

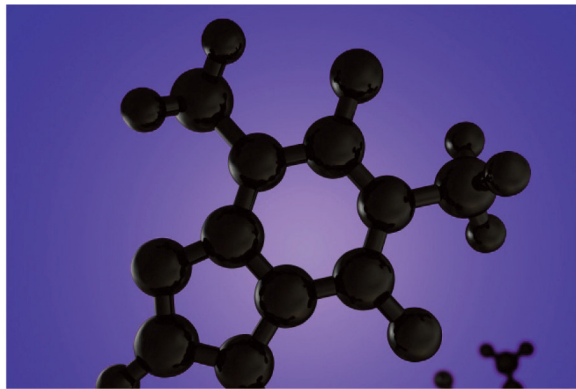


# Food Safety Action Plan

## REPORT

2010-2011 Targeted Surveys

Chemistry



### *Melamine in Milk-based and Soy-based Products*

TS-CHEM-10/11

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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 objective of this survey was to generate baseline surveillance data on the level of melamine in milk-based and soy-based products available on the Canadian retail market.

Melamine is a synthetic chemical used in commercial and industrial applications. It does not occur naturally in the environment or in food and is not permitted for use in food. However, it may be found in food at low levels that are not of concern to human health, as a result of its industrial uses, such as from fertilizers or as a by-product from the use of certain pesticides (e.g., cyromazine). In the past<sup>1</sup>, melamine was found to have been added to foods intended for human consumption in China, including infant formula, in order to fraudulently boost the apparent protein content. Since protein content is calculated from the level of nitrogen in a food, melamine was intentionally added to increase the total nitrogen value which results in a greater apparent protein content.

The 2010-2011 Melamine Survey targeted domestic and imported milk-based and soy-based products. A total of 590 samples were collected from grocery and specialty stores in 11 Canadian cities between October 2010 and March 2011. The samples collected included 302 milk-based and 288 soy-based products.

One hundred percent of the results obtained from the testing of milk-based and soy-based products in this targeted survey were below Health Canada's melamine interim standard of 2.5 parts per million (ppm) for foods containing milk or milk-derived ingredients. None of the infant formula/cereal samples tested positive (< 0.05 ppm) for melamine.

# 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.

In response to a past history of melamine adulteration of food in China<sup>1</sup>, a melamine targeted survey in milk-based and soy-based products was initiated to establish baseline data in protein-rich foods of domestic and imported origin. The melamine levels observed in this survey were compared with data from the 2007-2008 Directed Melamine Sampling and the 2009-2010 FSAP Targeted Survey on melamine residues in fluid milk, milk-based products and soy-based products, both conducted by the CFIA.

## 1.3. Acts and Regulations

The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing Canadian laws and regulations on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act & Regulations* (FDAR).

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. There are also a number of maximum levels that do not appear in the regulations and are referred to as standards. In the case of melamine, Health Canada has set an interim standard of 0.5 parts per million (ppm) in infant formula and sole source nutrition products (e.g., meal replacement products) and 2.5 ppm in other food products containing milk and milk-based ingredients<sup>ii</sup>. The interim standards set by Health Canada are consistent with those adopted by other food regulatory agencies in Europe, Australia, New Zealand and the United States<sup>ii</sup>.

The analytical results from targeted survey samples were compared to the Canadian interim melamine standard. Levels at or below the interim standard did not require further action. Levels above the interim standard were further assessed by Health Canada for potential risk to consumers' health. Follow-up actions are initiated on a case-by-case basis 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.

It should be noted that there is no standard set for melamine in soy-based products. For the purposes of this targeted survey, the interim standard of 2.5 ppm melamine established for milk-based products was used to determine if follow-up action should occur for soy-based products.

## 2. Survey Details

### 2.1. Melamine

Melamine is produced as a high-volume synthetic chemical and is used in a variety of industrial applications (e.g., electrical equipment, laminates, permanent-press fabrics, flame-retardants)<sup>i</sup>. It does not occur naturally in food, nor is it permitted to be added to food. However, trace amounts of melamine can be present in food as a result of uses in food contact materials, including articles made of melamine-formaldehyde plastics, can coatings, adhesives, paper and board<sup>iii</sup>. Also, melamine can be present as a result of environmental degradation of sanitizing solutions used for cleaning food-processing equipment and food-contact articles<sup>iii</sup>. Detectable levels of melamine may be present in foodstuffs through the use of certain pesticides (e.g., cyromazine). In the case of cyromazine, melamine is a degradation product of the pesticide. Melamine may be

present in animal products (i.e., milk, meat) at baseline concentrations owing to cyromazine use on crops used as animal feed or its use as a veterinary drug<sup>iv</sup>.

