

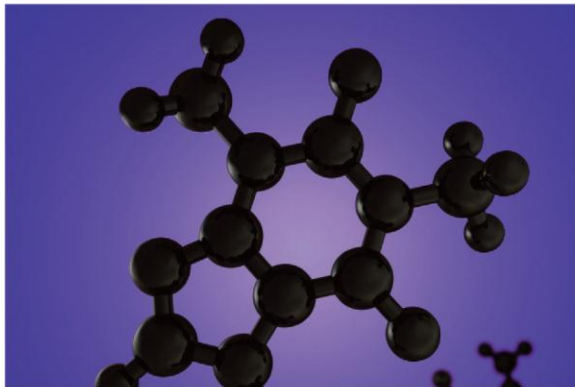


Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Melamine in Selected Foods

TS-CHEM-11/12

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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 targeted survey was to generate baseline surveillance data on the level of melamine in meat and seafood alternatives, meal replacements, protein powders, and snack 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 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 past¹, melamine was found to have been added to foods intended for human consumption in China, including infant formula, in order to fraudulently boost the total nitrogen 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 resulted in greater apparent protein content.

The 2011-2012 Melamine in Selected Foods survey targeted domestic and imported meat and seafood alternatives, meal replacements, protein powders and snack products. A total of 590 samples were collected from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012. The samples collected included 175 meat alternatives (wheat- and soy-based), 21 seafood alternatives (plant-, soy-, and wheat-based), 95 meal replacements (powders, ready-to-drink shakes), 102 protein powders (casein protein, egg white protein, soy protein, and whey protein), and 197 snack products (biscuits, cookies, crackers, and wafers).

Melamine was not detected in any sample in this survey. Given that none of the samples in this survey were positive for melamine; 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 12 main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess and prioritize potential food safety hazards through risk mapping, information gathering and 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 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 commodity types and/or geographical areas.

Due to the vast number of chemical hazards and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all chemical hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, media reports, and/or a risk-based model developed by the Food Safety Science Committee, a group of federal, provincial and territorial subject matter experts in the area of food safety.

In response to a past history of melamine adulteration of food¹, this melamine survey was initiated to further establish baseline data in protein-rich foods of domestic and imported origin. Where applicable, the results observed in this survey were compared to data from the 2007-2008 Directed Melamine Sampling (unpublished data presented in the 2009-2010 FSAP Melamine survey report)¹³, and both the 2009-2010 FSAP Melamine Residues in Fluid Milk, Milk-based Products and Soy-based Products¹³, and 2010-2011

FSAP Melamine in Milk-based and Soy-based Products (unpublished) surveys, all conducted by the CFIA.

1.3. Acts and Regulations

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

Health Canada establishes the health-based 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 ingredients². The interim standards set by Health Canada were developed using a consistent approach adopted by other food regulatory agencies such as Europe, Australia, New Zealand and the United States³.

Elevated levels of melamine 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.

Currently, there is no standard set for melamine in wheat-based and soy-based products. For the purposes of the 2009-2010 FSAP Melamine Residues in Fluid Milk, Milk-based Products and Soy-based Products¹³, and 2010-2011 FSAP Melamine in Milk-based and Soy-based Products (unpublished) surveys, 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)¹. 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 board⁴. Also, melamine can be present as a result of environmental degradation of sanitizing solutions used for cleaning food-processing

equipment and food-contact articles⁴. 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 (e.g., milk, meat) at baseline concentrations owing to cyromazine use on crops used as animal feed or its use as a veterinary drug⁵.

Melamine has been used as a food adulterant for economic gain in China¹. The combustion method, used to analyze the protein content of food, measures 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 China¹. It was discovered that melamine had been deliberately added to raw milk for a number of months⁶. The presence of melamine was linked to an increased incidence of kidney stones and renal failure observed in infants, resulting in hospitalizations and even death. It is important to note that major manufacturers of infant formula sold in Canada do not source milk ingredients from China³. 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, fresh eggs, and creamers^{7,8,9}.

2.2. Rationale

The main objective of this survey was to generate baseline surveillance data on the level of melamine in meat alternatives, seafood alternatives, meal replacements, protein powders, and snack 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. Products such as biscuits containing milk or milk products are regularly imported into Canada from countries where adulteration with melamine has been known to occur. In 2008, Taiwan's Department of Health found elevated melamine levels in ammonium bicarbonate (a leavening agent used in the making of baked goods) imported from China¹⁰. Occurrence data on melamine in products from different countries revealed that in addition to milk-based products, biscuits, cookies and crackers were found to be contaminated with melamine⁵.

