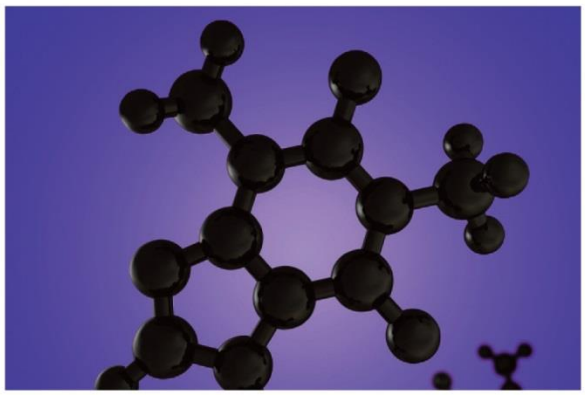
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Chemistry



Arsenic, Cadmium, Lead, Mercury and Aluminum in Infant Formulas, Meal Replacement Beverages, and Nutritional Supplement Beverages

TS-CHEM-11/12

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 examine various foods for specific chemical and microbiological hazards.

The main objective of this targeted survey was to establish baseline data on the levels of arsenic, cadmium, lead, mercury, and aluminum in food products that may be used as a sole source of nutrition or nutritional supplement by Canadians. Specifically, infant formulas (both milk-based and soy-based), meal replacement beverage products, and nutritional supplement beverage products (specifically marketed to provide supplemental protein) were targeted.

There are a number of naturally-occurring metals that may be of concern to human health at certain levels of exposure. Most notably, arsenic, cadmium, lead, and mercury have been shown to effect human health, even at low levels of exposure. These metals may be present in finished foods due to their presence in the ingredients used to manufacture those foods, and/or may be unintentionally incorporated along the food production chain. Whether from natural or man-made sources, all food industries are expected to minimize as much as possible the presence of metals of concern to human health by any and all processes available to them. This is practiced in accordance with the ALARA (As Low As Reasonably Achievable) principle. Aluminum is not generally considered to be of concern to human health. However, the hazard characterisation and the exposure assessment for aluminum were recently re-assessed by Health Canada and the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA), therefore it was included in the current survey.

In this survey, meal replacement beverages, nutritional supplement beverages, and infant formulas were examined for the presence of metals that may be of concern to human health. These types of products are meant to supplement and/or act as a complete nutritional source for specific subsets of the population. Infants, children, and the elderly/infirm may be more likely to use single source nutritional products to ensure that their dietary needs are being met.

Three hundred and five samples (157 samples of infant formula, 66 samples of meal replacement beverages, and 82 nutritional supplement samples) were collected from Canadian retail stores between November 2011 and March 2012. Samples were analyzed for the presence of arsenic, cadmium, lead, mercury, and aluminum. All products were tested "as sold", meaning that they were not prepared as per manufacturer's instructions (i.e. as they would typically be consumed).

Ninety-one percent of the infant formulas tested did not contain detectable levels of arsenic, cadmium, lead, or mercury. Meal replacement and nutritional supplement beverages generally had higher frequencies and concentrations of detectable metals. It was not possible to determine the source of the metals in the products tested as they were highly processed finished foods. Health Canada's Bureau of Chemical Safety (BCS) was consulted on the observed levels of metals and provided the opinion that, in general, the samples tested herein do not pose a concern to human health. No follow-up action was warranted given the lack of 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 Canada's safety system for food, health and consumer products. 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 current regulatory framework, some commodities (such as meat products) traded internationally and interprovincially are regulated by specific Acts. These are referred to as federally registered commodities. Under the current regulatory framework, the non-federally registered commodities encompass 70% of domestic and imported foods that are regulated solely under the *Food and Drugs Act* and *Regulations*. Targeted surveys are primarily directed towards non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to gather information regarding the potential occurrence of hazards in defined food commodities. The surveys are designed to answer specific questions; therefore, unlike monitoring activities, testing for a particular chemical 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, a group of federal, provincial, and territorial subject matter experts in the area of food safety.

The CFIA regularly monitors a variety of metals in federally regulated commodities under the National Chemical Residue Monitoring Program (NCRMP) and the Children's Food Project (CFP). Targeted surveys focus mainly on products not monitored under these two programs. The purpose of this targeted survey was to establish baseline data on the level of the aforementioned metals in infant formulas, meal replacement beverages, and nutritional supplement beverages available on the Canadian retail market. The scope of this survey is complementary to the NCRMP and CFP in that it builds upon previous data for infant formulas, and this survey includes additional commodities (i.e., meal

replacement and nutritional supplement beverages) not routinely monitored under those programs.

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 standards for chemical residues and contaminants in food sold in Canada. Certain standards for chemical contaminants in food appear in the Canadian *Food and Drug Regulations (FDR)*, 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, which are available on Health Canada's website.

There are tolerances in the *FDR* (Section B.15.001-TABLE I) for arsenic in beverages (when ready-to serve) and lead in beverages (when ready-to-serve) and in infant formula (when ready-to-serve), however these tolerances are considered outdated and are in the process of being reviewed by Health Canada's Bureau of Chemical Safety (BCS)[12]. Health Canada has not established tolerances or standards for cadmium or mercury in the products tested in this survey. Furthermore, Health Canada has not developed standards for aluminum in foods, but does regulate the amounts of certain aluminum-containing food additives that are permitted for use in Canada.

Although there are presently tolerances for arsenic and lead published in the Canadian Food and Drug Regulations, Health Canada has indicated that these tolerances are outdated and should not be used for comparative purposes. Furthermore, the forms of the products targeted in this survey are varied (i.e. powdered and liquid concentrates, ready-to-serve), which makes comparison to any type of regulation intended for application to a ready-to-serve product difficult unless dilution factors are first applied to the product. For this reason, comparison to a tolerance is not undertaken in this survey. Rather the results of the risk assessment conducted by Health Canada's Bureau of Chemical Safety will be discussed to support the safety of the product.

In the absence of applicable tolerances or standards, elevated levels of metals may be assessed by Health Canada's BCS on a case-by-case basis using the most current scientific data available. If BCS identifies a potential safety concern, the Canadian Food Inspection Agency can exercise follow-up actions. 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.

2 Survey Details

2.1 Metals of Concern

Metals are naturally-occurring elements that may be present in trace amounts in rock, water, soil, or air. The degree of uptake by plants or animals in contact with metals is dependent on the nature of the metal, the environment, and the biology of the organism exposed to that metal. Elevated levels of metals can result from natural phenomenon, as well as human activities such as mining, improper disposal of waste, or other industrial processes.

There are a number of metals that may be of concern to human health at certain levels of exposure. Most notably, arsenic, cadmium, lead, and mercury have been shown to have effects on human health[3], even at low levels of exposure. Aluminum is not thought to have harmful effects on human health[4]; however, in 2007 the Joint Food and Agriculture Organization/World Health Organization Expert Committee on Food Additives (JECFA) re-evaluated the toxicology of aluminum[5]. As a result of that re-evaluation, Health Canada has initiated a review of the aluminum levels in foods available in Canada, and is assessing the dietary exposure of Canadians to aluminum[6]. It was thought appropriate to include this metal under the current survey to generate baseline Canadian data which has the potential to be used by Health Canada during their review.

Below is a general overview of each of these metals, including the possible human health effects related to long-term exposure.

2.1.1 *Arsenic*

Arsenic is an element that can be present in the environment naturally through erosion and weathering of soils, or may enter the environment as the result of industrial processes and pollution. Arsenic can be found naturally in a variety of different foods at low levels (such as meat, seafood, dairy products, baked goods, cereals, vegetables, and fruits[7]), generally due to accumulation from the environment (i.e. air, water, and soil).

Long term exposure to high levels of arsenic in its inorganic form may lead to chronic health effects, including damage to the kidneys, liver, lungs, and skin, as well as an increased risk of cancers of the bladder and lungs[8].

