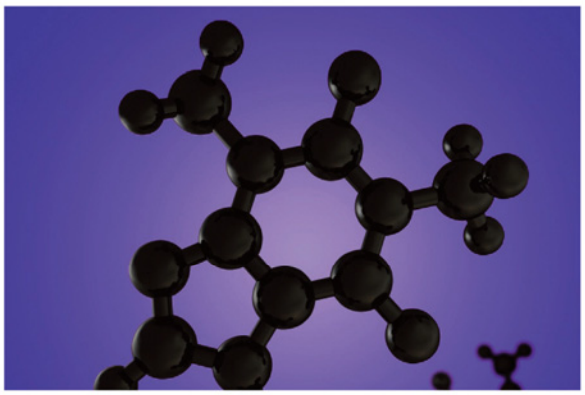
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2009-2010 Targeted Surveys

Chemistry



Bisphenol-A in Infant Food and Formula

TS-CHEM-09/10-03

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 test various foods for specific hazards.

The main objectives of the bisphenol-A survey were:

- To provide baseline surveillance data for a variety of infant foods and infant formula
- To examine the link between different types of packaging and the levels of bisphenol-A in food

Two hundred samples were collected and analyzed for bisphenol-A. They consisted of 100 infant food samples (cereals, fruit & vegetable purees and mixed meals) and 100 infant formula samples (powdered, ready-to-serve and concentrated). Samples with a wide variety of packaging materials were selected to explore the link between packaging and levels of bisphenol-A. The types of packaging were:

- plastic cups/trays (plastic)
- paperboard coated with waterproof plastic (paper-plastic)
- paperboard cans with metal ends (paper-metal)
- metal cans (metal)
- glass jars with metal lids (glass-metal).

From a total of 200 samples, 59% did not contain detectable levels of bisphenol-A. Bisphenol-A was not detected in any of the powdered infant formulas or infant cereals sampled for this survey. These samples were packaged in metal, paper-plastic or paper-metal containers, and consisted of dry ingredients, which would make migration of bisphenol-A from any potential packaging source unlikely. Detection of bisphenol-A was minimal in infant food (9%). These samples were packaged in glass containers with metal lids or individual serving plastic containers. Conversely, 65% of ready-to-serve infant formula and 100% of concentrated infant formula samples tested contained measurable residues of bisphenol-A. All concentrated infant formula samples selected were in metal cans. Ready-to-serve infant formulas were mostly in metal cans, but a few were also found in glass bottles with metal lids.

When examined as a function of food packaging, no detectable levels of bisphenol-A were found for samples in plastic, paper-plastic and paper-metal packaging. The 82 samples in which bisphenol-A was detected were in metal cans (70 of 89 samples, 79%) and glass jars with metal lids (12 of 32 samples, 38%). Bisphenol-A is a component of the can/lid liner which is used to prevent direct contact of food with metal. Residues in these linings can migrate into foods especially at elevated temperatures. The levels of bisphenol-A in infant food and infant formula observed in this survey ranged from 1.4 ng/g to 9.6 ng/g. These levels are consistent with previous findings obtained in Canada and the United States. Consumption of these products would result in exposures well below the provisional tolerable daily intake of 25 µg/kg body weight per day established by Health Canada.

1. Introduction

1.1 Food Safety Action Plan

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. The FSAP unites multiple partners in providing safe foods for Canadians.

Within FSAP, the Canadian Food Inspection Agency (CFIA) gained increased authority to monitor potential food risks and to prevent unsafe food products from entering the Canadian marketplace. The CFIA fulfils this mandate through an enhanced surveillance initiative which includes targeted surveys. The CFIA works on these initiatives with input from Federal partners such as Health Canada, as well as Provincial and Territorial (P/T) representatives.

1.2 Targeted Surveys

Targeted surveys are pilot surveys used to gather preliminary 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 specific 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 media reports, scientific literature and/or a risk-based model developed by the Food Safety Science Committee (FSSC).

1.3 Rationale

Consumers are becoming increasingly aware of the chemicals that may be present in their food. Bisphenol-A in infant foods and infant formula continues to be an area of public concern. Testing for bisphenol-A in liquid infant formula in metal and glass packaging has been undertaken by Health Canada in the past[3,4]. The purpose of this targeted survey is to complement existing data by expanding bisphenol-A testing to a wider variety of infant products and packaging. Together, these data will be valuable in establishing a baseline for bisphenol-A levels in infant foods and infant formula. It should be noted that the presence of bisphenol-A in infant food is not unexpected, as it is known to be used in the food packaging industry.