Limited data is available on the occurrence of melamine in products containing soy protein or wheat gluten intended for human consumption. Soy and wheat gluten is often added as a protein source in imitation meats and beverage powders. Elevated levels of melamine have been detected in various powdered protein (milk and soy) ingredients⁵. High levels of melamine were also detected in protein powders derived from milk⁶. Although supplements with high protein (e.g., whey) content available on the Canadian market are usually made in the United States¹¹, the raw ingredients may be imported.

Therefore, it was considered important to examine the melamine levels in meat and seafood alternatives, protein powders, and meal replacements products to ensure that the population consuming these products is not at risk.

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

2.3. Sample Distribution

The 2011-2012 Melamine in Selected Foods survey targeted imported and domestic meat and seafood alternatives, meal replacements, protein powders, and snack products. A total of 590 samples were collected in pre-packed retail containers from grocery and specialty stores in 11 Canadian cities between April 2011 and March 2012.

The 590 samples collected included 350 domestic products, 238 imported products (from 26 countries) 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 samples collected included 175 meat alternatives (wheat- and soy-based), 21 seafood alternatives (plant-, soy-, and wheat-based), 95 meal replacements (powders, ready-to-drink shakes/boosters), 102 protein powders (casein protein, egg white protein, soy protein, and whey protein), and 197 snack products (biscuits, cookies, crackers, and wafers). Table 1 illustrates the distribution of samples by category and by country of origin.

**Table 1. Distribution of survey samples by category and by country of origin
(in order of decreasing number of samples)**

Country of Origin	Number of Meat Alternative Samples	Number of Seafood Alternative Samples	Number of Meal Replacement Samples	Number of Protein Powder Samples	Number of Snack Samples	Total Number of Samples
Canada	113	7	52	60	118	350
United States	46	1	36	41	16	140
Taiwan	5	13			2	20
Italy					9	9
Israel	7				1	8
Switzerland			7		1	8
China	1				6	7
Singapore					7	7
India	1				4	5
United Kingdom					5	5
Hong Kong	1				3	4
Spain					4	4
Austria					2	2
Greece					2	2
Malaysia					2	2
Philippines					2	2
Thailand					2	2
United Arab Emirates					2	2
Unknown*	1				1	2
Croatia					1	1
Jamaica					1	1
Mexico					1	1
Netherlands				1		1
Portugal					1	1
Scotland					1	1
Turkey					1	1
Vietnam					1	1
Yugoslavia					1	1
Overall	175	21	95	102	197	590

*Unknown refers to those samples for which the country of origin could not be determined from the label or sample information

2.4. Method Details

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 method.

Samples were tested as sold, meaning that the product was not prepared as per the package instructions (if applicable). The analytical method used by the testing laboratory was based on the CFIA method entitled ‘Determination of Melamine using Cation Exchange and Liquid Chromatography Electrospray Ionization Mass Spectrometry (LC/ESI-MS/MS)’, and only analyzed for melamine. The method consisted of 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.

The current survey, 2007-2008 Directed Melamine Sampling¹³, and both the 2009-2010¹³ and 2010-2011 (unpublished) FSAP melamine surveys utilized similar analytical methods and had similar reporting limits.

2.5. Limitations

The melamine survey was designed to provide a snapshot of the melamine levels in meat and seafood alternatives, meal replacements, protein powders, and snack products available in Canada and had the potential to highlight commodities that warrant further investigation. The limited sample sizes analyzed represent a small fraction of products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results. Country of origin was assigned for all but two samples based on the 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 Melamine Results

The 2011-2012 Melamine in Selected Foods survey consisted of testing 590 samples obtained at the Canadian retail level. Melamine was not detected in any sample in the survey. Given that none of the samples in this survey were positive for melamine, follow-up actions were not deemed necessary.

The samples collected included 175 meat alternatives (wheat- and soy-based), 21 seafood alternatives (plant-, soy-, and wheat-based), 95 meal replacements (powders, ready-to-drink shakes, and shake boosters), 102 protein powders (casein protein, egg white protein, soy protein, and whey protein), and 197 snack products (biscuits, cookies, crackers, and wafers).

