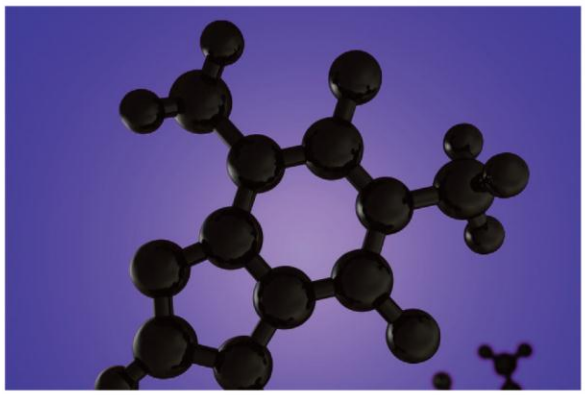
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Chemistry



Bisphenol A in Infant Formulae and Foods

TS-CHEM-10/11

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 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 infant formulae, processed, pre-packaged fruit products, and fruit juices 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 (for example, in hot-filled or heat-processed canned foods)[1].

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[2]. This conclusion has been re-affirmed by other international food regulatory agencies, including those of Canada's major trading partners[3,4]. 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 newborns[5].

The 2010-2011 BPA Survey targeted domestic and imported infant formulae, processed, pre-packaged fruit products, and fruit juices. A total of 234 samples were collected from retail stores in 11 Canadian cities between October 2010 and March 2011. The samples collected included 127 dairy and soy infant formula samples (powdered, ready-to-serve and concentrate), 92 processed, pre-packaged fruit product samples, and 15 fruit juice samples. A variety of food packaging materials were sampled, particularly those expected to have epoxy coatings (including plastic, paperboard coated with waterproof plastic, paperboard cans with metal ends, metal cans, and glass jars with metal lids).

Bisphenol A was not detected in any sample in this survey. Given that none of the samples in this survey were positive for BPA, follow-up actions were not deemed necessary.

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. While opinions vary about the health effects of BPA[6], some studies have shown that BPA is an estrogenic chemical[7,8], may act as an endocrine disruptor[9,10], and may be associated with other negative health effects[8,11]. Due to uncertainties raised in some experimental studies relating to the potential effects of low levels of bisphenol A, the Government of Canada has initiated various risk management actions in order to further reduce exposure.

CFIA 2009-2010 targeted survey[12], as well as several Health Canada surveys[5,13], generated baseline data on levels of BPA in various foods sold in Canada, including infant foods and formula. The purpose of this targeted survey was to add to existing baseline data on the levels of BPA in foods consumed by infants and young children, particularly vulnerable sub-populations.

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 did set a provisional tolerable daily intake (pTDI) for BPA of 0.025 mg/kg body weight/day in 1996. This pTDI was recently reviewed during Health Canada's risk assessment for BPA, and remains unchanged[2].

Health Canada[5,14], Canada's major trading partners[3], and other international food safety authorities[15] have 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.

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. When the BPA level in a food product is deemed to pose a human health concern, follow-up actions are initiated in a manner that reflects the magnitude of the health concern. Actions may include notification of the producer or importer, follow-up inspections, additional directed sampling, and recall of products.

2 Survey Details

2.1 Bisphenol A (BPA)

BPA is an industrial chemical used in the production of polycarbonate plastics and epoxy-phenolic resins[16]. It does not occur naturally in the environment. BPA is permitted for use in food contact materials in many countries, including Canada[17]. However, Health Canada recently banned the importation, sale, and advertising of polycarbonate baby

bottles containing BPA, and many countries have since followed suit[18,19,20,21]. Food and beverage packaging, particularly metal cans, may be internally coated 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)[13]. Opinions vary about the health effects of BPA, and uncertainties remain about BPA-related effects at low dose levels[22]. Some studies have shown that BPA is an estrogenic chemical, can act as an endocrine disruptor, and may have other negative health effects[7,8,9,10,11]. Given the concerns of consumers, and lack of consensus on health effects and safety of BPA, some companies are now voluntarily phasing out use of the chemical in their food packaging[23].