2. Bisphenol-A Survey

2.1 Bisphenol-A Overview

Bisphenol-A is an industrial chemical used to make epoxy resins and clear hard plastic known as polycarbonate. It can be found in many items including tableware, storage

containers, and food packaging. Epoxy resins are used as protective linings on the inside of metal containers and metal lids to prevent the corrosion of the metal and subsequent contamination of foods and beverages by dissolved metals. However, as a result of these liners, chemical components of food packaging like epoxy resins and polycarbonate come in contact with food. Residues of bisphenol-A can then migrate from the liners into the food, especially at elevated temperatures (such as in hot-fill or heat-processed canned foods)[5].

Newborns and infants are thought to be more vulnerable to bisphenol-A since 1) they are in an important developmental phase and 2) pre-packaged food and formulas can be the sole source of nutrition in this population. As a result, the Government of Canada supports the need for additional research in this area, including infant exposure to bisphenol-A through infant foods and infant formula[5].

Polycarbonate is used to make baby bottles. Newborn and infant exposure to bisphenol-A from polycarbonate baby bottles may increase when bottles are subjected to high temperatures. For infants, this could occur when hot or boiling water is poured into polycarbonate baby bottles and then mixed with powdered infant formula. As a precautionary measure, the Government of Canada announced in 2009 it was taking action in prohibiting importation, sale and advertising of polycarbonate bottles[7]. Alternatives to polycarbonate baby bottles, such as non-polycarbonate bottles and baby bottle liners, have been studied by Health Canada scientists and found to contain only trace levels of bisphenol-A[8].

An additional source of bisphenol-A for newborns and infants comes from the epoxy resins lining metal containers and lids. Recent testing of infant formula samples for bisphenol-A levels suggests that bisphenol-A levels in canned infant formula are considered safe[3]. As a precautionary measure, the Government of Canada is currently working towards setting bisphenol-A migration targets for infant formula cans[9].

Health Canada's Food Directorate has concluded that the current dietary exposure to bisphenol-A through food packaging uses 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 health agencies in other countries, including the United States, the European Union and Japan[2]. As a result, the use of bisphenol-A in food packaging has not been prohibited in Canada, however Health Canada has recommended that the general principle of ALARA (as low as reasonably achievable) be applied to continue efforts on limiting bisphenol-A exposure from food packaging applications to infants and newborns.

2.2 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* (FDAR). The safety of all

materials used for packaging foods is controlled under Division 23 of the Food and Drugs Regulations, Section B.23.0001, which prohibits the sale of foods in packages that may impart harmful substances to their contents. This regulation puts the onus clearly on the food seller (manufacturer, distributor, etc.) to ensure that any packaging material that is used in the sale of food products will meet this requirement.

Legal limits for contaminants in food are determined by Health Canada and are referred to as Maximum Limits (ML). Analytical results of targeted surveys are compared to their respective maximum limits, if they have been established. Levels above ML are identified as non-compliant and are assessed by the CFIA and/or Health Canada for potential health risk to consumers. Follow-up actions are initiated in a manner which reflects the magnitude of the health risk. If an ML is lacking, the results from targeted surveys can provide baseline data which may be used to perform or refine health risk assessments and subsequently establish MLs where needed.

In the case of bisphenol-A, no ML has been established by Health Canada.

2.3 Sample distribution

The 2009-2010 bisphenol-A survey targeted a wide variety of infant food and infant formula. Samples were taken based on availability at retail, no specific brands or products were targeted. The distribution of samples by commodity is listed in Table 1. One hundred samples of infant foods were collected. These included cereals, fruit & vegetable purees, and mixed meals (e.g. meat and potatoes). One hundred samples of infant formula were also collected. They consisted of powdered formula, ready-to-serve formula, and concentrated formula.