Melamine has been used as a food adulterant for economic gain in China<sup>i</sup>. The combustion method used to analyze the protein content of food measured the level of nitrogen. Since melamine is an inexpensive compound high in nitrogen, this characteristic led to its illegal addition to food in order to boost its apparent protein content. In September 2008, melamine adulteration was found in a number of different brands of infant formula manufactured and sold in China<sup>i</sup>. It was discovered that melamine was deliberately added to raw milk for a number of months<sup>v</sup>. The presence of melamine was linked to an increased incidence of kidney stones and renal failure observed in infants resulting in hospitalization and even death. It is important to note that major manufacturers of infant formula sold in Canada do not source milk ingredients from China<sup>ii</sup>. In 2008, a number of countries, including Canada, detected elevated levels of melamine in certain food products manufactured in China or containing ingredients sourced from China. Recalls were issued for a variety of products, including milk-based candies, instant powdered coffee products, biscuits, chocolates, milk-based drinks, cakes, ammonium bicarbonate, animal feed and feed ingredients, egg powders and fresh eggs, and creamers<sup>vi, vii, viii</sup>.

Available data indicates that simultaneous exposure to melamine and cyanuric acid is more toxic than exposures to each compound individually<sup>v</sup>. The target for melamine and cyanuric acid toxicity is the urinary system in humans. Of the infants who were affected by the adulteration of infant formula, many of them had stones in the kidney, ureter or bladder that were composed of melamine and uric acid (the latter being naturally present in urine)<sup>iii</sup>.

## 2.2. Rationale

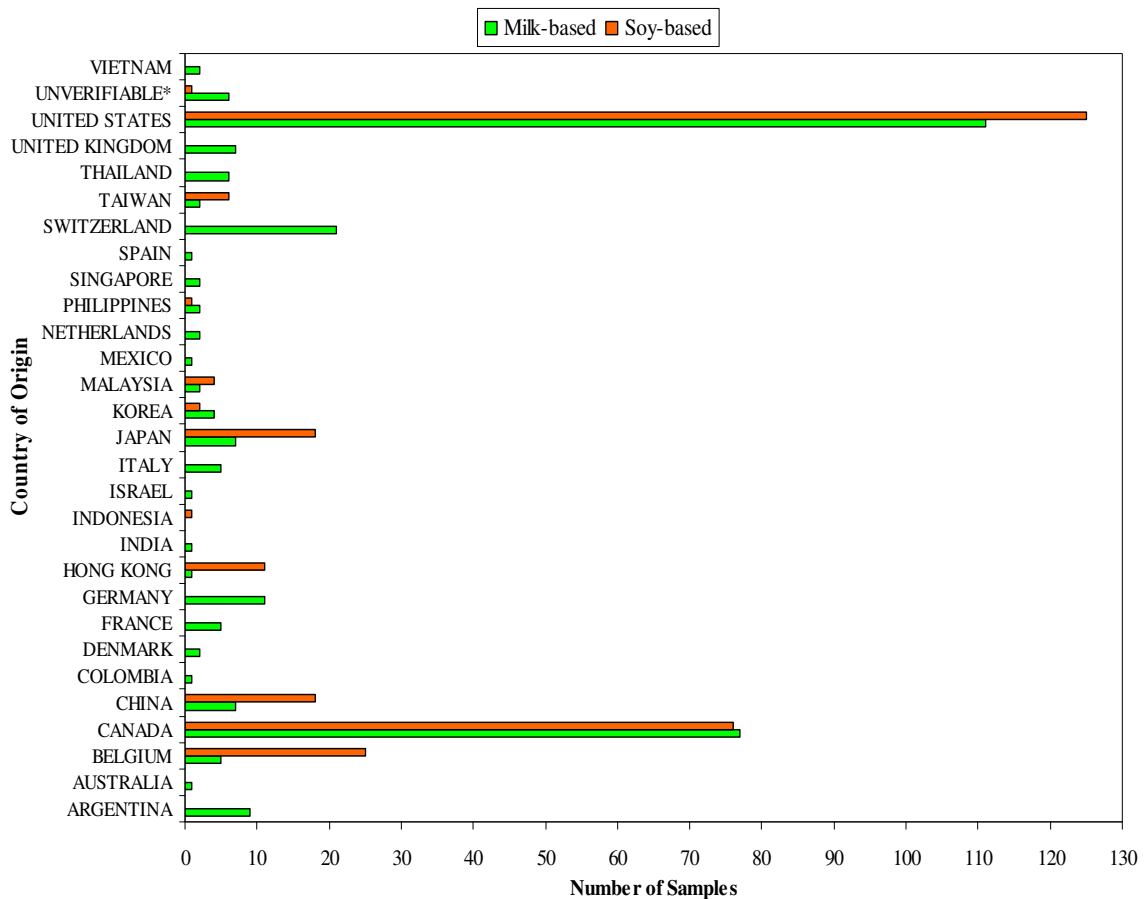
The main objective of this survey was to generate baseline surveillance data on the level of melamine in milk-based and soy-based products available on the Canadian retail market. As a result of the previous cases of melamine adulteration, the criterion used to select products sampled in this survey was that they contain protein-rich ingredients such as milk powder or soy protein. Products such as chocolate, candy, biscuits containing milk or milk products are regularly imported into Canada from countries where adulteration with melamine has been known to occur. Therefore, it was considered important to continue surveying for potential contamination in these products. As well, soy is often added as a protein source in imitation meats, beverage powders, cheeses and creamers.