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 children[5]. Health Canada also acknowledged that certain rodent studies demonstrated a heightened sensitivity to BPA during stages of neural and behavioural development. These studies highlighted the potential vulnerability of newborns and infants to BPA given that pre-packaged foods and formula can be the sole source of nutrition in this segment of the population.

A CFIA 2009-2010 targeted survey[12], as well as several Health Canada surveys[5], generated baseline data on levels of BPA in various foods, including infant foods and formula. These surveys indicated very low levels of BPA in some infant foods, ready-to-serve and concentrate infant formulae, particularly those in metal cans and glass jars with metal lids.

The purpose of this targeted survey was to add to baseline data on the levels of BPA in foods consumed by infants and young children, particularly vulnerable sub-populations.

2.3 Sample Distribution

The 2010-2011 BPA Survey targeted infant formulae, processed, pre-packaged fruit products, and fruit juices. The 234 samples collected included 39 domestic products, 191 imported products (from seven countries) and 4 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 October 2010 and March 2011. The samples included 127 infant formulae (powdered, ready-to-serve and concentrate), 92 processed, pre-packaged fruit products, and 15 fruit juices. A variety of food packaging materials were sampled, particularly those expected to have epoxy coatings. This included plastic, canned (referring to either paperboard cans with metal

ends or metal cans), tetra pak-style (paperboard coated with waterproof plastic), and glass (jars with metal lids) packaging materials. The distribution of samples by packaging type is presented in Figure 1 below.

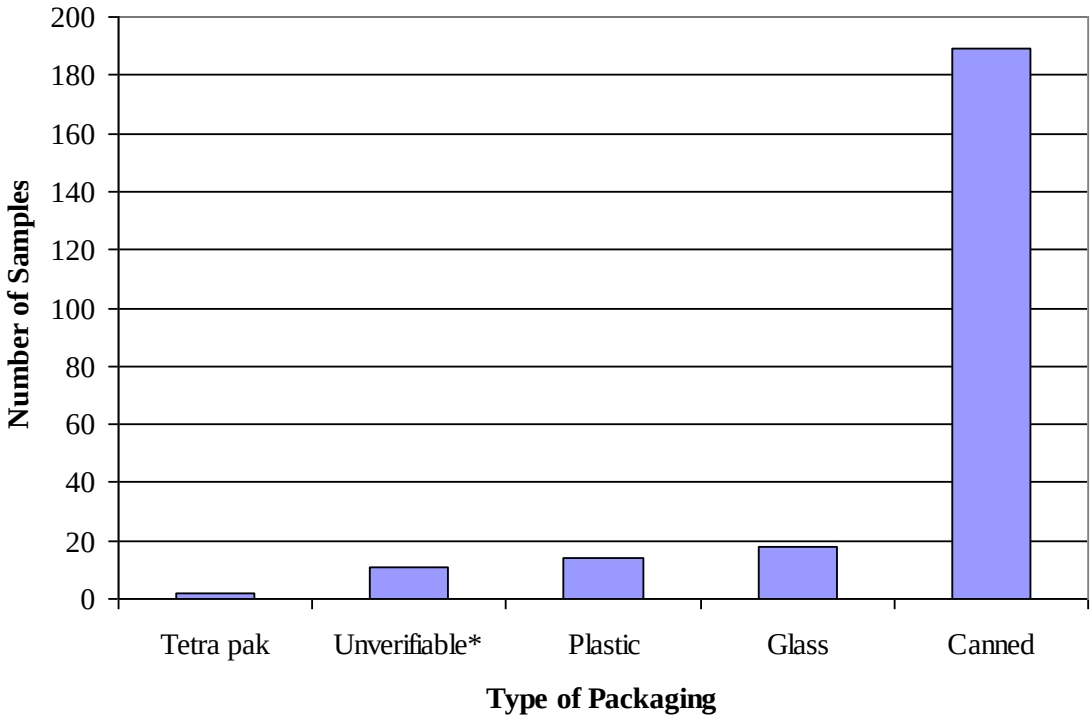

Figure 1 - Distribution of samples by packaging type

*Unverifiable refers to samples for which type of packaging could not be determined based on the available information

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 prepared as per the package instructions (if 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 and Soft Drink 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 infant formulae, processed, pre-packaged fruit products, and fruit juices available in Canada and had the potential to highlight commodities that warranted 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 four 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 2010-2011 BPA targeted survey consisted of testing 234 samples obtained at the Canadian retail level. BPA was not detected in any sample in the survey.