Table 1. Sample distribution by food category

Infant food		**Infant formula**	
Cereals	26	Powdered	20
Fruits & vegetables	35	Ready-to-serve	20
Mixed dishes	39	Concentrate	60
Total	**100**	**Total**	**100**

These commodities were obtained in a variety of packaging types to explore the link between packaging and bisphenol-A. For infant foods, the packaging types included:

- glass jars with metal lids (glass-metal)
- plastic cups/trays (plastic)
- paperboard coated with waterproof plastic (paper-plastic)

For infant formula, packaging included:

- glass jars with metal lids (glass-metal)
- metal cans (metal)
- paperboard cans with metal ends (paper-metal)

Sampling was performed in Dartmouth, Nova Scotia and surrounding area. The countries of origin as specified on the product labels for these samples were Canada, USA, the Netherlands and Ireland. It is important to note however that the term 'country of origin' only refers to the country of manufacture and may not accurately reflect the origin of the product's ingredients. Likewise, the 'country of origin' does not represent the origin of the packaging material (i.e. the potential source of bisphenol-A).

2.4 Analytical testing

Bisphenol-A analysis was carried out by the CFIA Dartmouth Laboratory using the following method: "Determination of Bisphenol A in Liquid Infant Formula by Gas Chromatography-Mass Spectrometry". This method was provided to CFIA by Health Canada research scientists. The method was also adapted and validated for analysis of infant food. Care was taken by laboratory personnel to ensure that samples were not exposed to any laboratory equipment/vessels that could have the potential to leach bisphenol-A. The formula samples (both powdered and concentrate) were diluted to the concentrations specified on the package label prior to analysis to allow for the concentrations to represent "as consumed" products. The limit of detection (LOD) and limit of quantitation (LOQ) are 0.33 ng/g (ppb) and 1.1 ng/g (ppb), respectively.

2.5 Limitations

The bisphenol-A in infant food and infant formula targeted survey was designed to provide a snapshot of the products available to Canadians. In total, 200 samples were collected and analyzed. This represents of small fraction of the products available to consumers, and therefore care must be taken when interpreting results. The data cannot be considered representative of bisphenol-A levels found in all food categories or from specific regions/countries of origin.

3. Results and Discussion

3.1 Bisphenol-A and infant food/formula

From a total of 200 samples, 118 samples (59%) did not contain detectable levels of bisphenol-A. The remaining 82 samples (41%) contained bisphenol-A at levels ranging from 1.4 to 9.6 ng/g. The prevalence of bisphenol-A was lower in infant food (9%) than in infant formula (73%). Figure 1 illustrates the average bisphenol-A concentrations detected in infant foods and formula tested. Average bisphenol-A residues were calculated using only those samples that had detectable residues, so as to not artificially decrease the average based on the number of non-detects. Results are also grouped by the

packaging type of each product. This information can also be found in Table 2, which shows the range of bisphenol-A concentrations in positive samples by packaging type.