2.1.2 *Cadmium*

Cadmium can be found in the earth's crust and is generally found in combination with other inorganic compounds. Contamination of the environment with cadmium may be due to natural erosion and weathering of the rocks and soil, or may result from the presence of cadmium in industrial and municipal wastes, galvanized products, sewage sludge, and fertilizers.

Dietary exposure to cadmium is most commonly associated with the consumption of shellfish, liver, and kidney meats[9]. Chronic dietary exposure to cadmium may cause kidney damage, bone mineral density loss and hypertension[10].

2.1.3 *Lead*

Lead occurs naturally in the earth's crust and may also be present as a result of its many industrial uses. Battery production is currently the largest global market for lead[11]. Lead was historically present in the environment and in foods at higher levels due to its previous uses in gasoline, paint, and solder used in food cans.

Ongoing exposure to even very small amounts of lead can be harmful, especially to infants and young children, who have higher absorption rates of ingested lead and less effective renal excretion and usually have a higher exposure to lead on a body weight basis compared to adults[11,12,13]. Infants and children are also at higher risk because they are particularly vulnerable to the adverse effects of lead on the development of the nervous system. Other health effects associated with elevated lead exposure may include anaemia, hypertension, kidney toxicity, and damage to the brain.

2.1.4 *Mercury*

Mercury is a metal that can be found naturally in rocks, soil, and volcanic emissions. It can also be deposited into the environment from industrial activities such as coal-fired power generation, mining, smelting, and waste incineration.

In the general population, the major sources of exposure to mercury occur through the consumption of certain fish species and from dental amalgam[14]. Elevated exposure to mercury may result in rashes, birth defects, or effects on the central and peripheral nervous systems[15].

2.1.5 *Aluminum*

Aluminum is an abundant metal with many industrial and commercial uses. Aluminum may be naturally present in foods we eat; it may migrate into food from cookware or packaging sources, or may be intentionally incorporated through food additives. Aluminum is a permitted component of some food additives that are approved for use in Canada, such as those used as food colourings, anti-caking agents, and emulsifiers. Health Canada is updating its dietary exposure assessment for aluminum, which will help identify if further controls on aluminum in foods in Canada are required[6].

Aluminum has no known function in the human body and is not readily absorbed by the gastrointestinal tract. It is generally thought to be relatively non-toxic; however, there has been some suggestion that aluminum exposure may be a risk factor for the development or acceleration of onset of Alzheimer's disease,[16] although research to substantiate this claim has been inconclusive[17].

2.2 Infant Formulas, Meal Replacements, and Nutritional Supplements

There are a variety of food products on the Canadian market which are intended for use as a complete substitute for one or more daily meals or to act as a supplemental source of nutrients for the purpose of increased nutrition.

Infant formula is generally accepted as being a safe complementary food and a suitable substitute for breast milk[18]. Infant formula is designed to meet the known nutritional requirements of the healthy term infant. The *FDR* set the nutritional composition and labelling of commercial infant formula sold in Canada. The regulations also restrict the food additives that may be used. All new infant formulas, as well as products that undergo a change in formulation, processing, or packaging, are subject to a premarket notification. Health Canada requires the manufacturer to submit details of the formulation, ingredients, processing, packaging, and labelling for review. Manufacturers must also submit evidence that the formula is nutritionally adequate to support growth and development.

Meal replacements are similar to infant formulas in that they are meant to act as a sole source of nutrition. These products are a formulated food that can replace one or more daily meals by itself. To be labelled a meal replacement, a product must meet a variety of compositional and labelling requirements as defined in Division 24 of the *FDR*. These foods may be in the form of powders or prepared liquids, and state "meal replacement" on the label.

Nutritional supplements are foods sold or represented as supplementary to a diet that may be inadequate in energy and essential nutrients (such as protein, vitamins or minerals), but are not meant to completely replace one or more daily meals. Nutritional supplements may be found in many forms such as bars, liquids, extracts, concentrates, or powders. Common examples of nutritional supplements may include protein powders, ready-to-consume beverages, or dry beverage mixes. Within this survey, nutritional supplement beverages (including liquid and powdered products), marketed as being an additional source of protein, were targeted. These products contained protein sources including whey, casein, soy, rice, albumin, and other plant proteins.

2.3 Rationale

There have been recent media reports surrounding the levels of some metals found in both protein drinks[19] (a form of nutritional supplement) and infant formulas[20].

There is a general lack of Canadian-specific information regarding the levels of metals that could be found in these products. The CFIA has tested a wide variety of food products for metals in the past under the National Chemical Residue Monitoring Program, the Children's Food Project and various FSAP Chemistry Targeted Surveys. This survey looks to complement and expand on these datasets by generating baseline

data on the levels of certain metals in food products that may act as a sole or supplemental source of nutrition to Canadians.

All survey data generated were shared with Health Canada's BCS for risk assessment.

2.4 Sample Distribution

A total of 305 samples were collected from retail stores in 11 Canadian cities between November 2011 and March 2012.

The 305 products collected included 74 domestic products, 216 imported products, and 15 products of "unspecified origin", meaning the country of origin could not be confirmed based on the available information on the packaging. 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", and though the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of "Product of", "Prepared in", "Made in", "Processed in", and "Manufactured by" were considered as being from a specific country of origin.

The samples collected included 116 dairy-based infant formulas, 41 soy-based infant formulas, 66 meal replacements, and 82 nutritional supplements. Infant formula samples were in the form of powders, liquid concentrates (which require water to be added before consumption), and liquid ready-to-serve products. Meal replacements and nutritional supplements included both liquid ready-to-serve and powdered products. Table 2 gives the distribution of samples with respect to the form of the product and country of origin. There were eight samples for which the product form could not be identified through sample information. These are included in the Table as "Unspecified".

Table 2. Summary of samples by product form and country of origin

Product type	Product Form	Origin	Total
Infant Formula - Dairy	Liquid - Ready to Serve	Canada	6
		Switzerland	5
		Unspecified	1
		USA	16
	Liquid - Concentrate	Switzerland	2
		USA	3
	Powder	Canada	3
		Ireland	10
		Switzerland	14
		Unspecified	4
		USA	52
Infant Formula - Soy	Liquid - Ready to Serve	USA	1
	Powder	Canada	1
		Netherlands	6
		Switzerland	7
		Unspecified	1
		USA	24
	Unspecified	Unspecified	1
Meal Replacement	Liquid - Ready to Serve	Canada	11
		Switzerland	2
		Unspecified	1
		USA	15
	Powder	Canada	17
		Switzerland	1
		Unspecified	2
		USA	13
	Unspecified	Canada	2
		USA	2
Nutritional Supplement	Liquid - Ready to Serve	Canada	1
		USA	4
	Powder	Canada	32
		Switzerland	1
		Unspecified	5
		USA	36
	Unspecified	Canada	1
		USA	2

*****Unspecified refers to samples for which the country of origin or product form could not be determined based on the available information on the label.

2.5 Method Details

Survey samples were analyzed for aluminum, arsenic, cadmium, lead, and mercury by a Canadian laboratory ISO 17025 accredited for food testing under contract with the Government of Canada.

The laboratory used inductively coupled plasma mass spectrometry (for aluminum, arsenic, cadmium, and lead analysis) and cold vapor atomic fluorescence spectroscopy (used for mercury analysis) for detection of metal analytes in the samples. Method limits of detection (LOD) and limits of quantitation (LOQ) for the five metals can be found in Table 3.