Samples analyzed for BPA came in a variety of food packaging materials. This included 189 canned samples (paperboard cans with metal ends and metal cans), 18 samples in glass (with metal lids), 14 samples packaged in plastic, and two tetra pak-style (paperboard coated with waterproof plastic) samples. Eleven samples were packaged in a type that was unverifiable (type of packaging could not be determined based on the available information). See Figure 1 above for distribution of commodity type by the type of food packaging material used. Results by product type are presented in the following sections, with comparison to results obtained in the previous 2009-2010 CFIA FSAP targeted survey on BPA[12] where feasible.

3.2 Infant Formula

One hundred and twenty seven infant formula samples (16 domestic, 108 imported, three of unverifiable origin) were analyzed in this survey. Some formula samples were iron-fortified, low iron, or lactose-free. Dairy-based infant formulae included 58 concentrate samples (liquids and powders) and 58 ready-to-consume samples. Soy-based infant formulae included only three concentrate samples (liquids and powders). For eight samples of infant formula (referred to as “unverifiable”), it was not possible to confirm either the type of formula (dairy- or soy-based), whether it was a concentrate or ready-to-consume product, and/or the type of packaging used. See Figure 2 below for distribution of infant formulae samples by type and packaging material.

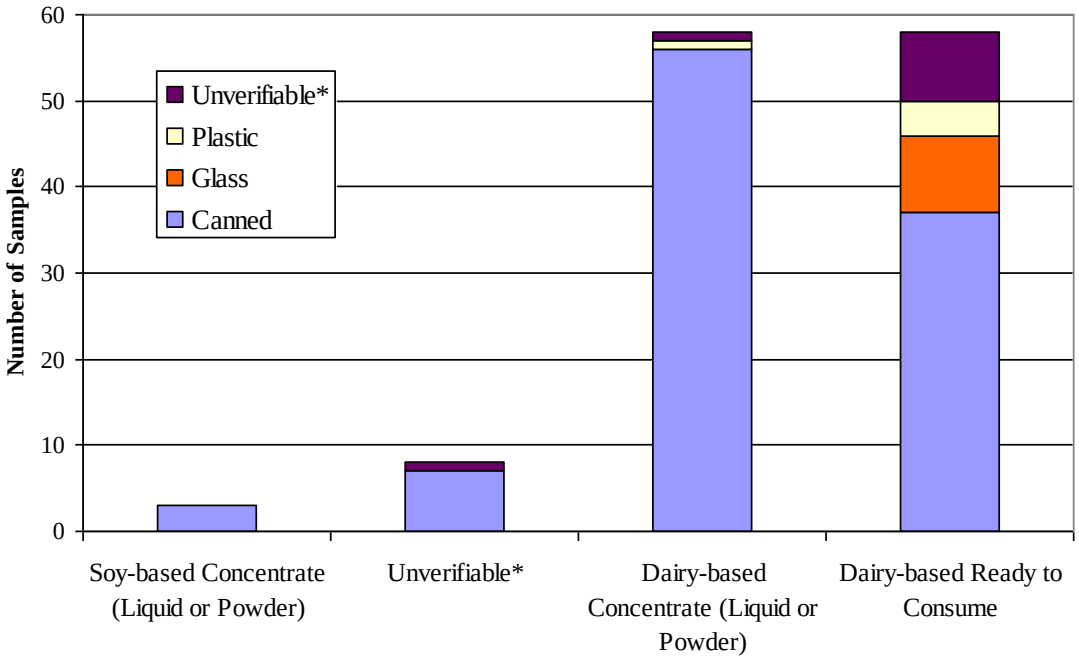

Figure 2 - Distribution of infant formula samples by type

*Unverifiable refers to samples for which type of packaging or type of formula (or both) could not be determined based on the available information

BPA was not detected in any of the infant formula samples. The results of this survey were compared to the previous 2009-2010 CFIA FSAP targeted survey on BPA in Infant Food and Formula[12], in which 100 samples of infant formulae were analyzed. In the 2009-2010 survey, 13 ready-to-consume (in metal cans or glass) and 60 concentrate products (all in metals cans) had very low levels of BPA (0.0016 – 0.0092 ppm). Many of these samples positive for BPA were the same brands/products that were also sampled in the current survey. Both surveys utilized the same analytical method, however, the reporting limits in the current BPA survey are slightly higher.