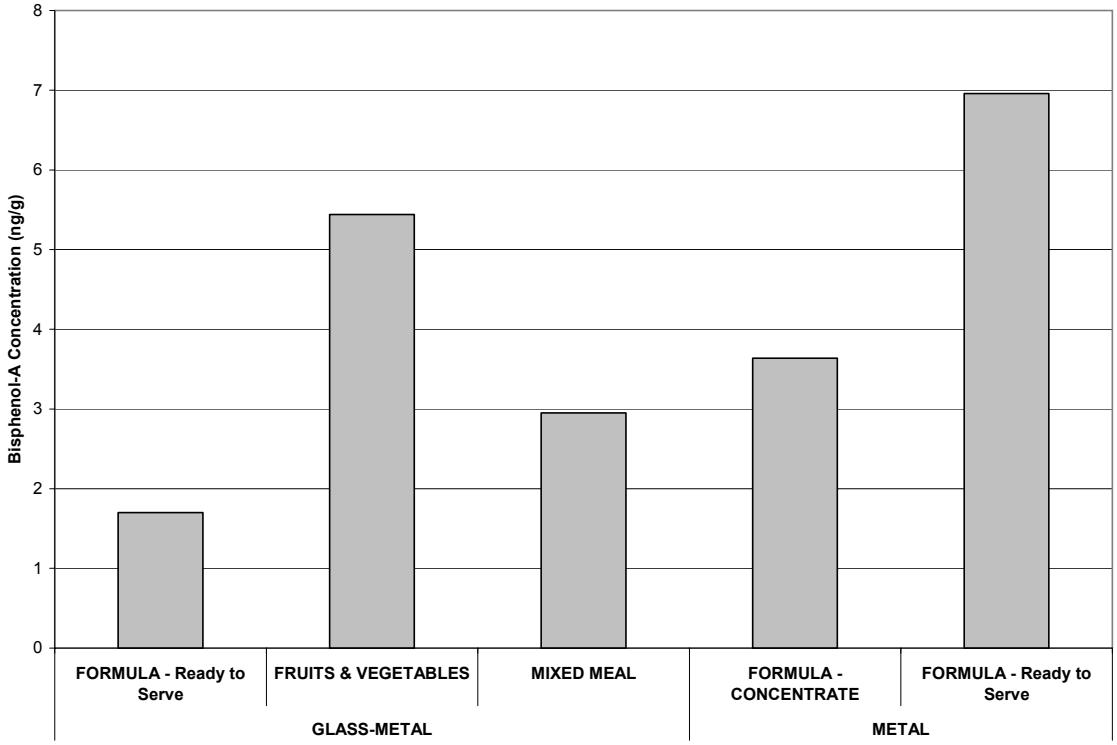

Figure 1. Average* concentration of bisphenol-A in infant foods and infant formula samples presented by packaging type.
(*Average of positive samples only)

Table 2. Positive samples and corresponding bisphenol-A levels presented by type of packaging

Packaging	Commodity	No. Positive/ Commodity	BPA Range (ng/g)	BPA Average* (ng/g)
Glass	Formula - RTS	3 / 3	1.6 – 1.9	1.70
	Fruits & vegetables	5 / 20	<1.1 – 9.6	5.44
	Mixed meals	4 / 7	<1.1 – 5.2	2.95
Metal	Formula - Concentrate	60 / 60	1.7 – 5.4	3.64
	Formula - RTS	10 / 17	<1.1 – 9.2	6.96

* Average of positive samples only

Infant food

As depicted below in Figure 2, no detectable levels of bisphenol-A were found in infant cereals (0 of 26 samples). Bisphenol-A was detected in a limited number of fruit and vegetable samples (5 of 30, 17%) and mixed meals (4 of 39, 10%). All of the samples with detectable levels of bisphenol-A were packaged in glass containers with metal lids. The range of bisphenol-A concentrations in fruits and vegetable samples was <1.1–9.6 ng/g, whereas in mixed meals the range of concentrations was <1.1-5.2 ng/g.

Infant formula

No detectable levels of bisphenol-A were found in powdered infant formula (0 of 20 samples). Conversely, bisphenol-A was detected in 13 of 20 (65%) ready-to-serve formula samples and 100% (60 of 60 samples) of concentrated infant formula samples. The ready to serve formula samples with detectable levels of bisphenol-A were packaged in either metal cans (n=10), or glass containers with metal lids (n=3); all of the concentrated formula samples were packaged in metal cans. The range of bisphenol-A concentrations was 1.7-5.4 ng/g in concentrated infant formula, and <1.1-9.6 ng/g for ready-to-serve formulas. These findings are consistent with results from similar surveys examining bisphenol-A in infant formula in Canada and the United States[3,4,10] (See appendix A).

