

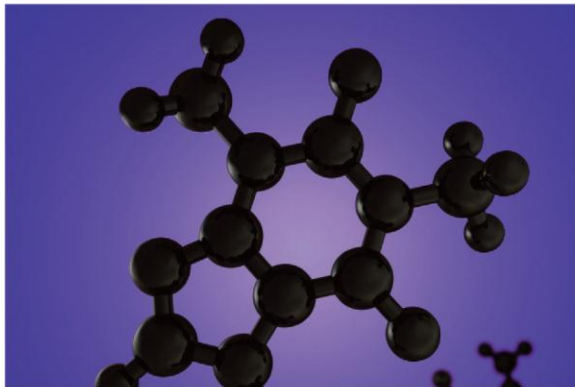


Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Bisphenol A in Canned Foods

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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 chemical and microbiological hazards.

The main objective of this targeted survey was to generate baseline surveillance data on the levels of bisphenol A (BPA) in canned fruits, juices, beverages, vegetables, legumes, pasta, and soup available on the Canadian retail market.

BPA is a chemical used in the production of polycarbonate and epoxy resins. Food and beverage packaging, particularly metal cans, may be internally coated with epoxy resins to protect food from direct contact with metal. BPA can migrate from the epoxy coatings into food, particularly at elevated temperatures (e.g., in hot-filled or heat-processed canned foods)¹. Elevated BPA concentrations have been associated with products contained in syrups, sauces (i.e., tomato sauce), and salted water².

Health Canada has concluded that the current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including newborns and young children^{3,4}. This conclusion has been re-affirmed by other international food regulatory agencies, including those of Canada's major trading partners^{5,6}. As a result, the use of BPA in food packaging materials has not been prohibited in Canada. Health Canada has recommended that the general principle of ALARA (as low as reasonably achievable) be applied by food packaging manufacturers and food processors to limit dietary BPA exposure from food packaging, particularly for products consumed by infants and newborns⁷.

The 2011-2012 BPA survey targeted domestic and imported canned fruits, juices, beverages, vegetables, legumes, pasta, and soup. A total of 403 samples were collected from retail stores in 11 Canadian cities between April 2011 and March 2012. The samples collected included 101 fruit products, 50 juices/beverages, 151 vegetables/legumes, and 101 pastas/soups. Only canned products were sampled, as these products are likely to have epoxy coatings.

Bisphenol A was not detected in 98.5% of the survey samples. BPA was detected in six samples in this survey (one pasta in tomato sauce, three whole-style cut carrots, one tender peas, and one cream-style corn). BPA was not detected in any of the fruit products, juices, beverages, or soups. There are no Canadian regulations or maximum levels (tolerances or standards) for BPA in foods sold in Canada, so compliance to a numerical standard could not be assessed. The results were evaluated and, where appropriate, Health Canada was consulted on the observed BPA levels. None of the samples were determined to pose a concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the human 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'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.

Within the 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 analysis of foods in 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 under 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 contaminants (hazards) in defined food commodities. The surveys are designed to answer specific questions. Therefore, unlike monitoring activities, testing for a particular hazard is targeted to commodity types and/or geographical areas.

Due to the vast number of hazard/food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all 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.

Bisphenol A (BPA) has garnered attention in recent years because of potential human health concerns, widespread human exposure, and limited dietary exposure information. Various opinions exist as to whether BPA poses a health concern⁸. Some studies have shown that BPA is an estrogenic chemical^{9,10}, may act as an endocrine disruptor^{11,12}, and may have other negative health effects^{10,13}. Two CFIA targeted surveys¹⁴, the National Chemical Residue Monitoring Program, as well as several Health Canada surveys^{7,15}, have generated baseline data on levels of BPA in various foods sold in Canada. The

purpose of this targeted survey was to add to existing baseline data on the levels of BPA in canned foods.

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 & 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 BPA in food. However, Health Canada established a provisional tolerable daily intake (pTDI) for BPA of 0.025 milligrams per kilogram (mg/kg) body weight/day in 1996. This pTDI was reviewed during Health Canada's recent assessment update of BPA exposure from food sources and remains unchanged, although the dietary exposure assessments are lower than those estimated previously⁴.

