Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

FOOD SAFETY ACTION PLAN

REPORT

2012-2013
TARGETED SURVEYS - CHEMISTRY

Arsenic, Cadmium, Lead, and Mercury in Infant Formulas, Meal Replacements and Nutritional Supplements

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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 objectives of this targeted survey were to:

- expand upon baseline data on the levels of arsenic, cadmium, lead and mercury in food products that may be used as a sole source of nutrition or as a nutritional supplement by Canadians; and
- compare these results to the previous (2011-2012) FSAP survey

There are a number of naturally-occurring metals that may be of concern to human health when a certain level of exposure is reached. Most notably, arsenic, cadmium, lead and mercury have been shown to have effects on human health at elevated 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.

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.

Two hundred and ninety one samples (144 samples of infant formula, 46 samples of meal replacement beverages, and 101 nutritional supplement samples) were collected from Canadian retail stores between April 2012 and March 2013. Samples were analyzed for the presence of arsenic, cadmium, lead and mercury. 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).

Infant formulas had very low frequencies of detection and levels of arsenic, cadmium, lead and mercury. Meal replacements and nutritional supplement beverages generally had higher frequencies and concentrations of detectable metals. In general, the levels of arsenic, cadmium, lead and mercury were very consistent between FSAP survey years for infant formulas and meal replacements. Nutritional supplements had slightly higher

levels of lead and mercury in the current survey year, potentially due to disparity in product types and/or sample sizes. Health Canada's BCS did not identify concerns for human health based on the results. No product recalls were 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 and fish products) traded internationally and inter-provincially 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 objectives of this targeted survey were to establish and expand upon 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.

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 and lead in beverages 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)[1,2]. Health Canada has not established tolerances or standards for cadmium or mercury in the products tested in this survey.

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 (e.g. volcanic eruptions or weathering of rock/soil), 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], at elevated levels of exposure. 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. Most human exposure to arsenic is through consumption of drinking water and food[4].

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[5]), 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[6].

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, kidney meats, and grains/grain products[7,8,9]. Chronic dietary exposure to cadmium may cause kidney damage, loss of bone mineral density 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. Infants and children also usually have a higher exposure to lead on a body weight basis compared to adults[12] and are considered to be at higher risk because they are particularly vulnerable to the adverse effects of lead on the development of the central nervous system. Other health effects associated with elevated lead exposure may include anaemia, hypertension, kidney toxicity, and delayed onset of puberty[12].

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[13]. Elevated exposure to mercury may result in effects on the central and peripheral nervous systems, effects on the development of the central nervous system, or effects on the immune system[14,15].

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 in infants that cannot or should not be fed their mother's breastmilk[16]. Infant formula is designed to meet the known nutritional requirements of the healthy term infant. The *FDR* outlines the nutritional composition and labelling requirements 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, soy, hemp, rice and other blended proteins.

2.3 Rationale

There have been recent media reports surrounding the levels of arsenic, cadmium, lead, and mercury found in protein beverages[17] (a form of nutritional supplement) and of aluminum in infant formulas[18]. The CFIA has tested infant formulas, meal replacements, and nutritional supplements for various metals under the Children's Food Project (CFP)[19] and previous FSAP surveys[20]. This survey looks to complement and expand upon 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 use in conducting human health risk assessments of arsenic, cadmium, lead and mercury.

2.4 Sample Distribution

A total of 291 samples were collected from retail stores in 11 Canadian cities between April 2012 and March 2013. The products collected included 87 domestic products, 192 imported products, and 12 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 "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 96 dairy-based infant formulas, 48 soy-based infant formulas, 46 meal replacements, and 101 nutritional supplements. Table 1 summarizes the product types and forms sampled in the current survey. 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 1. Summary of samples by product type and form.

Product Type	Product Form	Total
Infant Formula - Dairy	Liquid - Concentrate	22
	Liquid - Ready to Serve	33
	Powder	41
Infant Formula - Soy	Liquid - Concentrate	13
	Powder	35
Meal Replacement	Liquid - Ready to Serve	18
	Powder	28
Nutritional Supplement	Liquid - Ready to Serve	11
	Powder	90
Grand Total		**291**

2.5 Method Details

Survey samples were analyzed for arsenic, cadmium, lead and mercury by an ISO17025 accredited food testing laboratory under contract with the Government of Canada.