All the survey data was shared with Health Canada for use in conducting human health risk assessments of melamine.

## 2.3. Sample Distribution

The 2010-2011 Melamine survey targeted domestic and imported milk-based and soy-based products. A total of 590 samples were collected in pre-packed retail containers from grocery and specialty stores in 11 Canadian cities between October 2010 and March 2011.

The 590 samples collected included 153 domestic products, 435 imported products and 2 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 true 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. The distribution of samples collected in this survey with respect to the country of origin is depicted in Figure 1.



\*Unverifiable refers to samples for which the country of origin could not be determined based on the product package.

**Figure 1. Distribution of samples by country of origin**

The 590 samples collected included 302 milk-based and 288 soy-based products. Milk-based products included any products in which milk was one of the first three ingredients indicated on the label. The milk-based samples included refrigerated beverages, candies, cheeses, condensed milks, creams (refrigerated ready-to-serve), infant formula/cereals (powders), milk (2%, evaporated), instant drink mixes, yogourt, and sauces. Soy-based products included refrigerated and non-refrigerated soy drinks/beverages, cheeses, creams, soy milk, soy sauces, tofu, food products containing soybean meal, yogourt and snacks.

## 2.4. Method Details

The analytical method used in the current targeted survey is a confirmatory method to detect for the presence of melamine only. Although cyanuric acid was not specifically tested for in this survey, there is the potential that the presence of melamine can act as an indicator compound.

Samples were analysed 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 reference method.

The analytical method used by the testing laboratory was based on the CFIA reference method entitled 'Determination of Melamine using Cation Exchange and Liquid Chromatography Electrospray Ionization Mass Spectrometry (LC/ESI-MS/MS)'. The method consisted of protein precipitation by acetonitrile/water, extraction of melamine by cation exchange solid phase extraction followed by sample analysis by liquid chromatography electrospray ionization tandem mass spectrometry (LC/ESI-MS/MS). The method has a limit of detection (LOD) of 0.05 ppm and a limit of quantitation (LOQ) of 0.06 ppm.

## 2.5. Limitations

The melamine survey was designed to provide a snapshot of the melamine levels in food available to Canadian consumers. In comparison to the total number of milk-based and soy-based products in the Canadian market, a sample size of 590 represents a small fraction of products available to consumers. Therefore, care must be taken when interpreting and extrapolating these results. Given that the product label may not unambiguously identify the actual origin of the product or ingredient, no distinct comparison could be made regarding the country of origin and the levels of melamine in products. Regional differences, impact of product shelf-life, packaging and storage conditions, or cost of the commodity on the open market were also not examined in this survey.