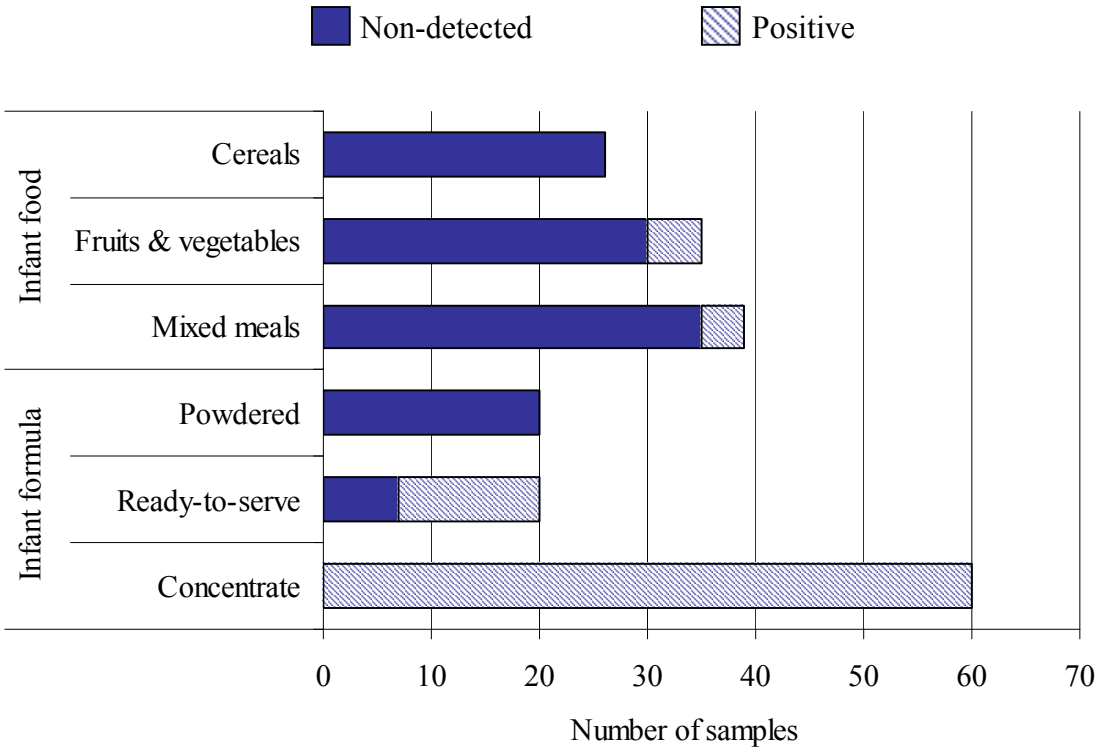

Figure 2. Number of samples with non-detected and positive results for bisphenol-A in infant food and infant formula

3.2 Bisphenol-A and food packaging

Since bisphenol-A is known to migrate out of food packaging into food[8], a comparison of results with respect to packaging type was undertaken. In this survey, plastic cups were common for fruit purees, and plastic trays were typical of infant 'TV-dinners' or mixed meals. In this survey, paper-plastic packaging refers to milk-carton type containers, sometimes with a screw-on cap typically containing infant cereals. Lastly, paper-metal packaging refers to cardboard cans with metal ends, which contained powdered infant formula. Samples in plastic, paper-plastic and paper-metal packaging did not contain detectable levels of bisphenol-A (see Figure 3). Rather, the 82 samples with bisphenol-A were found in metal cans or glass jars with metal lids.

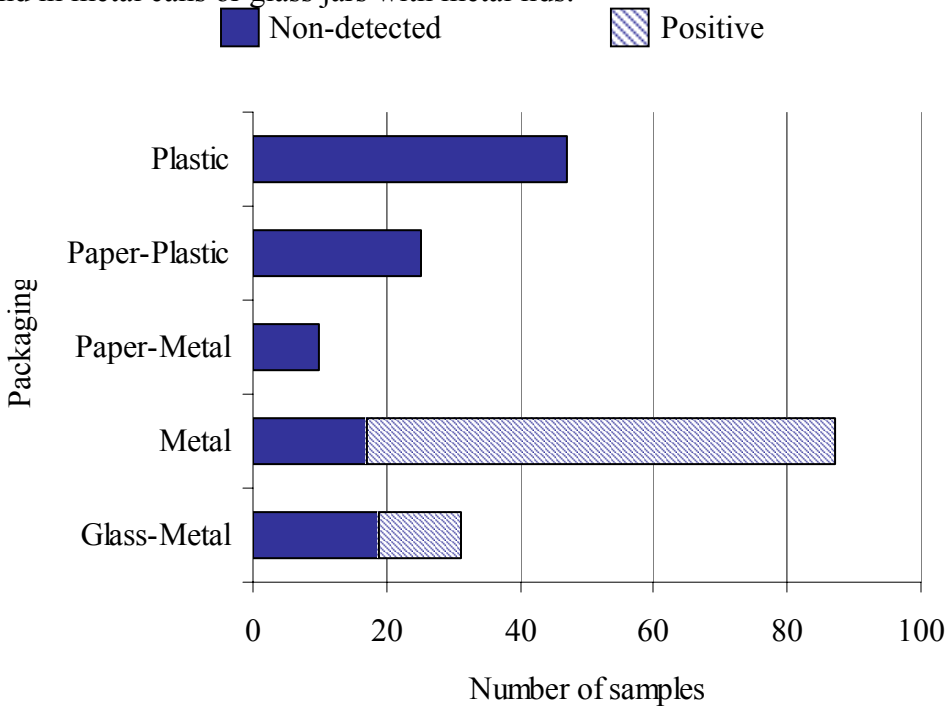

Figure 3. Number of samples with non-detected and positive results for bisphenol-A as a function of packaging