Health Canada^{7,16} has recommended that the general principle of ALARA (as low as reasonably achievable) be applied by food packaging manufacturers and food processors to limit BPA exposure from food packaging applications, particularly for products consumed by infants and newborns. Similarly, Canada's major trading partners⁵, and other international food safety authorities¹⁷ have supported initiatives to reduce BPA exposure from food packaging applications, including development of alternative materials. In addition, the European Union has introduced a specific migration limit for BPA into food from packaging (0.6 mg bisphenol A per kg food)*.

Elevated levels of BPA 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.

* COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

2 Survey Details

2.1 Bisphenol A (BPA)

Bisphenol A (BPA) is an industrial chemical used in the production of polycarbonate plastics and epoxy-phenolic resins¹⁸. It does not occur naturally in the environment. BPA is permitted for use in food contact materials in many countries, including Canada¹⁹. However, Health Canada recently banned the importation, sale, and advertising of polycarbonate baby bottles containing BPA, and many countries have since followed suit^{20,21,22,23}. Food and beverage packaging, particularly metal cans, may be coated on the inside of the container with epoxy resins to prevent corrosion and protect food from direct contact with metal. BPA can migrate from the epoxy coating into food, especially at elevated temperatures (for example, in hot-filled or heat-processed canned foods)¹⁵. Various opinions remain as to whether BPA poses a health concern, with some uncertainty about BPA-related effects at low dose levels²⁴. Some studies have shown that BPA is an estrogenic chemical, can act as an endocrine disruptor, and may have other negative health effects^{9,10,11,12,13}. However, various food regulatory agencies, including Health Canada, US FDA and EFSA, while recognizing the uncertainty, have indicated that current dietary exposure to BPA for the general population is not expected to represent a health concern. Given the concerns of consumers, and lack of consensus on health effects and safety of BPA, alternative, BPA-free can coatings have been developed and made available by the can coating industry (with pre-market assessment by Health Canada)²⁵, and some companies are now voluntarily phasing out use of the chemical in their food packaging²⁶.

2.2 Rationale

Upon completion of a health risk assessment, Health Canada concluded that current dietary exposure to BPA through food packaging is not expected to pose a health risk to the general population, including newborns and young children⁷. Health Canada also acknowledged rodent studies demonstrating a heightened sensitivity to BPA during stages of neural and behavioural development. Uncertainties remain about BPA-related effects at low dose levels and opinions vary about the health effects of BPA²⁴.

Two CFIA targeted surveys¹⁴, the CFIA National Chemical Residue Monitoring Program (NCRMP), as well as several Health Canada surveys⁷, have generated baseline data on levels of BPA in various foods. These surveys indicated very low levels of BPA in some infant foods, ready-to-serve and concentrate infant formulae, tuna, pasta, soup, juice, and vegetables, particularly those in metal cans or glass jars with metal lids. Additionally, data published by Canada's major trading partners showed low levels of BPA in some canned fruits, vegetables, pastas, chili, legumes, fish, and soups²⁷. Elevated BPA concentrations have been associated with products contained in syrups, sauces (i.e., tomato sauce), and salted water².

The purpose of this targeted survey was to add to baseline data on the levels of BPA in canned foods, in particular those packed in sauces, syrups, and salted water.

2.3 Sample Distribution

The 2011-2012 BPA survey targeted canned fruits, juices, beverages, vegetables, legumes, pasta, and soup. The 403 samples collected included 193 domestic products, 207 imported products (from 15 countries) and 3 products of unverifiable origin. 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.

Samples were collected from retail stores in 11 Canadian cities between April 2011 and March 2012 by samplers under contract with the Government of Canada. The samples included 101 fruit products, 50 juices/beverages, 151 vegetables/legumes, and 101 pastas/soups. Only canned products were sampled, as these products are likely to have epoxy coatings. Two of the 403 samples were considered to be “Unverifiable”, meaning the type of packaging could not be confirmed based on the available information recorded during sampling, but were assumed to be canned given the product type/brand and other similar samples collected.

2.4 Method Details

Samples were analyzed by a laboratory under contract with the Government of Canada. The laboratory is accredited to ISO/IEC 17025, *General Requirements for the Competence of Testing and Calibration Laboratories* (or its equivalent) by the Standards Council of Canada (SCC). The laboratory was required to use analytical methods that met or exceeded the requirements and limits of detection of the equivalent CFIA method.