Table 3. Limits of detection and quantitation used in the analysis of infant formulas, meal replacements, and nutritional supplements

Analyte	Product Form	LOD (ppm)	LOQ (ppm)
Arsenic	Liquids	0.005	0.005
	Powders	0.025	0.025
Cadmium	Liquids	0.002	0.002
	Powders	0.01	0.01
Lead	Liquids	0.002	0.002
	Powders	0.01	0.01
Mercury	Liquids	0.0005	0.0005
	Powders	0.0005	0.0005
Aluminum	Liquids	0.1	0.1
	Powders	0.5	0.5

2.6 Limitations

The current targeted survey was designed to provide a snapshot of the levels of selected metals of concern in infant formulas, nutritional supplements, and meal replacements available to Canadian consumers and to highlight commodities that warrant further investigation. The limited survey sample size represents a small fraction of the products available to Canadian consumers. Therefore, care must be taken when interpreting and extrapolating these results.

The products tested herein are highly processed foods that have a wide variety of ingredients. Due to the numerous sources of nutrients, ingredients, and additives, it is difficult to predict what metals may be present in these foods or the source of the metals.

Analysis was completed on products “as sold”. Some of the products sampled in this survey normally require preparation prior to consumption (e.g. the addition of water, juice, milk, etc.). The results should only be interpreted as products available as sold and not as they would be consumed.

Country of origin was assigned for nearly all of the samples collected based on information provided by the sampler or as indicated on the product label; however, no inferences or conclusions were made regarding the data with respect to country of origin. 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 Results

In this targeted survey, a total of 305 samples were collected from the Canadian retail market. The samples tested were further divided into infant formulas (dairy-based (116 samples) and soy-based (41 samples)), meal replacements (66 samples), and nutritional supplements (82 samples). Each of the metals of concern in this survey (namely arsenic, cadmium, lead, mercury, and aluminum) are presented individually in the sections below. Following the results for individual metals, a comparison of the results of this survey to other Canadian studies will be presented.

All data generated were forwarded to Health Canada's BCS for human health risk assessment. In general, the levels of metals found in the products included in this survey were not considered to pose a concern to human health. No follow up actions were required.

3.2 Results by Analyte

3.2.1 Arsenic

Of the 305 samples tested, a total of 189 (62%) did not contain a detectable level of arsenic. Dairy-based and soy-based infant formulas had the lowest prevalence of arsenic, with 77% and 76% of samples not having a detectable level of arsenic. 60% of nutritional supplements did not have a detectable level of arsenic, and 30% of meal replacements did not containing a detectable level of arsenic. See Figure 3 for the percentage of survey samples with a detectable level of arsenic by product type.

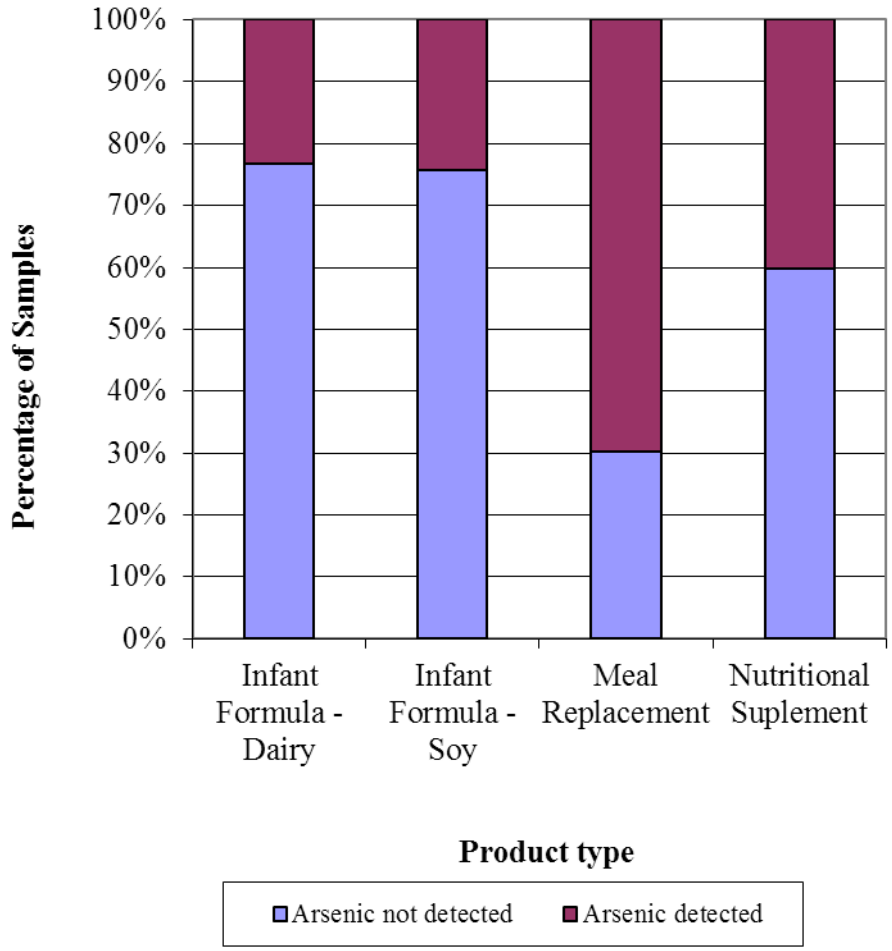

Figure 3. Arsenic occurrence by product type

Figure 4 illustrates the distribution of arsenic level detected by product type. Generally, dairy-based infant formulas, soy-based infant formulas, and meal replacements had similar distributions of arsenic concentrations. Many of the products tested, including the two samples with arsenic concentrations above 0.1 ppm, require the addition of liquid prior to consumption. If these two products with levels of arsenic above 0.1 ppm were prepared for consumption as per the manufacturer's instructions, the levels of arsenic observed would be comparable to concentrations observed in ready to serve products.