3.3 Processed, Pre-packaged Fruit Products

Ninety-two processed, pre-packaged fruit products (12 domestic, 79 imported, one of unverifiable origin) were analyzed in this survey. Some of these fruit product samples were considered baby food. All processed, pre-packaged fruit products sampled were packaged in cans, glass, or plastic. Fruit products included one mixed peach and mandarin orange, one apricot, 25 peach, 24 pear, 22 fruit cocktail, 10 pineapple, five mixed fruit (baby food), and four strawberry (baby food) samples. See Figure 3 below for distribution of processed, pre-packaged fruit product samples by type and packaging material.

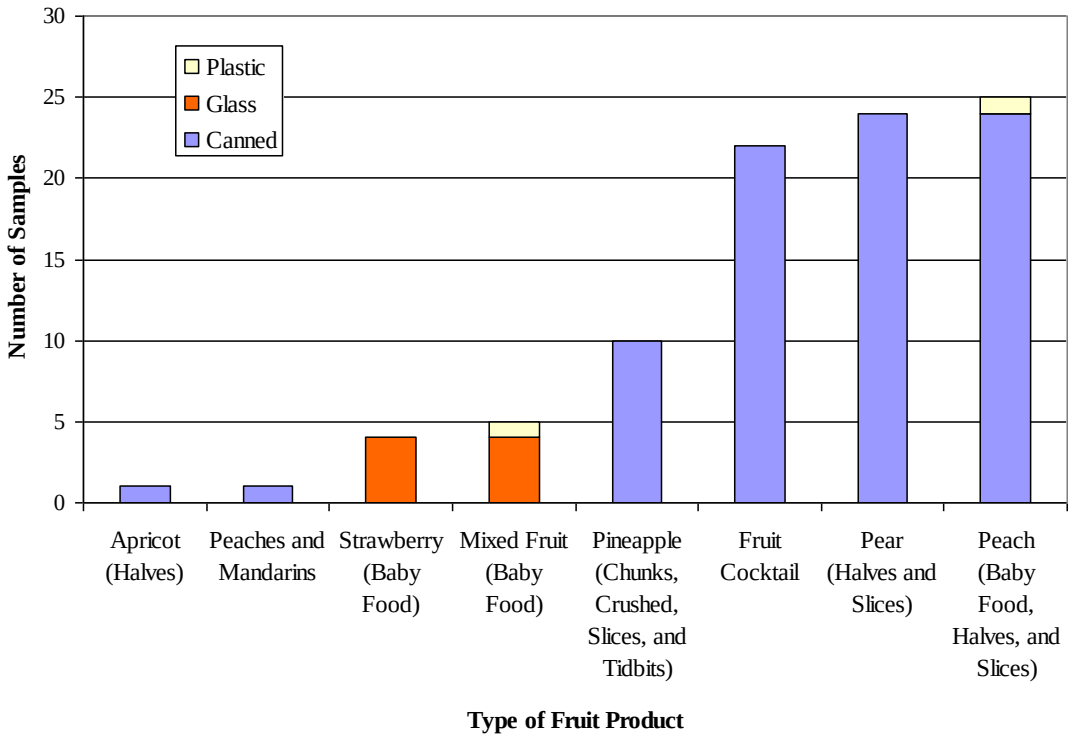

Figure 3 - Distribution of processed, pre-packaged fruit product samples by type

BPA was not detected in any of the processed, pre-packaged fruit products samples. The results of this survey were compared to the previous 2009-2010 CFIA FSAP targeted survey on BPA in Infant Food and Formula[12], in which 27 baby food fruit products were sampled. The results were similar in both survey years. In the 2009-2010 survey, only one baby food fruit product sample (in glass) had a very low level of BPA (0.0026 ppm). This type/brand of sample was not sampled in the current survey.