Samples were tested as sold, meaning that the product was not drained or heated as per the package instructions (as applicable). Appropriate laboratory materials were used and conditioned such that any environmental BPA that might be present was eliminated. The analytical method used by the testing laboratory, ‘Determination of Bisphenol A (BPA) in Infant Formula, Soft Drinks, Canned Fruits, and High Protein Products using LC/MS/MS’, was based on the CFIA method entitled ‘Determination of Bisphenol A (BPA) in Liquid Infant Formula by Solid Phase Extraction with Acetic Anhydride Derivatization and Gas Chromatography-Mass Spectrometry’. The method has a limit of detection (LOD) of 0.005 parts per million (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 BPA in canned fruits, juices, beverages, vegetables, legumes, pasta, and soup available 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 three samples based on information provided by the sampler or as indicated on the label. Regional differences, impact of product shelf-life, 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 BPA Results

The 2011-2012 BPA targeted survey consisted of testing 403 samples obtained at the Canadian retail level. Samples analyzed for BPA were canned foods, or were presumed to be canned due to the limitations of the information recorded during sampling.

The samples included 50 juices/beverages, 101 fruit products, 101 pastas/soups, and 151 vegetables/legumes. BPA was not detected in 98.5% of the survey samples. Bisphenol A was detected in six samples in this survey (one pasta in tomato sauce, three whole-style cut carrots, one tender peas, and one cream-style corn). BPA was not detected in any of the fruit products, juices, beverages, or soups. Figure 1 presents the number of samples per product type, and illustrates the number of samples with detectable levels of BPA.

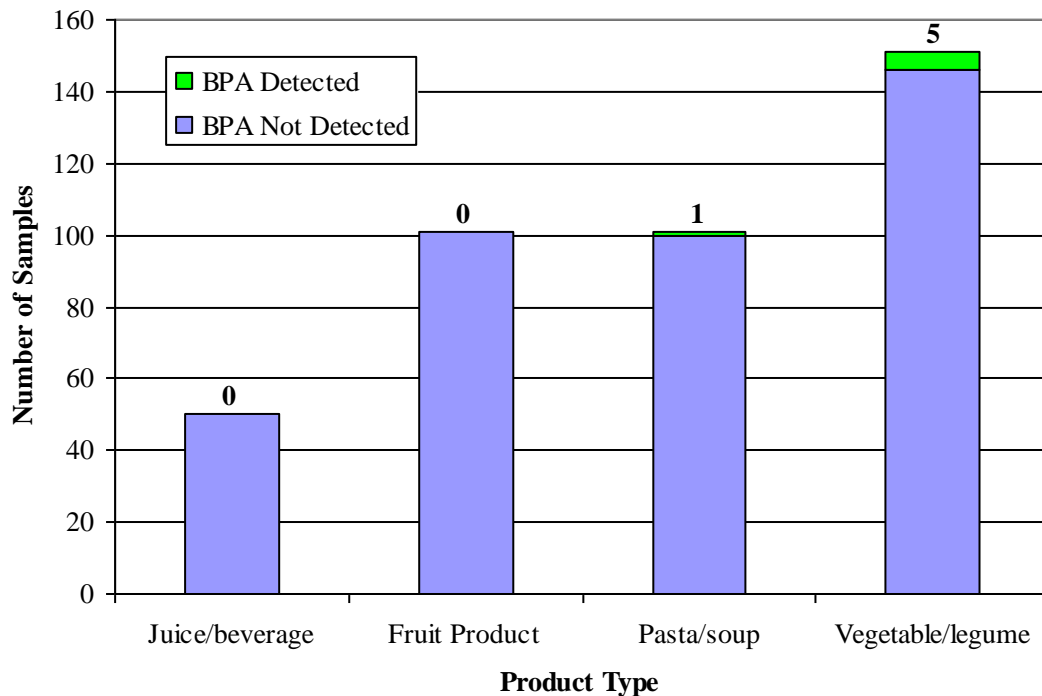


Figure 1 - Distribution of samples by product type (arranged by increasing number of samples)

There are no Canadian regulations or maximum levels (tolerances or standards) for BPA in foods sold in Canada, so compliance to a numerical standard could not be assessed. The six positive results were evaluated and, where appropriate, Health Canada was consulted on the observed BPA levels. None of the samples were determined to pose a concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

3.2 BPA Results by Product Type

Results by product type are presented in the following sections. Comparison to results obtained in the previous 2010-2011 CFIA FSAP targeted survey on BPA (unpublished), 2011-2012 NCRMP data (unpublished), Health Canada survey data⁷, and/or literature is given where appropriate and feasible.