3.2. Melamine Results by Product Type

Results by product type are presented in the following sections, with comparison to results obtained from the CFIA's 2007-2008 Directed Melamine Sampling¹³ and both the 2009-2010¹³ and 2010-2011 (unpublished) FSAP Melamine surveys, where feasible.

3.2.1. Meat and Seafood Alternatives

One hundred and seventy five meat alternative (113 domestic, 61 imported, and one of unverifiable origin) and 21 seafood alternative (7 domestic and 14 imported) samples were analyzed in this survey. Products classified as meat or seafood alternatives contained wheat gluten/wheat protein, soy (protein/bean/milk/meat), vegetarian meats/seafood, textured vegetable protein (TVP)/textured soy protein (TSP), or tofu/bean curd listed as one of the first two ingredients on the product label.

Meat alternative samples included 69 wheat-based (gluten meats (e.g., mock turkey/duck, seitan), wheat gluten, and vegetarian meats (e.g., chicken, sausages, wieners, burgers)) and 106 soy-based (plain and flavoured tofu (silken/soft, medium, firm, extra firm), TVP/TSP, tempeh, vegetarian meats (e.g., chicken, turkey)) products.

Seafood alternative samples included 12 plant-based (primary ingredient was Konjac plant powder; vegan shrimp/prawns/fish fillets/calamari), three wheat-based (veggie shrimp and fish fillet), and six soy-based (fish fillet, oysters, shrimp) products. The distribution of meat and seafood alternative samples by product type is presented in Figure 1.