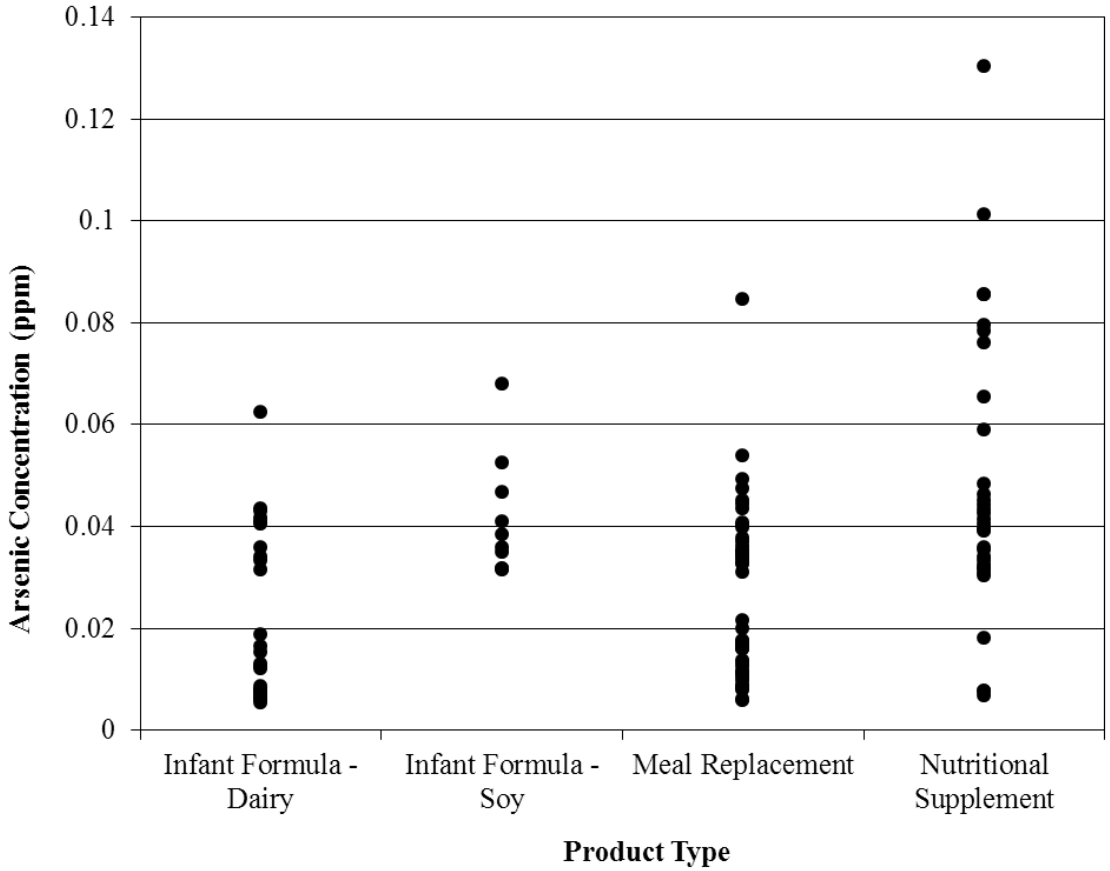

Figure 4. Distribution of detectable arsenic levels by product type

The dairy- and soy-based infant formula samples had similar maximum levels of arsenic detected. Seventy-seven percent of dairy-based infant formulas did not contain a detectable level of arsenic. Of those samples that did contain arsenic, the levels were low and ranged from 0.0054 ppm to 0.063 ppm. Similarly in the soy-based infant formulas, 76% of samples tested did not contain a detectable level of arsenic. The levels of arsenic in the remaining soy-based formula samples ranged from 0.031 ppm to 0.068 ppm.

Of the 66 meal replacement samples tested, 30% did not have a detectable level of arsenic. The arsenic levels in the remaining 46 samples ranged from 0.0058 ppm to 0.085 ppm.

Sixty percent of the nutritional supplement samples in this survey did not contain a detectable level of arsenic. Levels of arsenic in the remaining samples ranged from 0.0067 ppm to 0.13 ppm. Health Canada's BCS evaluated the results of the current survey and determined that none of the levels of arsenic observed in any of the products tested were associated with an unacceptable health concern to any segment of the Canadian population.

3.2.2 Cadmium

Of the 305 samples tested in this survey, 228 (75%) of them did not contain a detectable level of cadmium. Infant formulas had the lowest prevalence, where 100% and 98% of dairy- and soy-based infant formulas respectively did not have a detectable level of cadmium. Fifty-eight percent of meal replacement samples and 41% of nutritional supplements did not contain a detectable level of cadmium. See Figure 5 for a summary of the percentage of samples with detectable levels of cadmium.

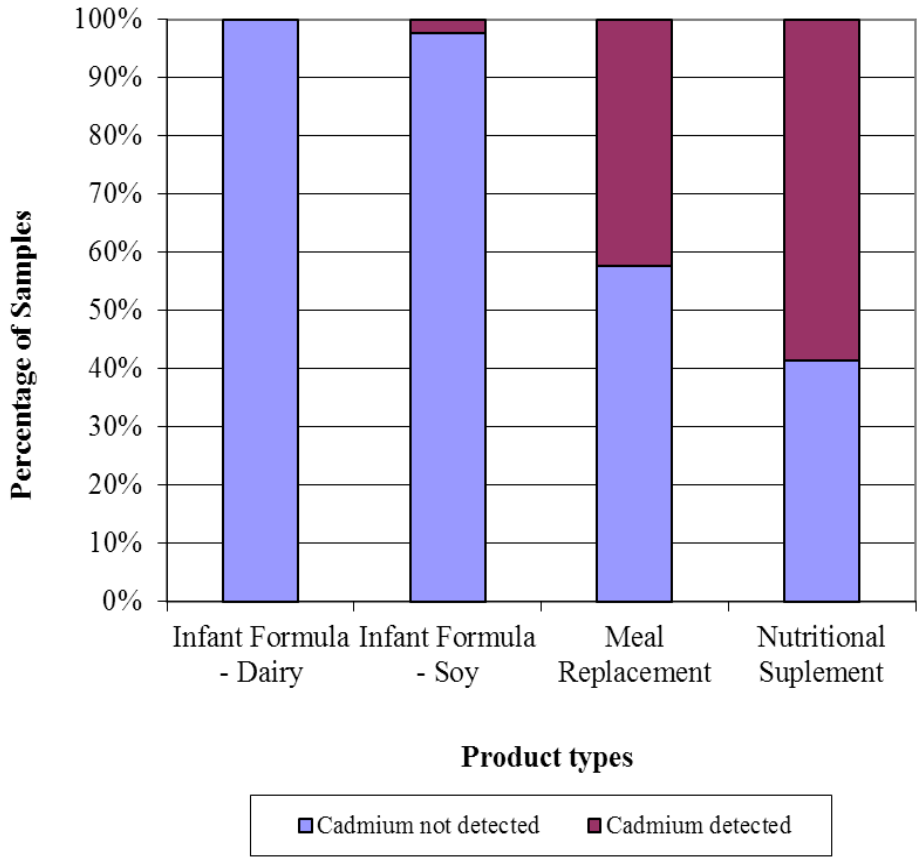

Figure 5. Cadmium occurrence by product type

Figure 6 illustrates the distribution of cadmium levels detected by product type. Only one sample of infant formula contained a detectable level of cadmium; a soy-based powdered formula was found to contain 0.043 ppm cadmium. In meal replacements, cadmium levels ranged from 0.0022 ppm to 0.069 ppm. Nutritional supplements exhibited cadmium levels of 0.0024 ppm to 0.22 ppm, with the exception of two unusually high samples which contained 1.6 ppm and 1.8 ppm of cadmium. The two nutritional supplement products that contained cadmium concentrations in excess of 1.5 ppm were both powdered products. If they were prepared according to the package directions, the

level of cadmium would be in the range of other cadmium values detected in ready-to-serve nutritional supplement samples.