3.2.1 Juices/Beverages

Fifty canned juice/beverage samples (30 domestic, 19 imported, and one sample of unverifiable origin) were analyzed in this survey. Forty-five of these samples were juices, (apple, pineapple, and tomato) and five were beverages (mango, mixed fruit, mixed vegetable, and tea). All juice/beverage samples were ready-to-consume. See Figure 2 below for distribution of juice/beverage samples by type.

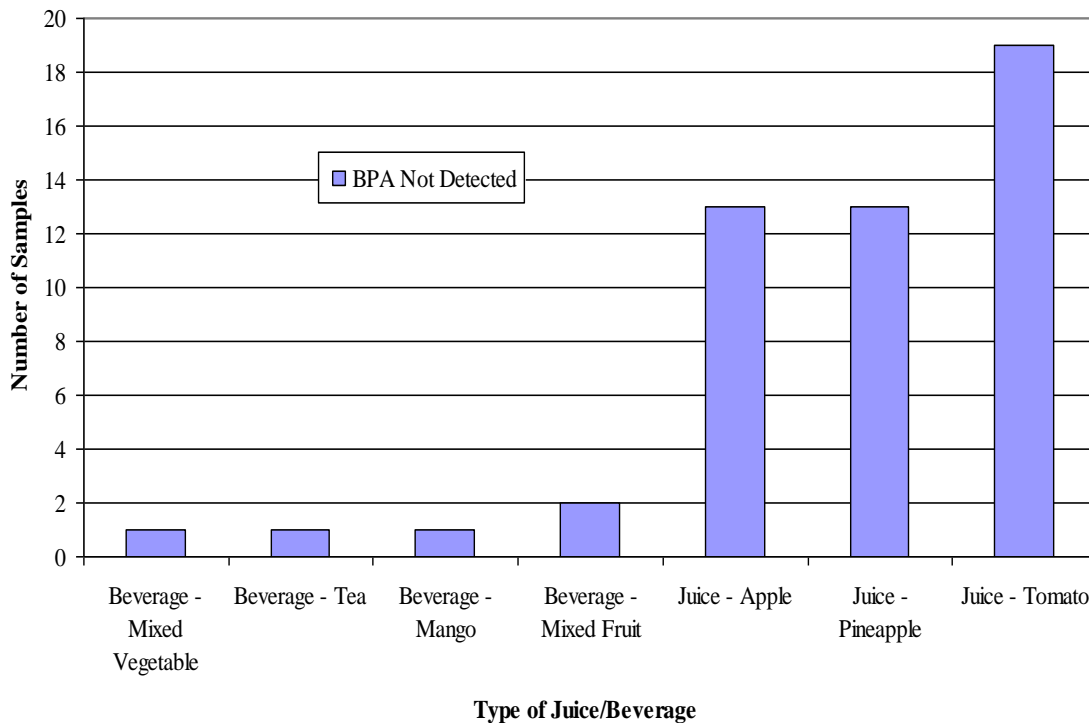


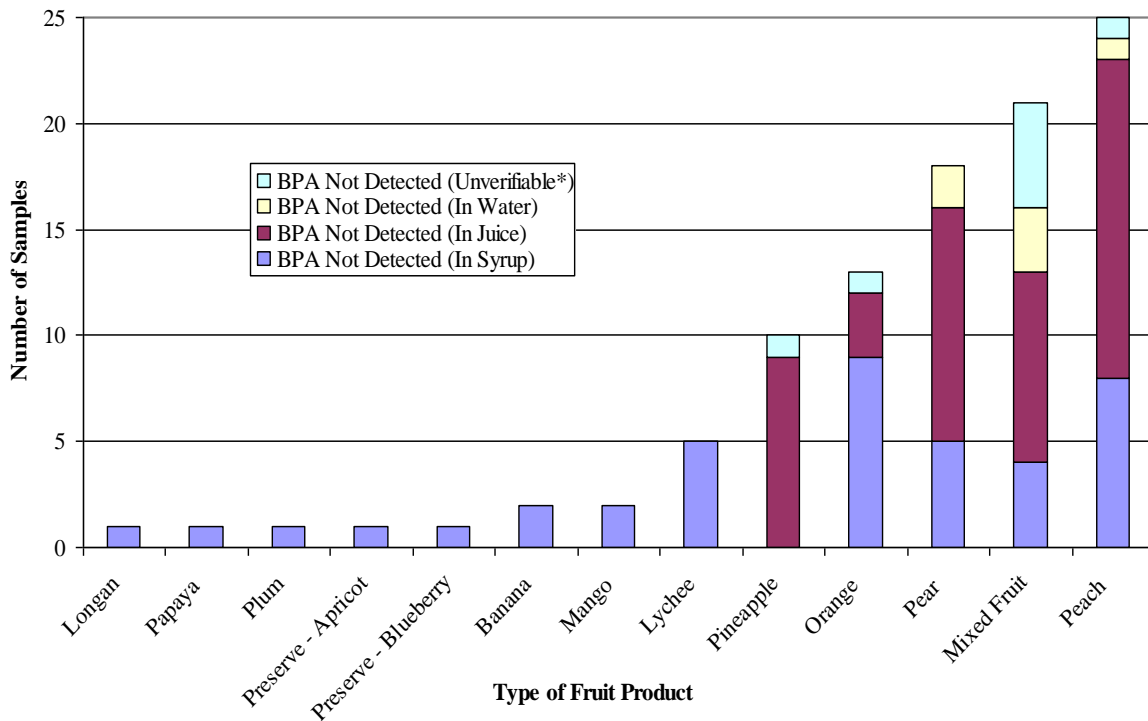
Figure 2 - Distribution of juice/beverage samples by type (arranged by increasing number of samples)

BPA was not detected in any of the juice or beverage samples. Similarly, BPA was not detected in any of the 4 comparable, canned samples in the previous 2010-2011 CFIA

FSAP Targeted Survey on BPA in Infant Formulae and Foods (ready-to-consume apple juice). Both surveys utilized the same analytical method, and the reporting limits for BPA were the same. No comparable, canned juices were analyzed under the NCRMP in the same sampling period as the current survey.

3.2.2 Fruit Products

One hundred and one imported, canned fruit products were analyzed in this survey. Fruit products included canned banana, longan, lychee, mango, mixed fruit/fruit cocktail, orange, papaya, peach, pear, pineapple, plum, and jam/preserves (apricot and blueberry). Ninety-three samples were packed in light/heavy syrup, fruit juice, or water. For eight samples, it was not possible to verify what packing media was used for the canned fruit product. See Figure 3 below for distribution of fruit product samples by type.