The laboratory used inductively coupled plasma mass spectrometry (ICP-MS) for analyte detection. Method limits of detection (LOD) for the four metals can be found in Table 2.

Table 2. Limits of detection used in the analysis of infant formulas, meal replacements, and nutritional supplements

Analyte	LOD (ppm)
Arsenic	0.004
Cadmium	0.002
Lead	0.001
Mercury	0.0015

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”. Many 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 291 samples were collected from the Canadian retail market. The samples tested were infant formulas (dairy-based (96 samples) and soy-based (48 samples)), meal replacements (46 samples), and nutritional supplements (101 samples). Table 3 summarizes the positive rate (number of samples with a detectable level), minimum/maximum, and average analyte levels detected in the current survey. Lead had the highest occurrence, with 180 samples (62 %) testing positive, whereas only 33 samples (11%) had a detectable level of mercury. Cadmium had the highest average detected level (0.114 ppm) and mercury had the lowest average level (0.0225 ppm).

Table 3. Minimum, maximum and average levels of metals detected in food samples by analyte.

Analyte	Number of Samples	Number (%) of Samples With Detectable Levels	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Arsenic	291	94 (32)	0.004	0.141	0.031
Cadmium	291	101 (35)	0.002	1.717	0.114
Lead	291	180 (62)	0.001	0.318	0.027
Mercury	291	33 (11)	0.0030	0.1298	0.0225

* Average of positive results only

Figure 1 shows the average analyte levels detected in each product type. Note that only values above the limit of detection were used to calculate averages. Infant formulas had the lowest average analyte levels and nutritional supplements had the highest. The overall highest average was for cadmium in nutritional supplements (0.181 ppm).

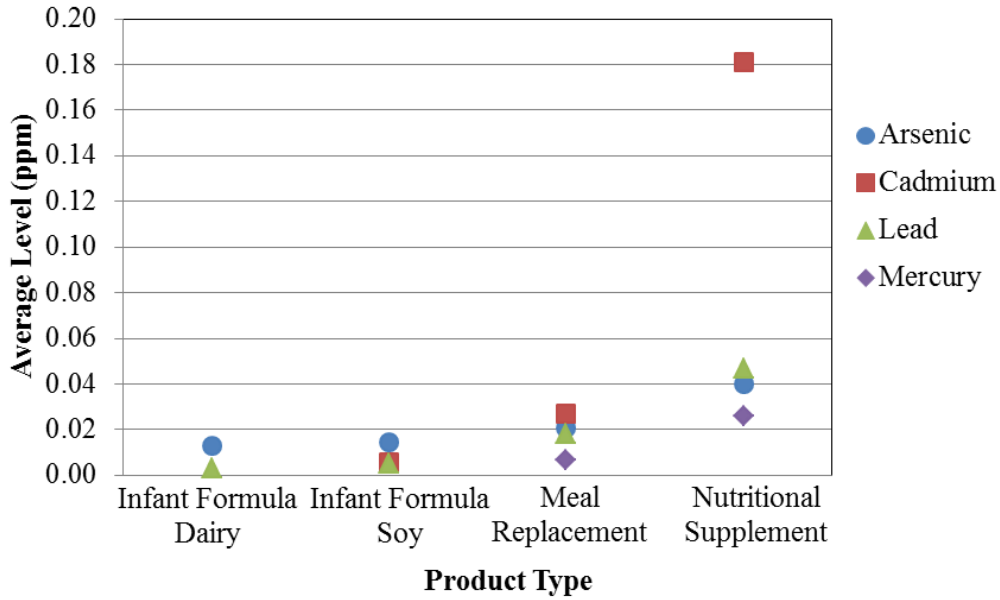


Figure 1. Average analyte levels detected by product type (in order of increasing average).

As is shown in Figure 2, the levels of arsenic, cadmium, lead and mercury in nutritional supplements varied by product form (liquid – ready to serve, powder) and by the type of protein included (e.g. whey, soy, rice). Here, “blend” refers to nutritional supplements where the primary ingredient was a protein mixture, usually of whey and soy protein. Vegetable proteins consisted of a mixture of vegetable-based proteins (e.g. rice, pea, hemp).