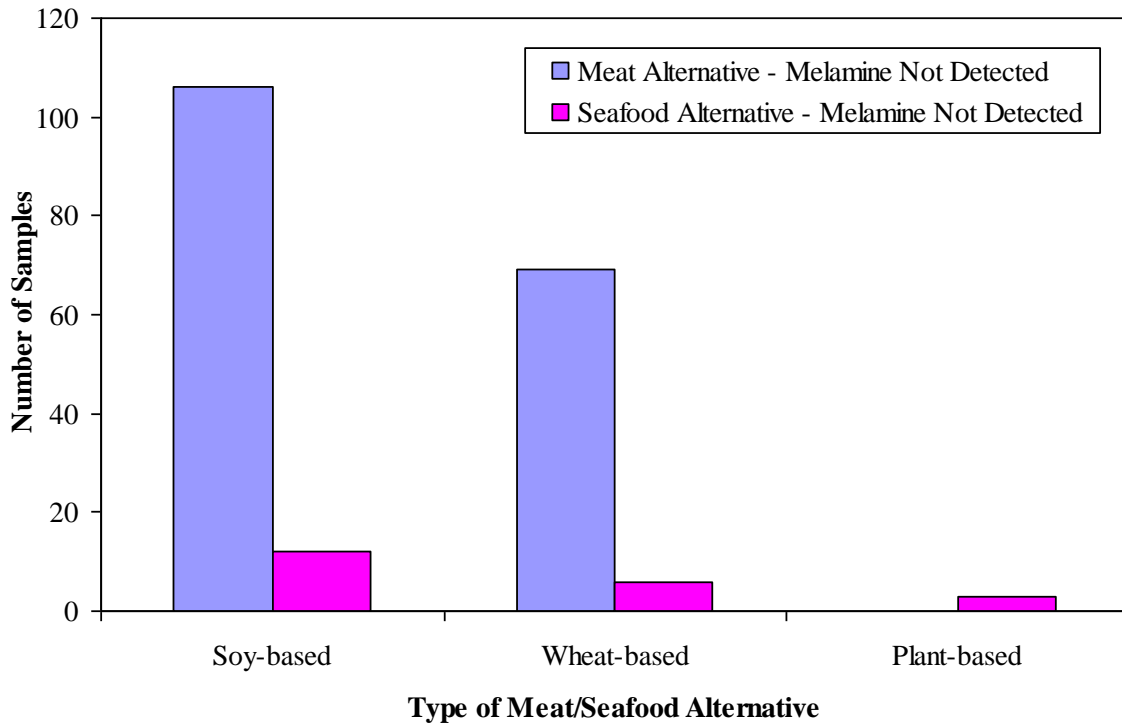


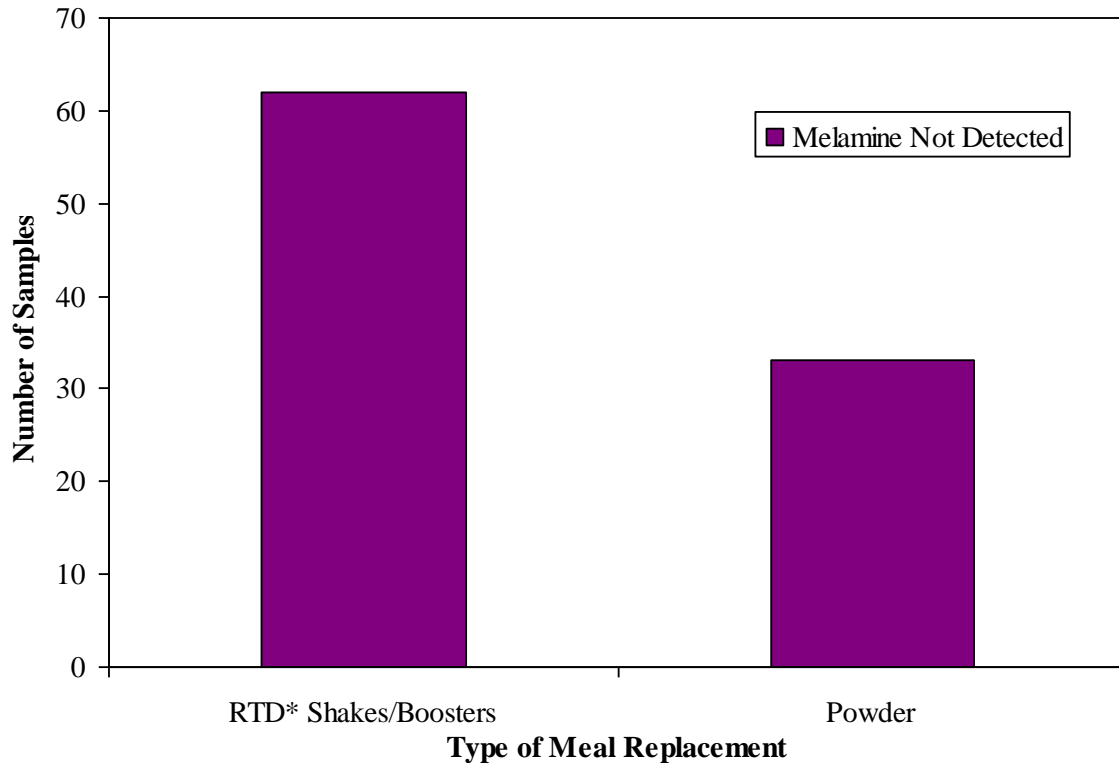
Figure 1. Distribution of meat and seafood alternative samples by type (arranged by decreasing number of samples)

Melamine was not detected in any of the meat and seafood alternative samples analyzed in the current survey. Similarly, melamine was not detected in any of the 25 meat alternative (wheat gluten or TVP/TSP) samples analyzed in the CFIA’s 2007-2008 Directed Melamine Sampling¹³, or in the 37 meat alternative (flavoured/plain tofu or vegetarian meats) samples analyzed in the 2010-2011 (unpublished) FSAP Melamine survey. Of the 123 meat alternative samples analyzed in the previous 2009-2010¹³ FSAP Melamine survey, six samples (miso and soybean pastes/soups) had a detectable melamine level well below Health Canada’s interim standard of 2.5 ppm (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 (Section 1.3)). No seafood alternative samples were analyzed in any of the previous FSAP Melamine surveys or Directed Melamine Sampling. The current survey, previous surveys, and the Directed Melamine Sampling utilized similar analytical methods and had similar reporting limits.

3.2.2. Meal Replacements

Ninety five meal replacement samples (52 domestic, 43 imported) were analyzed in this survey. Meal replacements are single foods which are intended to replace one or more meals or serve as the sole source of nourishment¹². Meal replacements contain approximately 25% of the “recommended nutrient intakes” of 12 vitamins and 10 minerals in a serving¹². In this survey, products classified as meal replacements contained a minimum of 10 grams of protein per serving. Meal replacement samples included 62

ready-to-drink shakes/boosters and 33 powder products. The distribution of meal replacement samples by product type is presented in Figure 2.



* RTD = ready to drink

Figure 2. Distribution of meal replacement samples by type (arranged by decreasing number of samples)

Melamine was not detected in any of the meal replacement samples analyzed in the current survey. No meal replacement samples were analyzed in the CFIA's 2007-2008 Directed Melamine Sampling, or in either of the previous FSAP Melamine surveys.