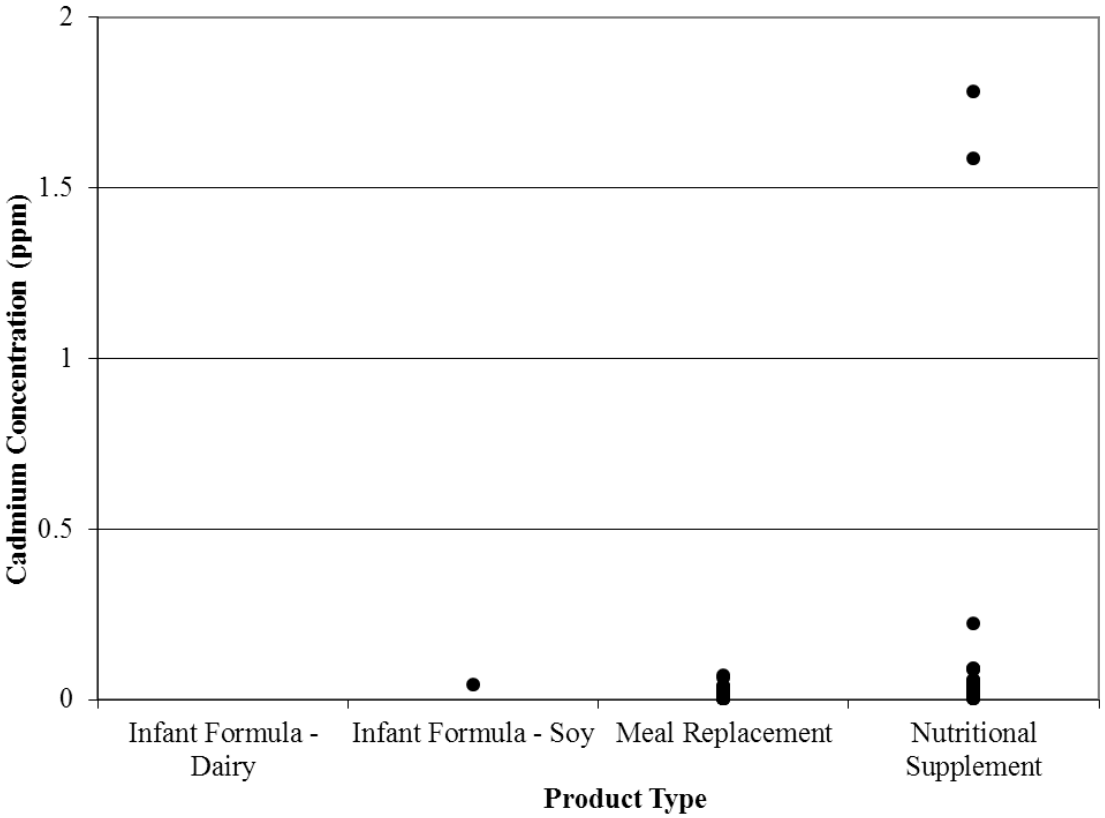

Figure 6. Distribution of detectable cadmium levels by product type

Health Canada's BCS was consulted about the levels of cadmium observed in this survey and concluded that, in general, the levels of cadmium observed are not associated with an unacceptable health concern to any segment of the Canadian population.

3.2.3 Lead

Of the 305 samples tested in this survey, 208 (68%) of them did not contain a detectable level of lead. See Figure 7 for the percentage of samples that contained detectable levels of lead.

In infant formula, 92% of dairy-based formula samples and 93% of soy-based formula samples tested did not contain a detectable level of lead. Of the meal replacements and nutritional supplements tested, 42% and 43% did not contain a detectable level of lead, respectively.

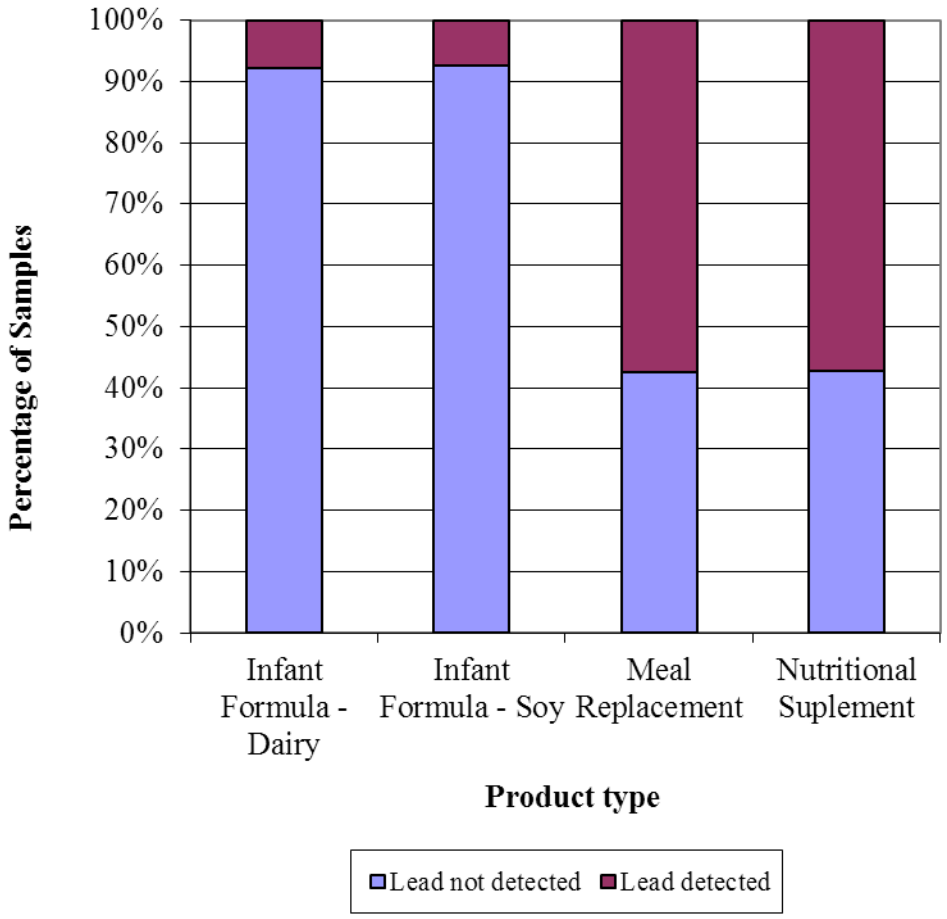

Figure 7. Lead occurrence by product type

Figure 8 illustrates the distribution of lead levels detected by product type. The maximum levels of lead observed in infant formulas were 0.022 ppm in dairy-based formulas and 0.034 ppm in soy-based formulas.

The maximum level of lead observed in meal replacements was 0.094 ppm. Nutritional supplements displayed the highest maximum level of lead detected, at 0.26 ppm.

The two nutritional supplements that exhibited levels of lead in excess of 0.25 ppm were powdered products that were intended for dilution prior to consumption. Taking into account the directions for use on the products, it would be expected that the concentration of lead in the product as consumed would be comparable to concentrations of lead in ready-to-serve products.

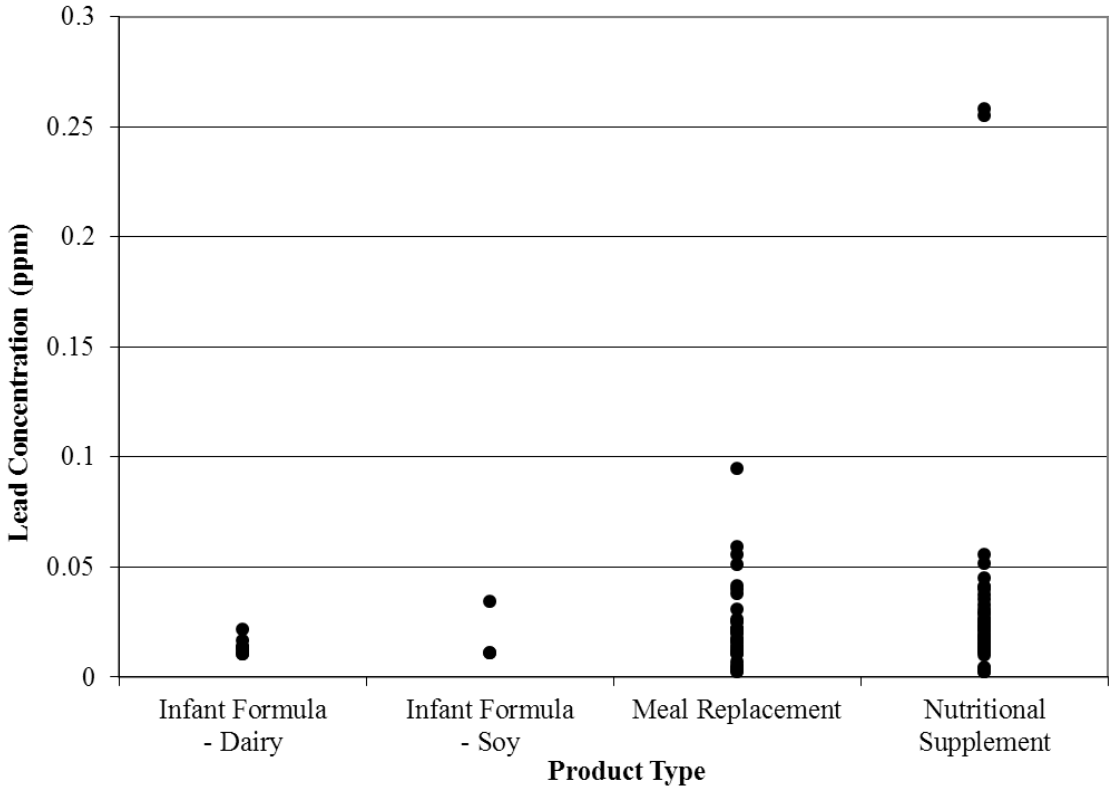

Figure 8. Distribution of detectable lead levels by product type

Health Canada's BCS evaluated the lead levels observed in all the products tested, and concluded that, in general, the levels of lead observed were not associated with an unacceptable health concern to any segment of the Canadian population.