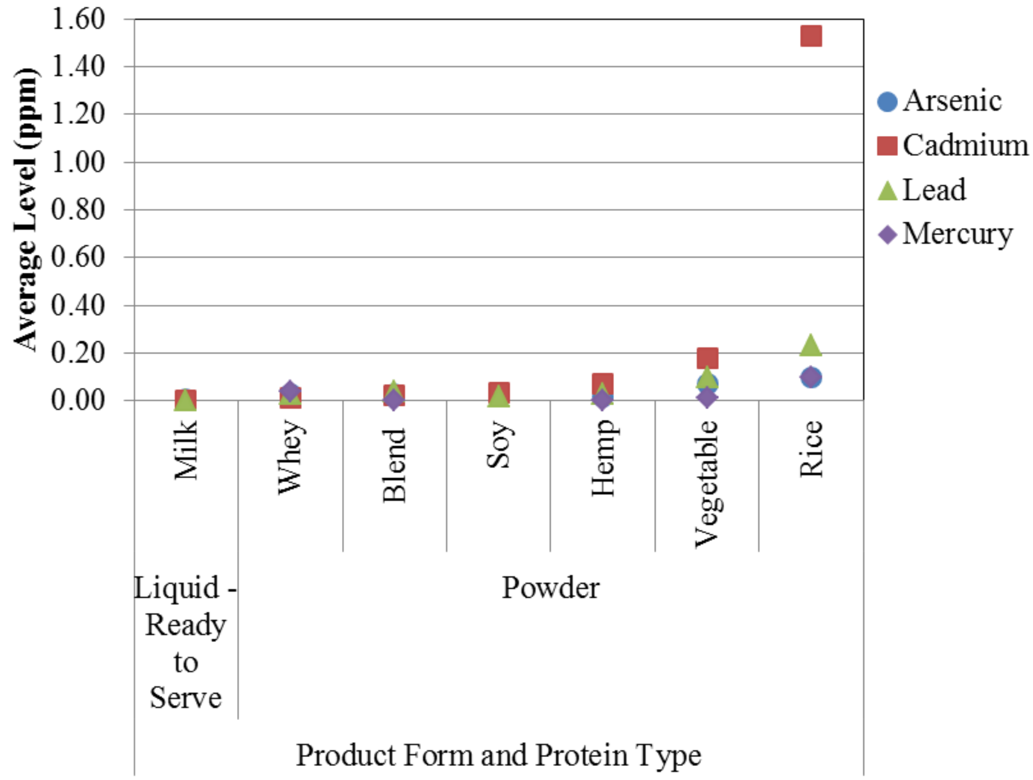


Figure 2. Average analyte levels detected in nutritional supplements by product form and protein type.

As expected, the ready-to-serve liquid products contained the lowest average analyte levels and the powder products, requiring the addition of water before consumption, contained higher levels. Note that when considering the dilution factors for powder products (according to the preparation instructions) the levels in the products "as consumed" would be approximately ten times lower. In general, dairy based nutritional supplements (milk and whey protein samples) contained the lowest average levels of each analyte. Of the protein types sampled, the five rice protein based nutritional supplements contained the highest levels of arsenic, cadmium, lead and mercury.

Arsenic, cadmium, lead, and mercury results are presented individually in the sections below. When possible, the current results are compared to a previous FSAP survey on metals in infant formulas, meal replacements and nutritional supplements[20], to a Children's Food Project (CFP) survey of metals in infant formulas[19], and to a multi-year Health Canada (HC) Total Diet Study (TDS) on metals in various commodities[21].

All data generated were evaluated by Health Canada's BCS. The BCS did not identify concerns for human health based on the results reported in this survey. No direct follow up actions were required.

3.2 Results by Analyte

3.2.1 *Arsenic*

Of the 291 samples analyzed, a total of 197 (68%) did not contain a detectable level of arsenic. Figure 3 shows the number of samples with a detectable level of arsenic, organized by product types. Dairy-based infant formulas had the lowest prevalence of arsenic (10%), followed by meal replacements (24%), and soy-based infant formulas (31%). Nutritional supplements had the highest proportion of positive samples with 57% of samples having a detectable level of arsenic.