*Unverifiable refers to samples for which packing media could not be determined based on the available information

Figure 3 - Distribution of fruit product samples by type (arranged by increasing number of samples)

BPA was not detected in any of the fruit product samples. Similarly, BPA was not detected in any of the 81 comparable, canned samples in the previous 2010-2011 CFIA FSAP Targeted Survey on BPA in Infant Formulae and Foods (mixed fruit/fruit cocktail, peach, pear, and pineapple; in light/heavy syrup, fruit juice, or water). Nine comparable, canned fruit products were analyzed under the NCRMP in the same sampling period as the current survey (lychee, mixed fruit/fruit cocktail, orange, peach, and pear; in light/heavy syrup, fruit juice, or water). One of these samples (pears in juice) had a very

low level of BPA (below 0.005 ppm). The current survey, previous survey, and the NCRMP utilized similar analytical methods and had similar reporting limits.

3.2.3 Pasta/Soup

One hundred and one canned pasta/soup samples (55 domestic, 45 imported, and one sample of unverifiable origin) were analyzed in this survey. Ninety-six of these samples were pasta, either in tomato-based sauce only (33 samples) or in tomato-based sauce with cheese and/or beef (63 samples). Five samples were soup, either with or without meat (beef or chicken). All pasta/soup samples were ready-to-consume (i.e., require heating but not addition of water). See Figure 4 below for distribution of pasta/soup samples by type.