3.2.3. Protein Powders

One hundred and two protein powder samples (60 domestic, 42 imported) were analyzed in this survey. Protein powder is dietary supplement that is made from one or more of the basic sources of protein (e.g., whey, eggs, soy and casein). In this survey, products classified as protein powders contained a minimum of 15 grams of protein per serving. Protein powder samples (flavoured/unflavoured shake mixes) included: 45 soy protein, 32 whey protein, 16 egg white protein, and 9 casein protein products. The distribution of protein powder samples by product type is presented in Figure 3.

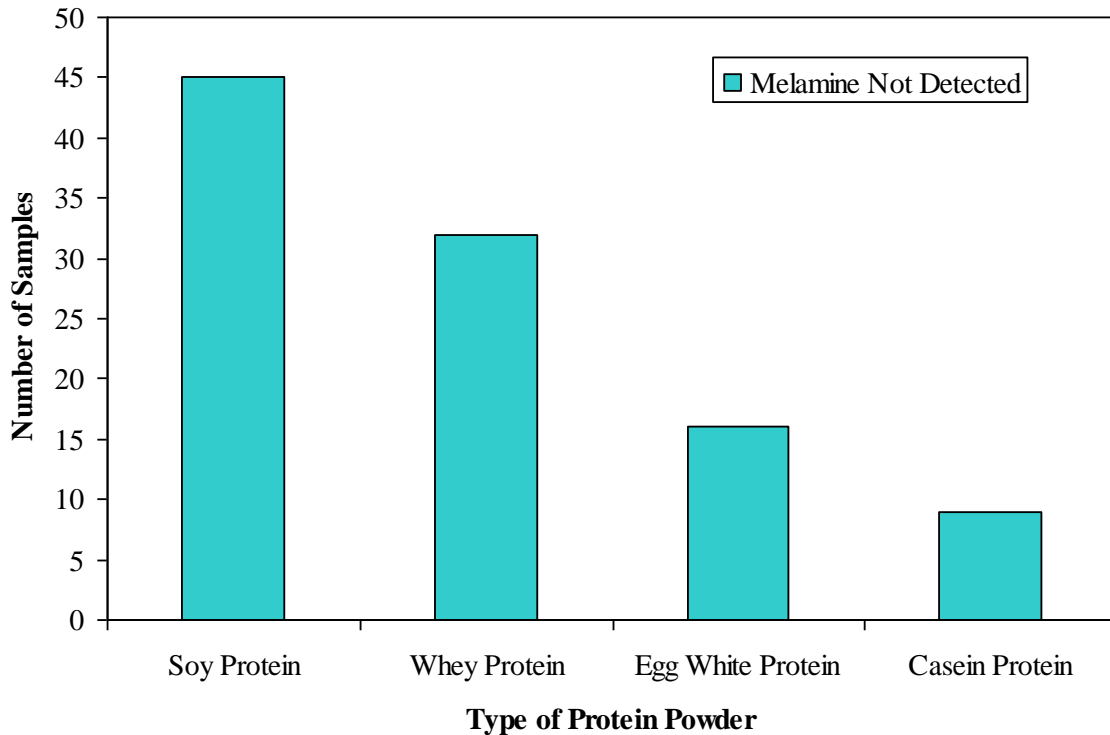


Figure 3. Distribution of protein powder samples by type (arranged by decreasing number of samples)

Melamine was not detected in any of the protein powder samples analyzed in the current survey. Similarly, melamine was not detected in the two whey protein powder samples analyzed in the CFIA’s 2007-2008 Directed Melamine Sampling¹³, the single soy protein powder sample analyzed in the 2009-2010¹³ FSAP Melamine survey, or the single whey powder sample analyzed in the 2010-2011 (unpublished) FSAP Melamine survey. The current survey, previous surveys and the Directed Melamine Sampling utilized similar analytical methods and had similar reporting limits.

3.2.4. Snack Products

One hundred and ninety seven snack samples (118 domestic, 78 imported, and one of unverifiable origin) were analyzed in this survey. Products classified as snacks were ready-to-consume and contained ammonium bicarbonate as an ingredient on the product label. Snack samples included: 73 cookies (plain, flavoured, nut, chocolate chip, fruit/cream filled), 73 crackers (plain, flavoured, multigrain), 38 biscuits (plain and flavoured) and 13 wafer (plain, flavoured, chocolate/fruit/cream filled) products. The distribution of snack samples by product type is presented in Figure 4.