The distribution of the 82 positive samples is presented in Table 2. Seventy of the 82 positive samples for bisphenol-A were packaged in metal cans while the remaining 12 were samples in glass jars. Metal cans are commonly used for ready-to-serve and concentrated infant formula. Studies have indicated that much of the bisphenol-A present in coatings migrate into food directly after heat processing[12]. Generally speaking, liquid milk based formula undergoes a heat treatment/sterilization process intended to maintain the integrity of the product, and generally involve either retort sterilization or ultrahigh-temperature treatment. No information on which processes were used on the specific products tested was available. In this survey, bisphenol-A was more prevalent in concentrated infant formula, but levels were lower than in ready to serve formula.

Overall, the levels of bisphenol-A observed in infant formula in metal cans agrees with previous findings by Health Canada[3] and are not considered a health risk for infants.

The remaining 12 positive samples were found in glass containers. The most likely source of bisphenol-A in glass packaging is the accompanying metal lid. Bisphenol-A is used to make the epoxy resins, which are used as protective linings on the insides of metal lids. Bisphenol-A was found in all three ready-to-serve infant formula samples packaged in glass jars, but at very low levels (1.6-1.9 ng/g). Prevalence was lower in fruits & vegetables, and mixed meals, but bisphenol-A levels were slightly higher (<1.1-9.6 ng/g). Based on previous surveys in Canada and the US, the levels of bisphenol-A observed in glass jars with metal lids are within the normal range for infant food and infant formula[3,4,10]

4. Conclusions

Two hundred samples were collected and analyzed for bisphenol-A. A wide array of infant food and formula were targeted, in a variety of food packaging types. Prevalence of bisphenol-A was greater in infant formula (73%) than infant food (9%). This is likely a result of food packaging since detectable levels of bisphenol-A were only found in metal cans and glass containers with metal lids. These types of containers accounted for the majority of positive infant formula samples, as concentrated or ready-to-serve infant formula. Samples in plastic, paper-plastic and paper-metal, often used for infant food, did not contain detectable levels of bisphenol-A. Overall, levels of bisphenol-A were similar to those previously observed and are not considered to pose a health risk to newborns and infants.

5. Future Considerations

The bisphenol-A targeted survey provided valuable information regarding the prevalence and levels bisphenol-A in infant food and infant formula as a function of packaging. A follow up survey should be designed to include the following:

- An increased total number samples to provide a more statistically robust dataset
- A focus on commodities in metal and glass packaging, including non-infant food which may be offered to infants (e.g. canned fruit juice, canned fruit cups etc)
- Assessment of bisphenol-A levels as a function of epoxy resin surface area

6. References

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Appendix A - Summary of bisphenol-A surveys conducted nationally and internationally in the recent past.

Year	Study	Matrix	Container	n	Range (ng/g)	Mean (ng/g)	MDL (ng/g)	Notes
2008-2009	Health Canada[3]	Liquid infant formula	Metal can	21	2.27 - 10.23	5.14	0.5	
2009	Health Canada[4]	Baby food	Glass with metal lid	99	MDL - 7.22	0.96	0.18	
2009	Health Canada	Powdered infant formula	Paperboard can	38	MDL	MDL	0.13	
2010	US Food and Drug Administration[10]	Ready to serve	HDPE	5	0.48 - 2.1	1.52	0.15	
			Glass	2	1.4 - 1.9	1.65		
			Metal can	33	0.56 - 10	5.79		
		Concentrate liquid formula	Metal can	30	0.56 - 11	5.71	0.15	Not diluted
		Powdered infant formula	Metal or other	26	MDL - 0.40	0.16	0.15	
2002	Food Standard Agency (UK)[13]	Infant formula	Easy open, three-piece	6	MDL	MDL	7	
2009/10	CFIA	CEREALS	glass and paper/plastic	26	MDL	MDL	1.1	
		FORMULA - CONCENTRATE	Metal can	60	1.7 - 5.4	3.64	1.1	
		FORMULA - POWDERED	metal and paper/metal	20	MDL	MDL	1.1	
		FORMULA - RTS	metal and glass	20	MDL - 9.2	3.74	1.1	
		FRUITS & VEGETABLES	glass and plastic	35	MDL - 9.6	0.78	1.1	
		MIXED MEAL	glass and plastic	39	MDL - 5.2	0.30	1.1	

*MDL=Minimum Detection limit

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