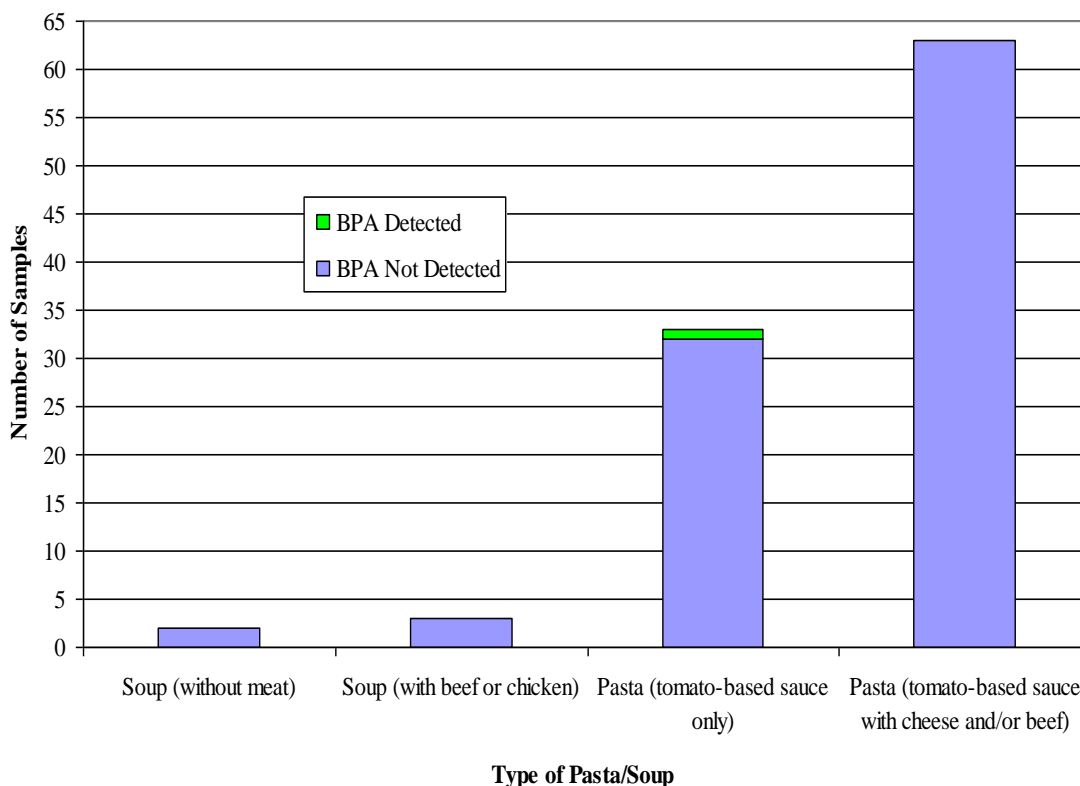


Figure 4 - Distribution of pasta/soup samples by type (arranged by increasing number of samples)

BPA was detected in one sample of domestic canned pasta in tomato-based sauce, at 0.073 ppm. Several other pasta samples of the same type/brand were analyzed in the current survey and did not have detectable levels of BPA. No comparable, canned samples were analyzed in the previous CFIA FSAP Targeted Surveys on BPA or under the NCRMP in the same sampling period as the current survey. The level of BPA detected in the pasta in this survey is similar to that in comparable products analyzed by both Health Canada and the U.S. FDA. A Health Canada survey reported one sample of pasta in tomato-based sauce with beef with a BPA concentration of 0.032 ppm^{7,15}. The