3.4 Fruit Juices

Fifteen fruit juices (11 domestic, four imported) were analyzed in this survey, all of which were ready-to-consume. Juices included one pear, one white grape, and 13 apple samples. See Figure 4 below for distribution of fruit juice samples by type and packaging material.

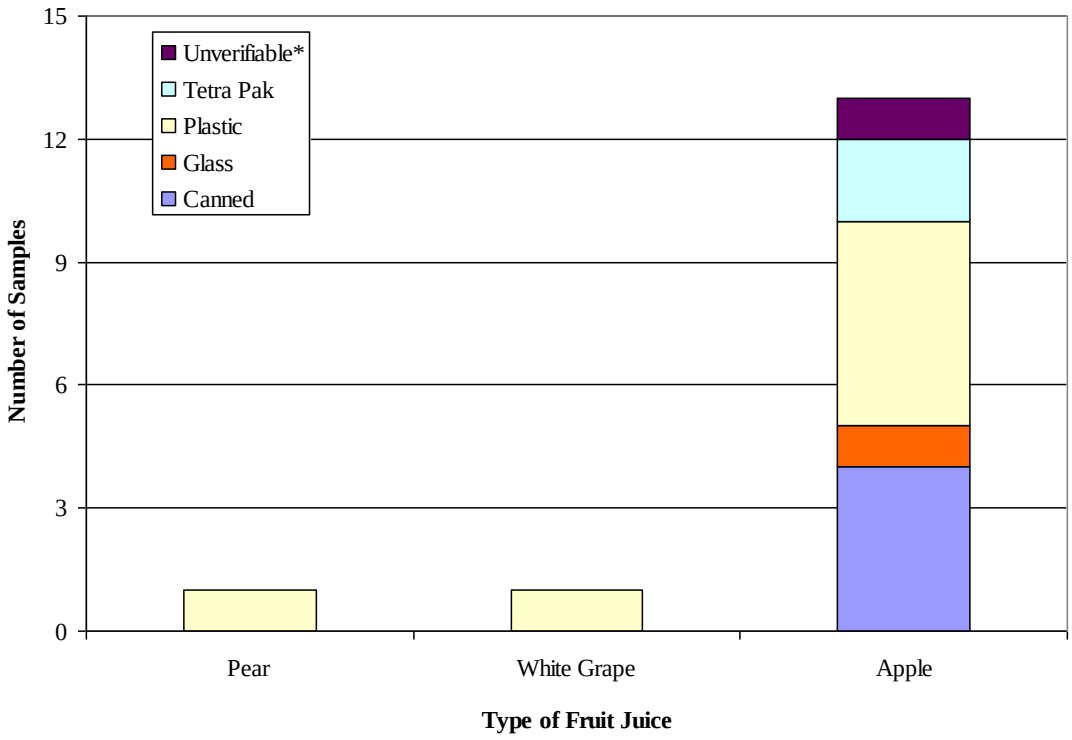

Figure 4 - Distribution of fruit juice samples by type

*Unverifiable refers to samples for which type of packaging could not be determined based on the available information

BPA was not detected in any of the fruit juice samples. The results of this survey could not be compared to the previous 2009-2010 CFIA FSAP targeted survey on BPA in Infant Food and Formula given that no juices were sampled in that survey.

4 Conclusions

The present survey generated additional baseline surveillance data on the levels of BPA in domestic and imported infant formulae, processed, pre-packaged fruit products, and fruit juices, in a variety of packaging types, 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, Canada's major trading partners, and other international food safety authorities have 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.

Two hundred and thirty four samples were collected in total, which included 127 dairy and soy-based infant formulae (powdered, ready-to-serve and concentrate), 92 processed, pre-packaged fruit products, and 15 fruit juices. A variety of food packaging materials were sampled, particularly those expected to have epoxy coatings (including plastic,

paperboard coated with waterproof plastic, paperboard cans with metal ends, metal cans, and glass jars with metal lids).

Bisphenol A was not detected in any sample in this survey. Given that none of the samples in this survey were positive for BPA, follow-up actions were not deemed necessary.

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