre-packaged/Heat and Serve Meals | 126 | Frozen "TV" dinners, vegetarian meals, soup |
| | Toddler/Baby Meals | 50 | Frozen and shelf-stable toddler meals |
| **Condiments** | Condiments, and Sauces | 190 | Mayonnaise, mustard, relish, soy sauce, steak/BBQ, teriyaki, plum, ketchup, vinegar, hoisin, salad dressing |
| **Processed Fruit and Vegetable Products** | Meat Alternatives, Preserves/Spreads Fillings/Toppings | 82 | Tofu, vegetable/soy-based products, fruit purees, spreads (jams, jellies, marmalade), pie fillings, fruit toppings/syrups |
| **Overall** | | 1208 | |

## 2.4 Method Details

Survey samples were analyzed for antimony by an ISO17025 accredited food testing laboratory under contract with the Government of Canada. Samples were tested as sold, meaning the

product was not prepared as per the package instructions (if applicable). The laboratory used microwave digestion and inductively coupled plasma mass spectrometry to analyse for antimony. The method has a limit of detection (LOD) for antimony of 0.02 - 0.1 ppm in different foods.

### 2.5 Limitations

The current targeted survey was designed to provide a snapshot of the levels of antimony in beverages, nut and seed butters, condiments, and frozen or shelf-stable heat-and-serve meals available for sale in Canada, and for the potential to highlight commodities that warrant further investigation. This survey cannot distinguish between antimony originating from natural sources, from environmental contamination, and/or leaching from packaging material.

## 3. Results and Discussion

The 2012-2014 Antimony in Selected Foods survey consisted of analyzing 1208 samples obtained at the Canadian retail level. None of the samples tested contained a detectable level of antimony. Given that none of the samples in this survey were positive for antimony follow-up actions were not necessary.

While there were variations in analytical parameters for analysis of antimony between the FSAP, NCRMP and CFP surveys performed to date, the prevalence and detected levels of antimony in product types similar to those analyzed in all the CFIA surveys were exceedingly low.

In a previous FSAP targeted survey only 2% of 621 samples analyzed contained levels of antimony greater than the LOD (0.003 ppm). Antimony levels ranged from 0.0032 ppm to 0.0199 ppm. Samples with detectable levels of antimony included beverages, condiments and RTE meals and were found in both glass and plastic containers.

Similar product types analyzed for the CFIA's NCRMP and CFP surveys also showed very low prevalence and concentrations that were generally at/near the method's limit of detection. In the 2010-11 CFP survey, there were a total of 286 beverage and RTE meal products analyzed. Only one sample of infant food was found to contain a detectable level of antimony (0.0039 ppm). In the 2011-12 CFP survey, 112 samples similar to the product types targeted in the current survey were analyzed for antimony. One sample of juice and one sample of flavoured water contained a detectable level of antimony (0.038 and 0.0095 ppm, respectively). In 2010-12, under the NCRMP monitoring program, 55 samples of beverages and condiments were analyzed for antimony. Three samples of pineapple juice were found to contain a detectable level of antimony, ranging from 0.0043 ppm to 0.0428 ppm.

# 4. Conclusions

The 2012-2014 Antimony in Selected Foods survey generated additional baseline surveillance data on the levels of antimony in beverages, nut and seed butters, condiments, frozen/shelf-stable heat-and-serve meals, and processed fruit and vegetable products available on the Canadian retail market.

None of the 1208 samples analyzed contained detectable level of antimony. The current survey data and previously published CFIA (previous FSAP surveys, NCRMP and CFP) results indicates that antimony is rarely found in food and when found, the levels are very low. Given that none of the samples in this survey were positive for antimony; follow-up actions were not deemed necessary.

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