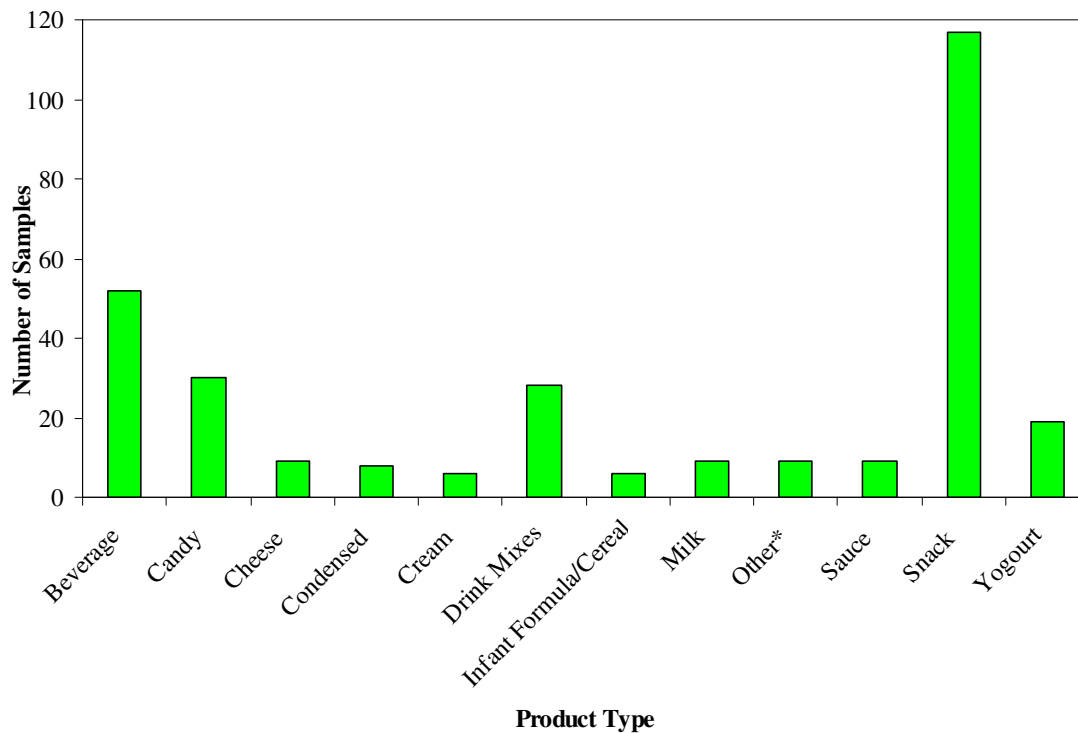
### 3. Results and Discussion

#### 3.1. Overview of Melamine Results

The 2010-2011 Melamine Survey consisted of testing 590 samples obtained at the retail level. Commodities collected included 302 milk-based and 288 soy-based products of both domestic and imported origins. Five hundred and eighty-eight samples had no detectable levels of melamine, while the remaining two samples had detectable levels of melamine well below Health Canada’s interim standard of 2.5 ppm established for milk-based products.

#### 3.2. Milk-based products

Three hundred and two milk-based samples (77 domestic, 224 imported, and one of unverifiable origin) were analyzed in this survey. Products were considered milk-based if milk was listed as one of the first three ingredients. Milk-based samples were separated into the following 12 product types: beverages (refrigerated ready-to-serve), candies, cheeses (soft, spreadable, dips), condensed milks, creams (refrigerated ready-to-serve), infant formula/cereals (powders), milk (2%, evaporated), instant drink mixes, snacks (puddings, cookies, biscuits, custards, etc.), yogourt, sauces (pasta, cooking) and other (cake and dessert mixes, milk powders). The distribution of milk-based samples by product type is shown in Figure 2.



\* Other included cake and dessert-type mixes and milk powders.

**Figure 2. Distribution of milk-based samples by product type**

One hundred percent of the results obtained from the testing of milk-based products in this targeted survey were below the interim standards. Only two (0.7%) of the 302 milk-based samples contained detectable levels of melamine (Table 1). The melamine levels detected in these two samples were well below Health Canada’s interim maximum limit of 2.5 ppm. None of the infant formula/cereal sample results were positive for melamine.