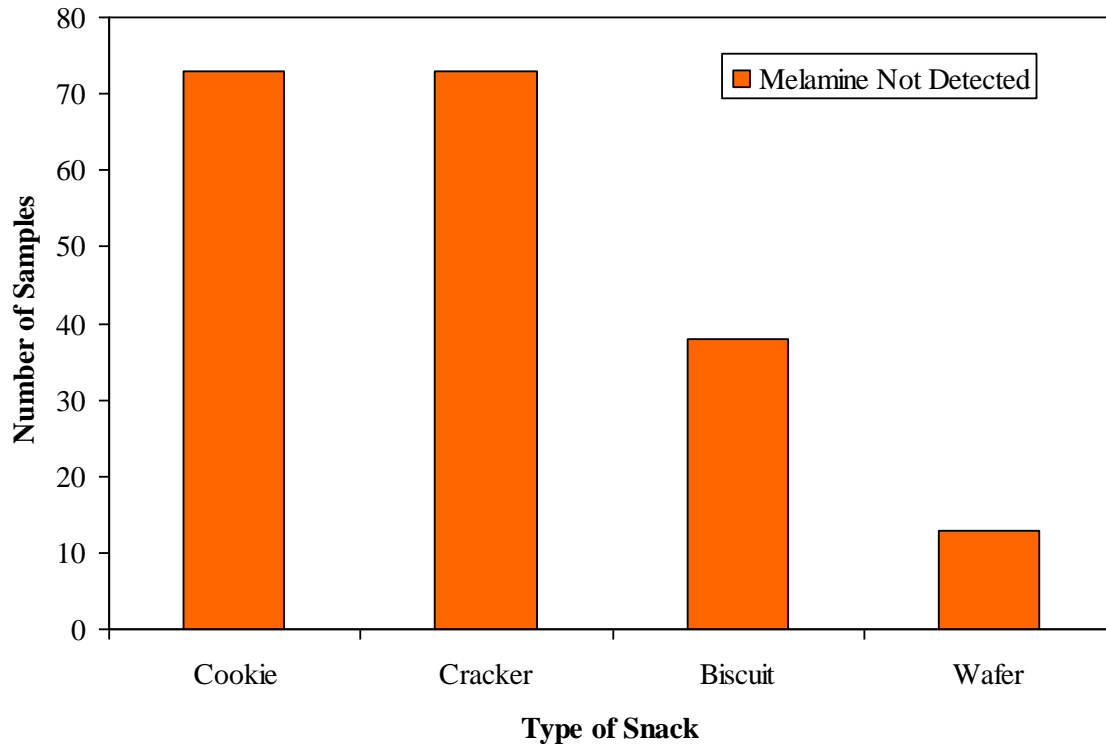


Figure 4. Distribution of snack samples by type (arranged by decreasing number of samples)

Melamine was not detected in any of the snack product samples analyzed in the current survey. Similarly, melamine was not detected in the 15 cookie (plain, flavoured, or nut) samples analyzed in the CFIA 2009-2010¹³ FSAP Melamine survey or the 14 cookie (chocolate, caramel, or nut) samples analyzed in the 2010-2011 (unpublished) FSAP Melamine survey. Of the 122 cookie/cracker/biscuit samples analyzed in the CFIA's 2007-2008 Directed Melamine Sampling¹³, 14 cookie/biscuit (chocolate/jam filled and strawberry/blueberry flavoured, assorted) samples had a melamine level above Health Canada's interim maximum standard of 2.5 ppm (appropriate follow-up actions reflecting the magnitude of the health risk were taken for each of those samples). The current, previous surveys and the Directed Melamine Sampling utilized similar analytical methods and had similar reporting limits.

4. Conclusions

The 2011-2012 Melamine in Selected Foods survey generated additional baseline surveillance data on the level of melamine in domestic and imported meat and seafood alternatives, meal replacements, protein powders, and snack products available on the Canadian retail market.

A total of 590 samples were collected and included 175 meat alternatives (wheat- and soy-based), 21 seafood alternatives (plant-, soy-, and wheat-based), 95 meal replacements (powders, ready-to-drink shakes/boosters), 102 protein powders (casein protein, egg white protein, soy protein, and whey protein), and 197 snack products (biscuits, cookies, crackers, and wafers). Melamine was not detected in any sample in this survey. Given that none of the samples in this survey were positive for melamine, follow-up actions were not deemed necessary.

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