3.2.4 Mercury

Of the 305 samples tested for this survey, 273 (90%) of samples did not contain a detectable level of mercury. See Figure 9 for the percentage of samples that contained detectable levels of mercury.

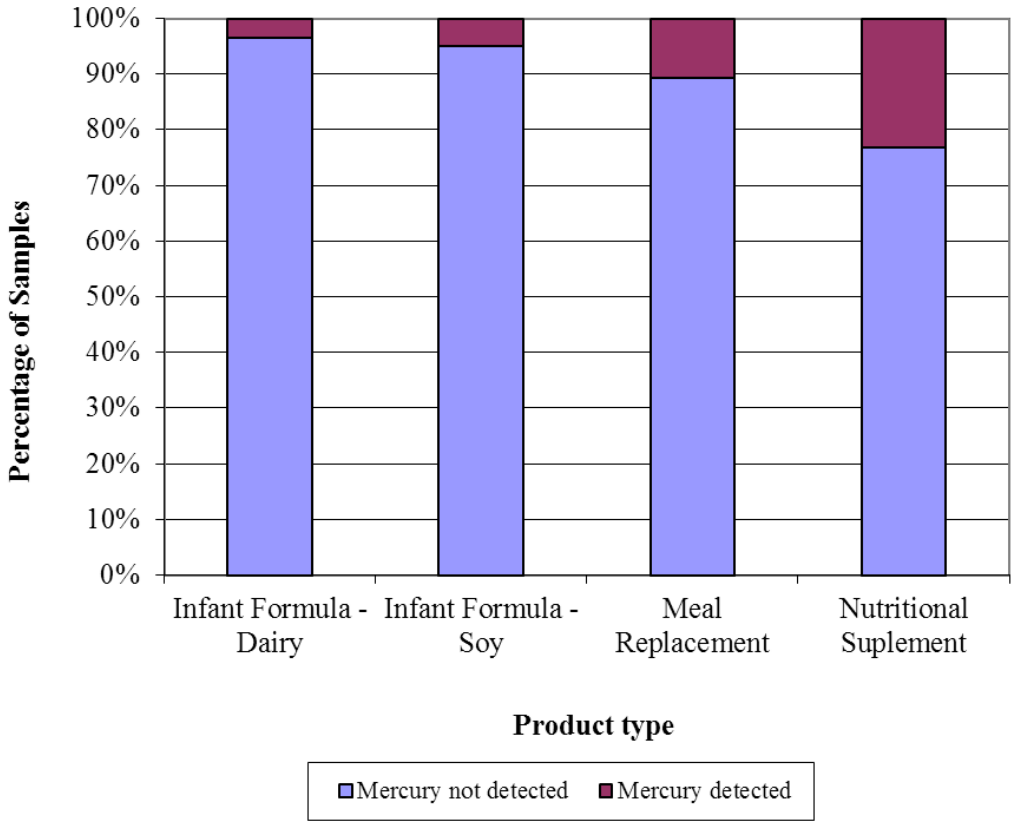

Figure 9. Mercury occurrence by product type

Ninety-seven percent of dairy-based infant formulas and 95% of soy-based infant formulas did not contain detectable levels of mercury. Eighty-nine percent of the meal replacement samples tested did not contain a detectable level of mercury. Nutritional supplements had the highest rate of mercury detected, where seventy-seven percent of samples did not contain detectable levels of mercury.

Figure 10 illustrates the distribution of mercury levels detected by product type. The maximum levels of mercury observed in infant formula samples were very low, at 0.0040 ppm and 0.0013 ppm in dairy- and soy-based samples, respectively. In meal replacement samples, the highest concentration of mercury observed was 0.0093 ppm. The highest level of mercury detected in nutritional supplements was 0.0098 ppm, which was also the highest mercury concentration observed in the survey overall. The two products that exhibited levels of mercury in excess of 0.0090 ppm were powdered products that were intended for dilution prior to consumption. Taking into account the directions for use on the products, it would be expected that the concentration of mercury in the product as consumed would be comparable to concentrations of mercury in ready-to-serve products.

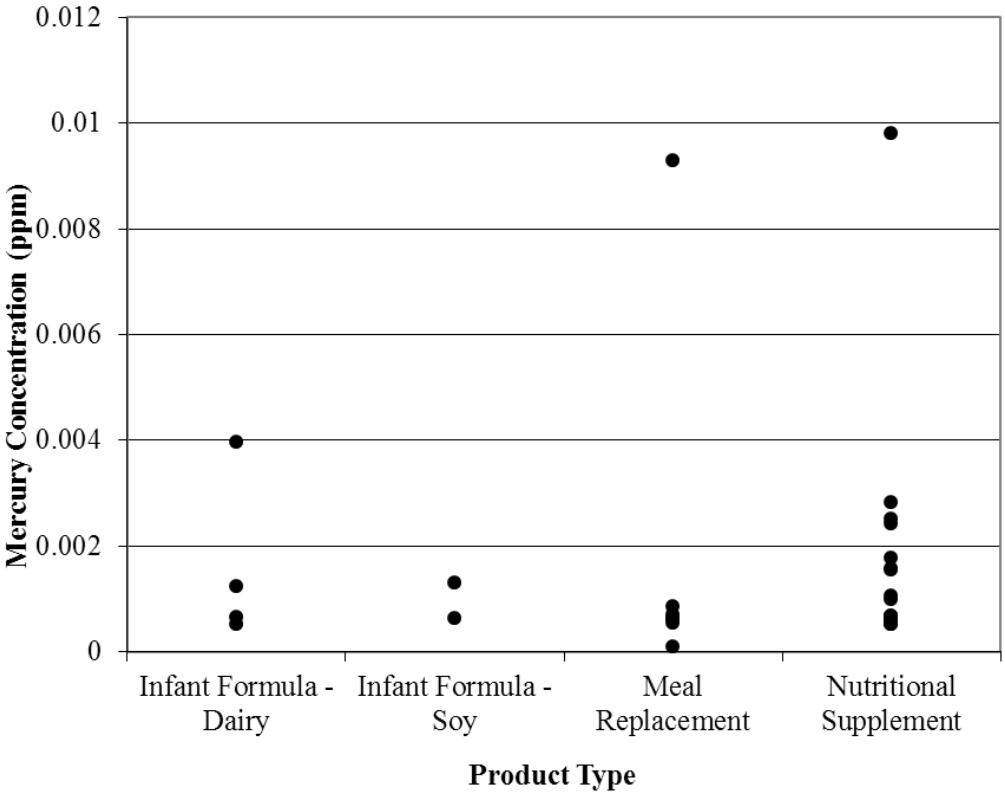

Figure 10. Distribution of detectable mercury levels by product type

All of the survey results for mercury were evaluated by Health Canada's BCS, who determined that none of the levels of mercury observed were associated with an unacceptable health concern to any segment of the Canadian population.

3.2.5 Aluminum

Of the 305 samples tested, 19% of samples had no aluminum detected. The high prevalence of aluminum is expected, as aluminum is naturally present in foods and is a known component of many permitted food additives. Thirty-eight percent of dairy-based infant formulas and 10% of soy-based infant formulas did not contain a detectable level of aluminum. In meal replacements, only 3% of samples did not contain a detectable level of aluminum, and in nutritional supplements, 11% of samples did not contain a detectable level of aluminum. See Figure 11 for the percentage of samples that contained detectable levels of aluminum.