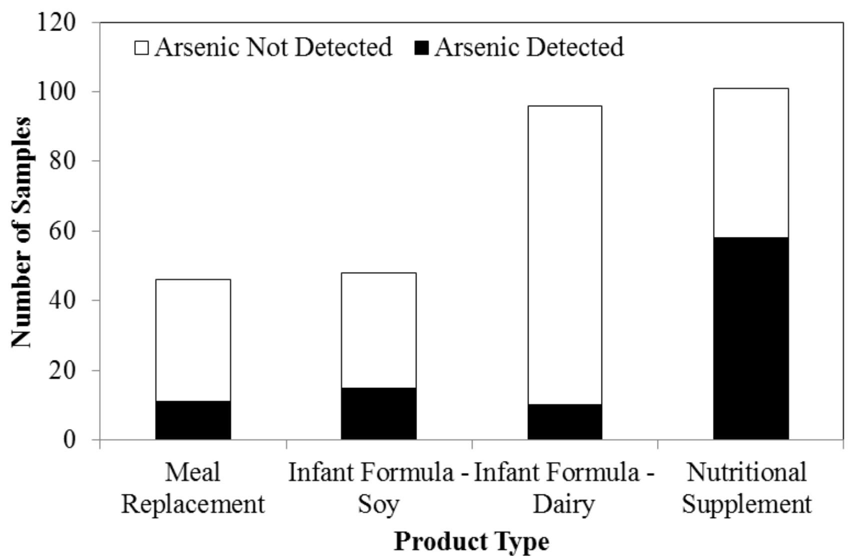
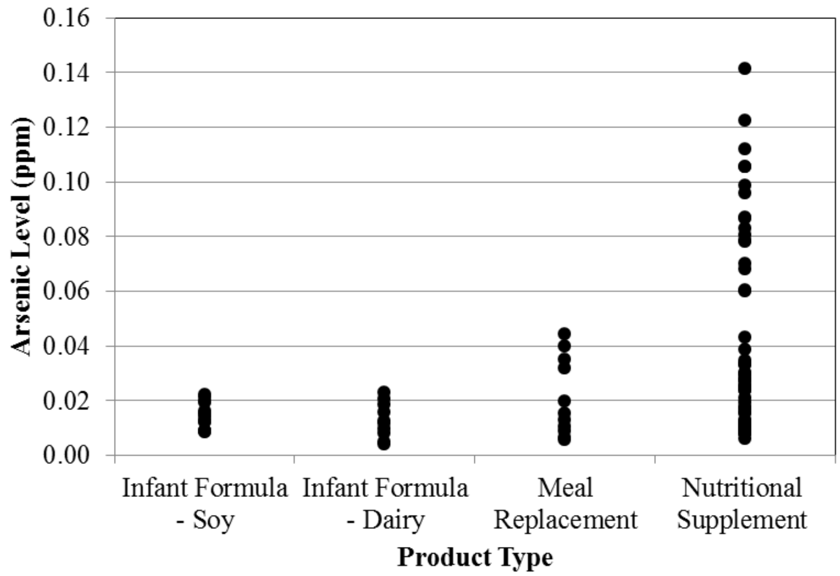


Figure 3. Arsenic occurrence by product type (in order of increasing number of samples).

Figure 4 illustrates the distribution of arsenic levels detected by product type. Generally, dairy-based and soy-based infant formulas had low and consistent concentrations of arsenic. Meal replacements had a maximum detected arsenic concentration of 0.044 ppm, with an average of 0.021 ppm. The maximum arsenic concentration in nutritional supplements was 0.141 ppm with an average concentration of 0.040 ppm.



Note: Only values above the limit of detection are displayed.

Figure 4. Detected arsenic levels by product type (in order of increasing maximum arsenic level).

Table 4 summarizes the current FSAP and CFP survey data on arsenic levels in infant formulas, meal replacements and nutritional supplements. As previously mentioned, infant formulas had the lowest average arsenic levels of the product types. In comparison to the previous FSAP and CFP surveys, both soy- and dairy-based infant formulas analyzed in the current survey have lower maximum and average arsenic levels. Meal replacements analyzed in the current survey year have lower detection rates and maximum detected values, with a very consistent average arsenic level between survey years. Nutritional supplements had a slightly higher arsenic occurrence for the current data; however, the maximum and average levels are consistent between survey years.

Table 4. Summary of FSAP and CFP survey data on arsenic levels in infant formula, meal replacements and nutritional supplements.