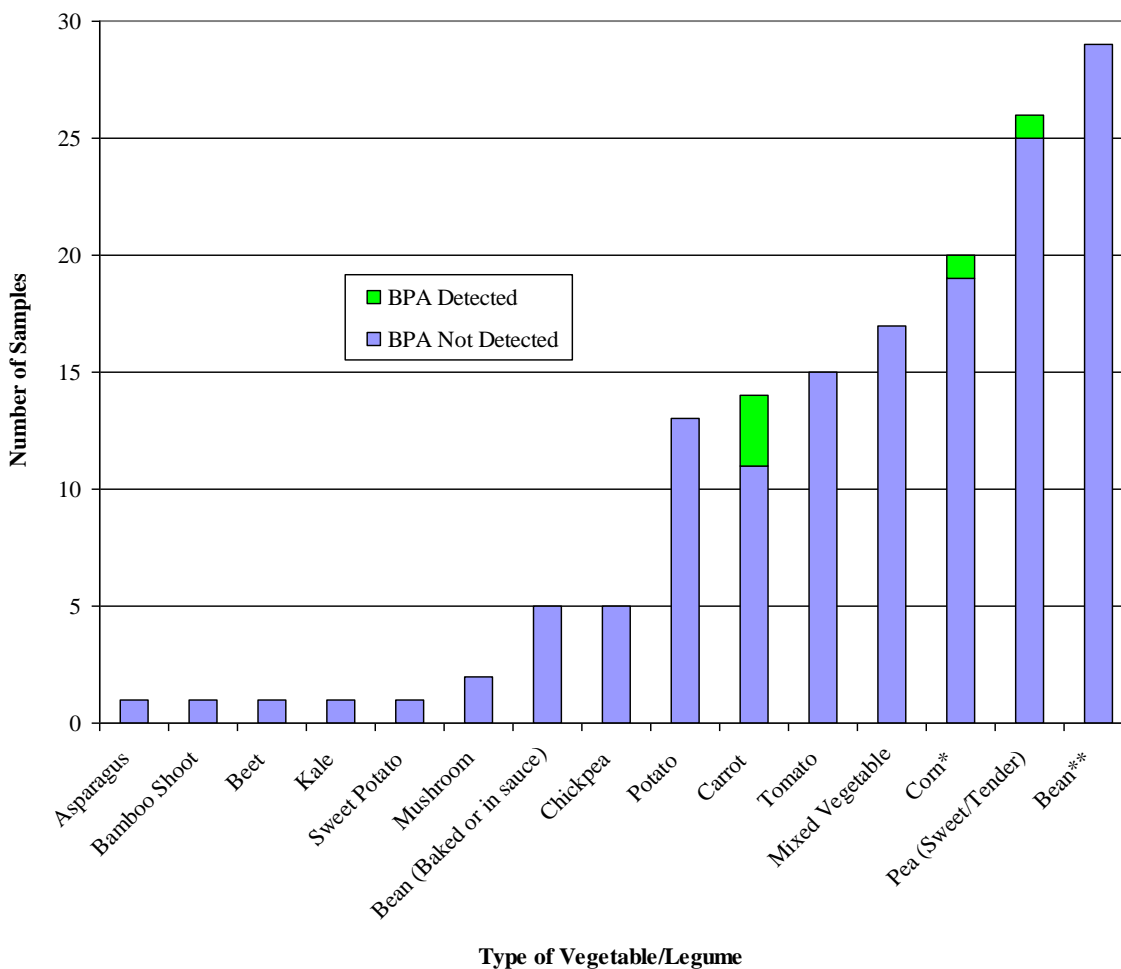
U.S. FDA has reported levels of BPA in canned ravioli ranging from 0.0075 to 0.062 ppm, and in canned pasta (tomato-based sauce) ranging from 0.012 to 0.043 ppm²⁷.

There are no Canadian regulations or maximum levels (tolerances or standards) for BPA in foods sold in Canada, so compliance to a numerical standard could not be assessed. Given that the two highest results for BPA in this survey (canned peas and canned carrots-refer to Section 3.2.4) were evaluated by Health Canada and neither sample was determined to pose a concern to human health, the lower level of BPA in the pasta sample was also considered unlikely to be of concern to human health.

3.2.4 Vegetables/Legumes

One hundred and fifty-one canned vegetable/legume samples (108 domestic and 43 imported) were analyzed in this survey. Vegetable/legumes included canned asparagus, baked beans, bamboo shoot, beans (black/fava/green/yellow/kidney/wax/mixed/romano/cannellini), beet, carrot, chickpea, corn (baby/sweet/peaches and cream/cream style), kale, mixed vegetables, mushroom, pea (sweet/tender), potato, sweet potato, and tomato. One hundred and thirty-three vegetable/legume samples were packed in their own juice (tomatoes) or water (with or without salt and/or sugar). For 18 samples, it was not possible to verify what packing media was used for the canned vegetable/legume, but were assumed to be in water/its own juice given the product type/brand and other similar samples in the dataset. See Figure 5 below for distribution of vegetable/legume samples by type.

BPA was detected in five vegetable/legume samples: three carrot samples (in water; two domestic and one imported), one domestic tender pea sample (in water), and one domestic cream-style corn sample.