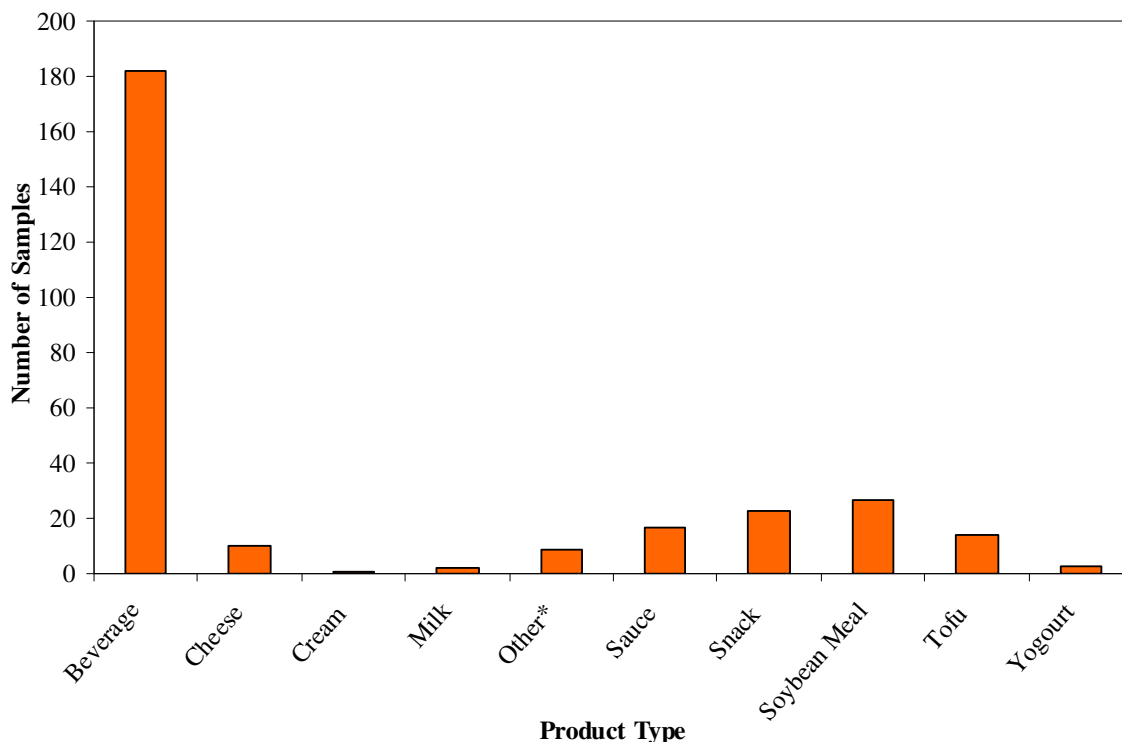
**Table 1. Summary of melamine detections in milk-based products**

<b>Product Type</b>	<b>Product</b>	<b>Country of Origin</b>	<b>Melamine Level (ppm)</b>
Beverage	Milk Coffee Drink	China	0.482
Snack	Creamed Rice Pudding	United Kingdom	0.087

Results of the present survey were compared to those of the 2007-2008 Directed Melamine Sampling and the 2009-2010 FSAP Targeted Survey on melamine residues in fluid milk, milk-based products and soy-based products, both conducted by the CFIA<sup>ix</sup>. In the 2007-2008 directed sampling survey, 808 samples, originating from 23 countries, were obtained by CFIA inspectors at the importer/manufacturer level. In total, 21 milk-based samples analysed under the directed sampling survey had melamine levels above Health Canada’s interim standard of 2.5 ppm established for milk-based products and the highest melamine level of 631 ppm was found in a single sour milk beverage<sup>ix</sup>. In the 2009-2010 survey, 237 samples of milk-based products from 14 countries were analysed. Similar types of milk-based products were analysed in both past and current survey. The compliance rate in the 2009-2010 survey (100%) and that of the present survey (100%) was higher than the 97% overall compliance rate observed in the 2007-2008 directed sampling survey.

### **3.3. Soy-based products**

Two hundred and eighty-eight soy-based samples (76 domestic, 211 imported, and of one unverifiable origin) were analyzed in this survey. Products were considered soy-based if soy, soybean meal and/or soy lecithin were listed in the ingredients. Soy-based products were separated into the following ten product types: soy drinks/beverages (refrigerated and non-refrigerated), cheeses, creams, soy milk, soy sauces, tofu, food products containing soybean meal, snacks (puddings), yogourt, and other (soy nuts and butters, spreads). The distribution of soy-based samples by product type is shown in Figure 3.



\* Other included soy nut and butters and soy-based spreads.

**Figure 3. Distribution of soy-based samples by product type**

The compliance rate for soy-based samples tested in this survey was 100% as none of samples had detectable level of melamine.

Results of the present survey were compared with those of the 2009-2010 FSAP Targeted Survey on melamine residues in fluid milk, milk-based products and soy-based products<sup>ix</sup>. Three hundred samples of soy-based products from ten countries were analysed in the 2009-2010 survey. The compliance rate in the 2009-2010 survey (100%) was the same as that of the present survey (100%).

## 4. Conclusions

The 2010-2011 melamine targeted survey was completed as a follow-up survey to the 2009-2010 melamine targeted survey. The main objective of this survey was to generate further baseline surveillance data on the levels of melamine in milk-based and soy-based products available on the Canadian retail market. The compliance rate was 100% for both the milk-based and soy-based products tested in this targeted survey. Only two of the 302 milk-based samples tested contained detectable levels of melamine. The melamine levels detected ranged from 0.087 – 0.482 ppm and were well below Health Canada’s interim maximum standard of 2.5 ppm. None of the infant formula/cereal sample results were positive for melamine.

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