Author	Year	Number of Samples	Number (%) of Samples With Detectable Levels	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Infant Formula - Dairy						
FSAP[20]	2012-2013	96	10 (10)	0.004	0.023	0.013
	2011-2012	116	27 (23)	0.005	0.063	0.021
CFP[19]	2008-2009	26	26 (100)	0.015	0.085	0.060
Infant Formula - Soy						
FSAP[20]	2012-2013	48	15 (31)	0.008	0.022	0.014
	2011-2012	41	10 (24)	0.031	0.068	0.041
CFP[19]	2008-2009	9	9 (100)	0.016	0.096	0.065
Meal Replacement						
FSAP[20]	2012-2013	46	11 (24)	0.006	0.044	0.021
	2011-2012	66	43 (65)	0.006	0.085	0.025
Nutritional Supplement						
FSAP[20]	2012-2013	101	58 (57)	0.006	0.141	0.040
	2011-2012	82	36 (44)	0.007	0.130	0.047

*Average of positive results only

3.2.2 *Cadmium*

Of the 291 samples analyzed in this survey, 190 (65%) of them did not contain a detectable level of cadmium. Figure 5 shows the number of samples and positive rates for cadmium, organized by individual product types. No dairy-based infant formulas tested positive for cadmium whereas 44% (21 samples) of soy-based infant formulas tested positive. Forty three percent of meal replacement samples and 59% of nutritional supplements tested positive for cadmium.

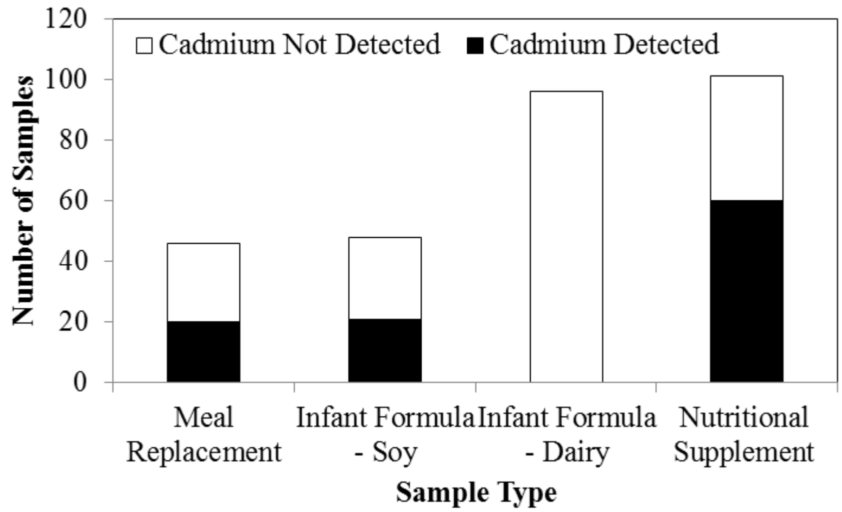
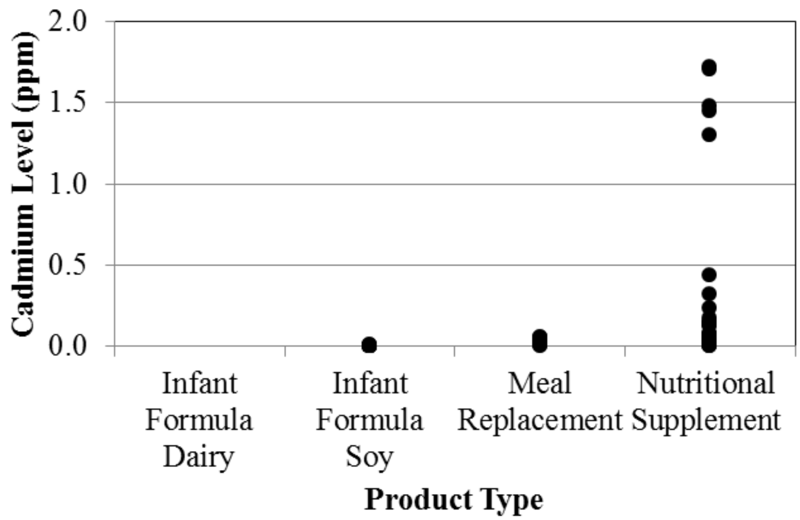


Figure 5. Cadmium occurrence by product type (in order of increasing number of samples).

Figure 6 illustrates the distribution of cadmium levels detected by product type. No samples of dairy-based infant formulas tested positive and, in general, soy-based infant formulas had very low levels of cadmium. The maximum and average cadmium levels detected in soy-based infant formulas were 0.008 ppm and 0.005 ppm, respectively.

Meal replacements had a maximum detected cadmium level of 0.055 ppm, with an average of 0.027 ppm. Nutritional supplements had the highest maximum detected value, and average cadmium levels of all the product types tested. The maximum cadmium level in nutritional supplements was 1.717 ppm with an average level of 0.181 ppm. The nutritional supplement products that contained the highest concentrations of cadmium were those that were rice-based.