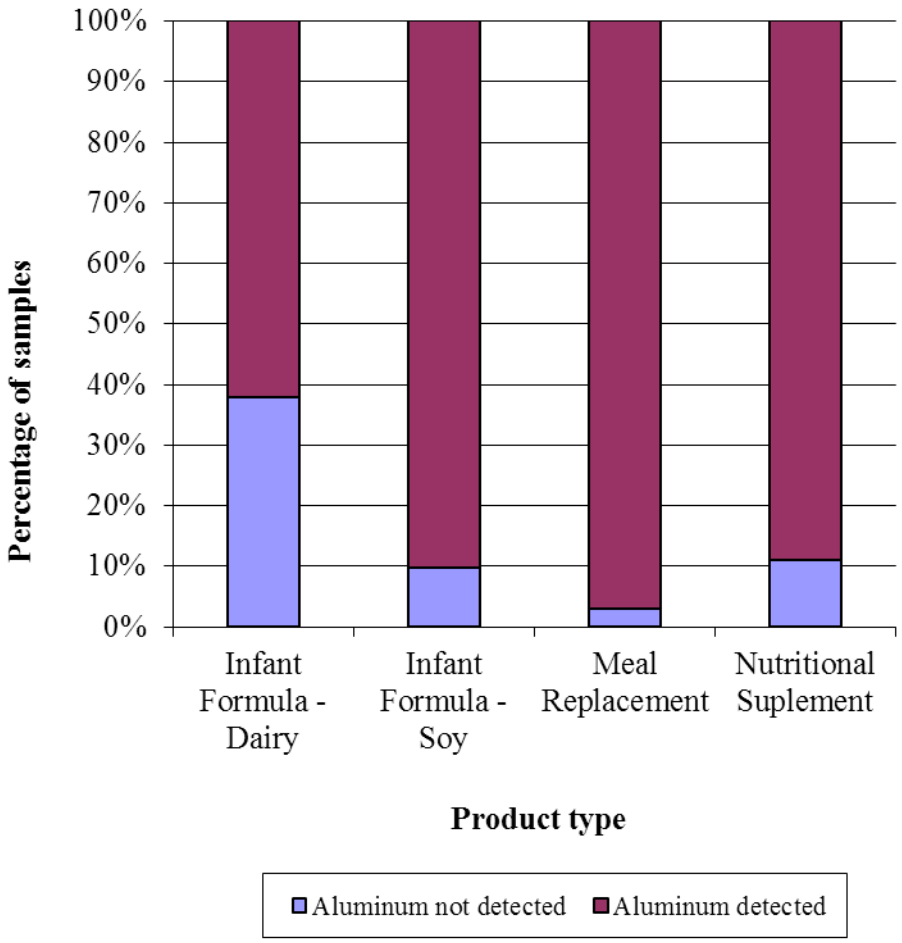

Figure 11. Aluminum occurrence by product type

Figure 12 illustrates the distribution of aluminum levels detected by product type. Dairy-based infant formula had a range of aluminum from 0.108 ppm to 5.27 ppm. Soy-based infant formulas had aluminum concentrations ranging from 0.745 ppm to 5.46 ppm. Meal replacements had aluminum levels ranging from 0.214 ppm to 117 ppm, and nutritional supplements had aluminum levels ranging from 0.263 ppm to 38.5 ppm.

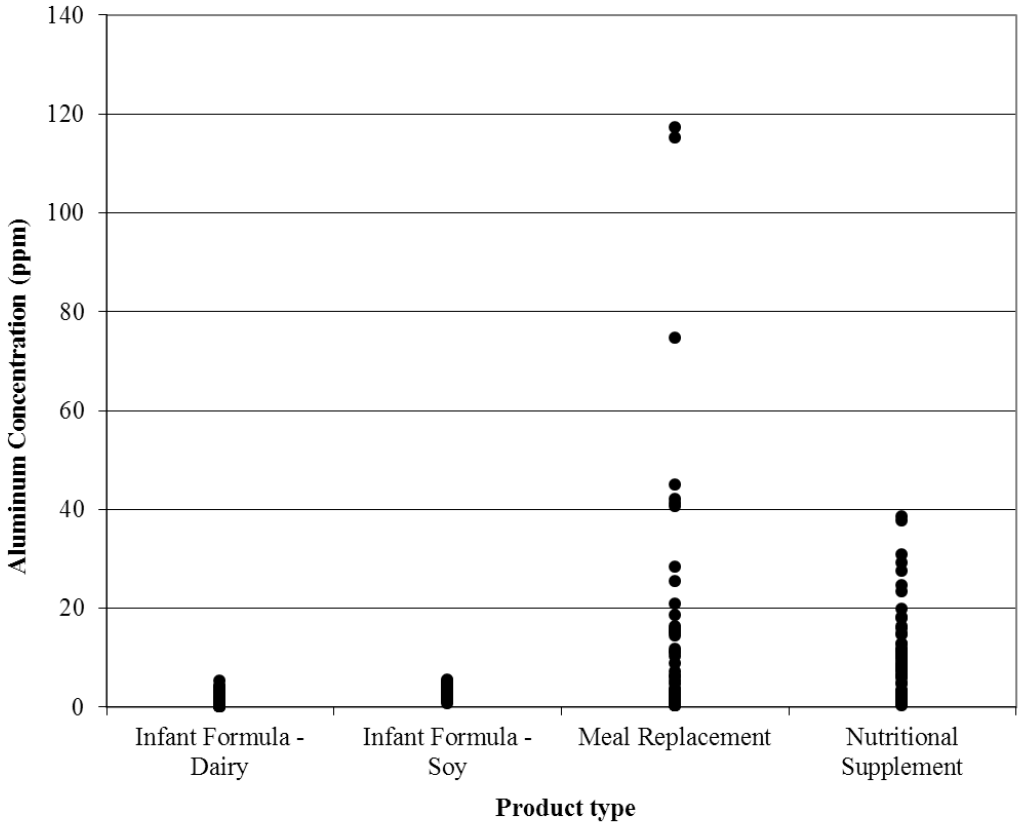

Figure 12. Distribution of detectable aluminum levels by product type

All of the survey results for aluminum were evaluated by Health Canada's BCS, who determined that none of the levels of aluminum observed were associated with an unacceptable health concern to any segment of the Canadian population.

3.3 Comparison of Survey Results with Other Canadian Studies

Both Health Canada and the CFIA have examined the concentrations of various metals in infant formulas in the recent past. A number of milk-based and soy-based infant formulas were analyzed for a variety of metals by the CFIA under the Children's Food Project (CFP) in 2008-2009[21]. A comparison of the maximum and average values observed in the CFP and this survey can be found below in Table 4.

Table 4. Average and maximum values observed (in ppm) in dairy-based and soy-based infant formulas in the Children's Food Project (CFP) and in this FSAP Targeted Survey (FSAP TS)

Formula Type	Data Source	Number of samples		Aluminum	Arsenic	Cadmium	Lead	Mercury
Milk-based	CFP	26	max	3.686	0.085	0.008	0.015	ND
			average	1.304	0.06	0.005	0.007	ND
	FSAP TS	116	max	5.276	0.063	ND	0.022	0.004
			average	1.217	0.021	ND	0.014	0.002
Soy-based	CFP	9	max	3.548	0.096	0.013	0.01	ND
			average	2.326	0.065	0.01	0.007	ND
	FSAP TS	41	max	5.467	0.068	0.043	0.034	0.001
			average	3.158	0.041	0.043	0.019	0.001

Note: ND means the analyte was not detected at levels above the LOD

A study completed by Health Canada's Food Research Division (FRD)[22] examined levels of cadmium, lead, and aluminum in a variety of infant formula samples. They reported results on an as-consumed basis, and thus only products considered ready-to-serve in this current survey were compared with the Health Canada study dataset. Cadmium levels in ready-to-serve formula tested by Health Canada ranged from 0.00015 ppm to 0.0030 ppm. Cadmium was not found above the method limit of detection (0.002 ppm) in any of the ready-to- serve infant formula products tested in the current survey. Health Canada's FRD found lead levels ranging from 0.00014 ppm to 0.0025 ppm in ready-to-serve infant formulas. In the current survey, there were no concentrations of lead above the method limit of detection (0.002 ppm) in any of the ready-to-serve products tested. Health Canada found that aluminum levels varied widely among different manufacturers, and levels in ready-to-serve formulas ranged from 0.010 ppm to 3.4 ppm. In the current survey, aluminum concentrations in ready-to-serve infant formulas ranged from 0.11 ppm to 0.72 ppm.