Note: Corn* - Baby/Sweet/Peaches and Cream/Cream Style; Bean** - Black/Fava/Green/Yellow/Kidney/Wax/Mixed/Other (Romano, Cannellini)

Figure 5 - Distribution of vegetable/legume samples by type (arranged by increasing number of samples)

Of the five vegetable/legume samples positive for BPA, three were whole-style carrots. Two of these three carrot samples were the same brand with similar levels of BPA, 0.0180 and 0.0219 ppm. The concentration of BPA in the third carrot sample was 0.307 ppm. Several other carrot samples of the same types/brands were analyzed in the current survey, and did not have detectable levels of BPA. No comparable, canned carrot samples were analyzed in the previous CFIA FSAP Targeted Surveys on BPA or under the NCRMP in the same sampling period as the current survey. The levels of BPA detected in this survey in canned carrots are similar to that found in a recent Health Canada survey, wherein they reported one sample of whole-style cut carrots with a BPA concentration of 0.0091 ppm^{7,15}.

Of the remaining two vegetable/legume samples positive for BPA, one was a sample of tender peas with a BPA concentration of 0.1833 ppm. Several other pea samples of the same type/brand were analyzed in the current survey, and did not have detectable levels of BPA. No comparable, canned pea samples were analyzed in the previous CFIA FSAP

Targeted Surveys on BPA, under the NCRMP in the same sampling period as the current survey, or in the Health Canada survey^{7,15}. However, similar values for peas (drained) were reported in the United States Food and Drug Administration (U.S. FDA) survey, ranging from 0.0026 to 0.310 ppm²⁷.

A single sample of cream-style corn analyzed in this survey had a BPA concentration of 0.074 ppm. Several other samples of canned corn were analyzed in the current survey and did not have detectable levels of BPA; however, none of these was cream-style corn. No comparable, canned corn samples were analyzed in the previous CFIA FSAP Targeted Surveys on BPA. Four canned corn samples were analyzed under the NCRMP in the same sampling period as the current survey, one of which was cream-style corn. These four samples were positive for BPA, with values similar to the positive corn sample in the current survey, ranging from 0.0079 to 0.112 ppm, the highest value being the cream-style corn. The current survey and the NCRMP utilized similar analytical methods. The level of BPA detected in the canned cream-style corn in this survey is also similar to that in comparable products analyzed by both Health Canada and the U.S. FDA. The Health Canada survey reported two samples of cream-style corn with BPA concentrations of 0.0073 and 0.092 ppm^{7,15}. Similar values for canned corn (drained) were reported in the U.S. FDA survey, ranging from 0.0042 to 0.076 ppm²⁷.

There are no Canadian regulations or maximum levels (tolerances or standards) for BPA in foods sold in Canada, so compliance to a numerical standard could not be assessed. The sample of canned carrots with a BPA concentration of 0.307 ppm and the canned peas (0.1833 ppm) were evaluated by Health Canada and, estimating probable daily intakes for both adults and children, they determined that these levels would result in BPA intakes that were well below Health Canada's provisional tolerable daily intake (pTDI) for BPA of 0.025 mg/kg body weight/day and, taking into account other possible sources of BPA in food, would not pose a concern to human health. The lower levels of BPA in the other two carrot samples and the corn sample were then also considered unlikely to be of concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

4 Conclusions

The present survey generated additional baseline surveillance data on the levels of bisphenol A (BPA) in domestic and imported canned fruits, juices, beverages, vegetables, legumes, pasta, and soup available on the Canadian retail market.

No maximum level, tolerance, or standard has been established by Health Canada for BPA in food. However, Health Canada, has recommended that the general principle of ALARA (as low as reasonably achievable) be applied by food packaging manufacturers and food processors to limit BPA exposure from food packaging applications, particularly for products consumed by infants and newborns.

Four hundred and three samples were collected in total, which included 50 juices/beverages, 101 fruit products, 101 pastas/soups, and 151 vegetables/legumes. Only canned products were sampled, as these products are likely to have epoxy coatings.

Bisphenol A was not detected in 98.5% of the survey samples. BPA was detected in six samples in this survey (one pasta in tomato sauce, three whole-style cut carrots, one tender peas, and one cream-style corn). BPA was not detected in any of the fruit products, juices, beverages, or soups. There are no Canadian regulations or maximum levels (tolerances or standards) for BPA in foods sold in Canada, so compliance to a numerical standard could not be assessed. The results were evaluated and, where appropriate, Health Canada was consulted on the observed BPA levels. None of the samples were determined to pose a concern to human health. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern.

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