Note: Only values above the limit of detection are displayed.

Figure 6. Detected cadmium levels by product type (in order of increasing maximum cadmium level).

Table 5 summarizes the current FSAP and CFP survey data on cadmium levels in infant formulas, meal replacements and nutritional supplements. As previously mentioned, no dairy-based infant formulas tested positive for cadmium in the current survey. In comparison to the previous FSAP and CFP surveys, soy-based infant formulas for the current survey year have lower maximum and average cadmium levels.

A total diet study conducted by Health Canada from 1993 to 2007 found average cadmium levels of 0.0004 ppm in dairy-based and 0.0014 ppm in soy-based infant formulas[21]. No detectable concentrations of cadmium were found in dairy-based formulas in the current survey, whereas the current average level in soy-based formulas is higher than the HC TDS average. Note that the HC TDS surveys tested as-consumed infant formula; therefore a lower average cadmium level is expected due to dilution.

The current data for cadmium levels in meal replacements agrees well with the previous FSAP survey. Nutritional supplements analyzed for the current survey had a higher average cadmium level; however, the positive rate and maximum level are very consistent between survey years.

Table 5. Summary of FSAP and CFP survey data on cadmium levels in infant formula, meal replacements and nutritional supplements.

Author	Year	Number of Samples	Number (%) of Samples With Detectable Levels	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Infant Formula - Dairy						
FSAP[20]	2012-2013	96	0 (0)	-	-	-
	2011-2012	116	0 (0)	-	-	-
CFP[19]	2008-2009	26	21 (81)	0.003	0.008	0.005
Infant Formula - Soy						
FSAP[20]	2012-2013	48	21 (44)	0.004	0.008	0.005
	2011-2012	41	1 (2)	0.043	0.043	-
CFP[19]	2008-2009	9	8 (89)	0.005	0.013	0.010
Meal Replacement						
FSAP[20]	2012-2013	46	20 (43)	0.005	0.055	0.027
	2011-2012	66	28 (42)	0.002	0.069	0.020
Nutritional Supplement						
FSAP[20]	2012-2013	101	60 (59)	0.002	1.717	0.181
	2011-2012	82	48 (59)	0.002	1.780	0.102

*Average of positive results only

3.2.3 *Lead*

Of the 291 samples tested in this survey, 111 (38%) of them did not contain a detectable level of lead. Figure 7 shows the number of samples and positive rates for lead, organized by individual product types. Dairy-based infant formulas had the lowest occurrence of lead, with only 22 samples (23%) testing positive, followed by soy-based infant formulas (73% tested positive). Meal replacements and nutritional supplements had the highest occurrence of lead, with 87% and 82% testing positive, respectively.

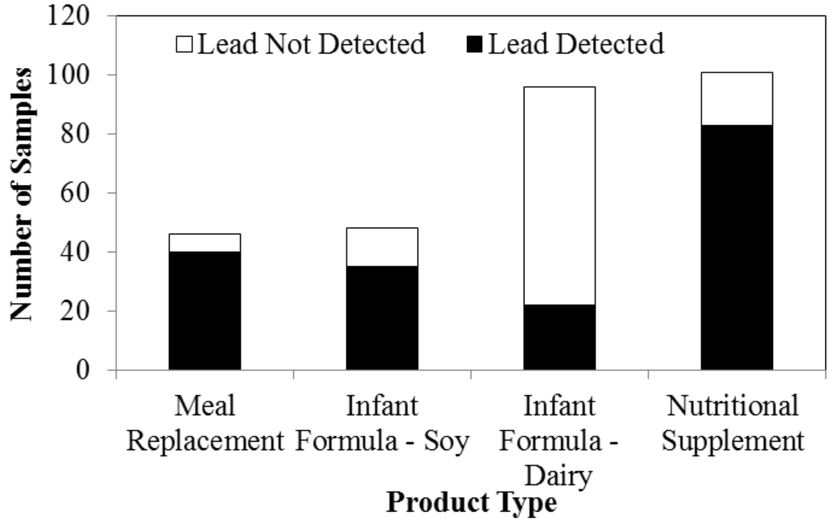
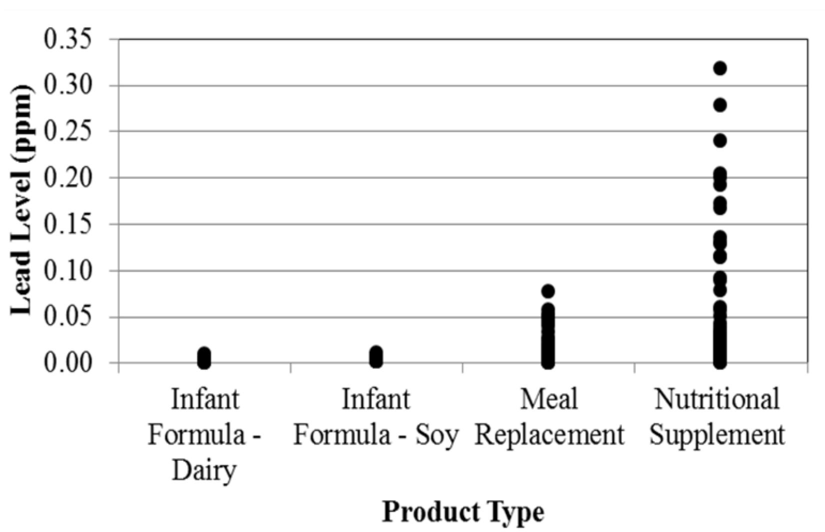