There is a lack of data available that examines the levels of metals present in meal replacement beverages and nutritional supplement beverages, which is one of the motivations behind this survey. It should be reiterated that all of the data produced in this study was evaluated by Health Canada's BCS, who concluded that the general levels of metals observed in the products would not be expected to pose an unacceptable health risk. Specifically, there were two nutritional supplement samples that contained elevated levels of both cadmium and lead. Health Canada estimated exposure to cadmium and lead from consumption of these products using serving size and dilution information provided on the product labels, and it was concluded that an unacceptable health risk would not be expected.

4 Conclusions

This survey established baseline surveillance data on the levels of arsenic, cadmium, lead, mercury, and aluminum in infant formulas, meal replacement and nutritional supplement beverages. A total of 305 samples were collected from 11 cities across Canada and analyzed for aluminum, arsenic, cadmium, lead, and mercury.

Overall, the majority (91%) of infant formula samples did not contain detectable levels of arsenic, cadmium, lead, or mercury. There appeared to be minimal differences between the occurrences of metals in dairy- or soy based formulas. The concentrations of arsenic, cadmium, lead, and mercury in infant formula samples found positive for those metals were very low. Health Canada determined that none of the infant formula samples analyzed in this survey contained arsenic, cadmium, lead, mercury, or aluminum at levels that would be considered to be of concern to human health, and took into account that these products may act as a sole source of nutrition meant for consumption by infants, a highly vulnerable population.

In meal replacement products tested, the occurrence of metals varied widely, with aluminum being the most commonly detected metal (97% of meal replacement samples had a detectable level of aluminum), and mercury having the lowest rate of detection (only 10% of samples had detectable levels of mercury). None of the meal replacement products analyzed in this survey would be expected to pose an unacceptable health risk.

The concentrations of metals detected in nutritional supplement beverages were similar to those detected in meal replacement products, with the exception of a few samples. Aluminum was the most frequently detected metal in nutritional supplements (89% of samples had a detectable level of aluminum); mercury was the least frequently detected metal (23% of samples contained a detectable level of mercury). In general, the levels of metals observed in the nutritional supplement products analyzed in this survey would not be expected to pose an unacceptable health risk. None of the nutritional supplement products analyzed in this survey were expected to pose an unacceptable health risk to Canadian consumers.

5 References

[1] Health Canada. *Risk Management Strategy for Lead* [online]. Modified July 2013, Accessed on September 23, 2013. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/prms_lead-psgr_plomb/index-eng.php#a131

[2] Health Canada. *Factsheet: Streamlining Food Regulations in Canada* [online]. Modified April, 2012. Accessed October 14, 2013. http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/_2012/2012-58fs-eng.php

[3] Hutton, M. (1987) Human Health Concerns of Lead, Mercury, Cadmium and Arsenic. In *Lead, Mercury, Cadmium and Arsenic in the Environment* [online]. Accessed on September 23, 2013. http://dge.stanford.edu/SCOPE/SCOPE_31/SCOPE_31_2.01_Chapter6_53-68.pdf

[4] Health Canada. *Aluminum* [online]. Modified September, 2009. Accessed October 28, 2013. http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/aluminum/index-eng.php

[5] Joint FAO/WHO Expert Committee on Food Additives. *WHO Technical Report Series 940: Evaluation of Certain Food Additives and Contaminants* [online]. 2007. Accessed October 28, 2013. http://www.who.int/ipcs/publications/jecfa/reports/trs940.pdf

[6] Health Canada. *Health Canada Review of Dietary Exposure to Aluminum* [online]. Modified August 2008, Accessed on October 14, 2013. http://www.hc-sc.gc.ca/fn-an/securit/addit/aluminum-eng.php

[7] Health Canada. *Arsenic.* [online]. Modified November, 2008. Accessed October 24, 2013. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/arsenic-eng.php

[8] World Health Organization. *Arsenic* [online] 2012. Accessed October 24, 2013. http://www.who.int/mediacentre/factsheets/fs372/en/

[9] US EPA. *Cadmium* [online]. Accessed October 14, 2013. http://www.epa.gov/osw/hazard/wastemin/minimize/factshts/cadmium.pdf

[10] Statistics Canada. Lead, Mercury, and Cadmium Levels in Canadians [online]. Accessed October 14, 2013. http://www.statcan.gc.ca/pub/82-003-x/2008004/article/10717/6500108-eng.htm

[11] Health Canada. *Final Human Health State of the Science Report on Lead* [online]. Modified July, 2013. Accessed October 14, 2013. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/dhhssrl-rpecscepsh/index-eng.php

[12] Health Canada. *Lead and Human Health* [online]. Modified February 2013. Accessed October 24, 2013. http://hc-sc.gc.ca/hl-vs/iyh-vsv/environ/lead-plomb-eng.php

[13] Health Canada. *Lead* [online]. October 2011. Accessed October 24, 2013. http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/environ/lead_plomb-eng.php

[14] Health Canada. *Mercury: Your Health and the Environment* [online]. Modified December 2012. Accessed online October 14, 2013. http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/mercur/index-eng.php

[15] World Health Organization. *Mercury and Health* [online]. Modified September 2013. Accessed November 8, 2013. http://www.who.int/mediacentre/factsheets/fs361/en/

[16] Tomlijenovic, L. (2011) *Aluminum and Alzheimer's Disease: After a Century of Controversy, Is There a Plausible Link?.* Journal of Alzheimers Disease. 23(4):567-98.

[17] Ohyagi, Y et. Al.(2013) *Aluminum and Alzheimer's Disease: An Update.* Journal of Alzheimers Disease & Parkinsonism. 3:2. Accessed online October 24, 2013. http://www.omicsonline.org/2161-0460/2161-0460-3-118.pdf

[18] Health Canada. *Nutrition for health term infants: Recommendations from birth to six months* [online]. Modified October 2012. Accessed November 7, 2013. http://www.hc-sc.gc.ca/fn-an/nutrition/infant-nourisson/recom/index-eng.php

[19] Consumer Reports. *Protein Drinks: You Don't Need the Extra Protein or the Heavy Metals Our Tests Found.* Modified July, 2010. Accessed online August 13, 2013. http://www.consumerreports.org/cro/2012/04/protein-drinks/index.htm

[20]Keele University. *"Too much aluminum in infant formulas, UK researchers find." ScienceDaily*, (Sep. 2010). Accessed online November 5, 2013. http://www.sciencedaily.com/releases/2010/09/100901111444.htm

[21] Canadian Food Inspection Agency. *Children's Food Project – 2008-2009 Report on sampling* [online]. Modified September 2012. Accessed October 12, 2013. http://inspection.gc.ca/food/chemical-residues-microbiology/chemical-residues/children-s-food-project/eng/1348587109286/1348587393958

[22] Dabeka, R. et al. (2011) *Lead, Cadmium and Aluminum in Canadian Infant Formulae, Oral Electrolytes and Glucose Solutions.* Food Additives and Contaminants Part A: 28(^):744-753.