Figure 7. Lead occurrence by product type (in order of increasing number of samples).

Figure 8 illustrates the distribution of lead levels detected by product type. In general, infant formulas had very low levels of lead, with maximum levels of 0.010 ppm in dairy-based formulas and 0.011 ppm in soy-based formulas. The maximum level of lead observed in meal replacements was 0.078 ppm. Nutritional supplements displayed the highest maximum level of lead detected, at 0.318 ppm.



Note: Only values above the limit of detection are displayed.

Figure 8. Distribution of detectable lead levels by product type (in order of increasing maximum lead level

Table 6 summarizes the current FSAP and CFP survey data on lead levels in infant formulas, meal replacements and nutritional supplements. Infant formulas had the lowest maximum and average levels of lead. In comparison to the previous FSAP and CFP surveys, dairy-based infant formulas analyzed in the current survey year have lower maximum and average lead levels. Soy-based infant formulas have a higher lead occurrence for the current year versus the previous FSAP survey; however, the current maximum and average levels are much lower. The current survey data for lead in soy-based infant formulas agrees well with the CFP survey.

A total diet study performed by Health Canada from 1993 to 2007 found average lead concentrations of 0.0022 ppm in dairy-based infant formulas, and 0.0042 ppm in soy-based infant formulas[21]. The average lead concentrations in dairy- and soy-based infant formulas from the current survey agree well with the HC TDS data.

In general, the current levels of lead in meal replacements agree well with the previous FSAP survey; with a lower maximum detected level and a very comparable average. The positive rates for lead vary considerably between survey years, the reason for which is unknown. Nutritional supplements had a higher occurrence of lead in the current FSAP survey compared to the previous study, as well as higher maximum and average levels.

Table 6. Summary of FSAP and CFP survey data on lead levels in infant formula, meal replacements and nutritional supplements.

Author	Year	Number of Samples	Number (%) of Samples With Detectable Levels	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Infant Formula - Dairy						
FSAP[20]	2012-2013	96	22 (23)	0.001	0.010	0.003
	2011-2012	116	9 (8)	0.010	0.022	0.014
CFP[19]	2008-2009	26	15 (58)	0.003	0.015	0.007
Infant Formula - Soy						
FSAP[20]	2012-2013	48	35 (73)	0.001	0.011	0.005
	2011-2012	41	3 (7)	0.011	0.034	0.019
CFP[19]	2008-2009	9	8 (89)	0.004	0.010	0.007
Meal Replacement						
FSAP[20]	2012-2013	46	40 (87)	0.001	0.078	0.018
	2011-2012	66	36 (55)	0.002	0.094	0.020
Nutritional Supplement						
FSAP[20]	2012-2013	101	83 (82)	0.001	0.318	0.047
	2011-2012	82	49 (60)	0.002	0.258	0.032

*Average of positive results only

3.2.4 *Mercury*

Of the 291 samples tested for this survey, 258 (89%) of samples did not contain a detectable level of mercury. Figure 9 shows the number of samples and positive rates for mercury, organized by product types. No samples of infant formula (soy or dairy-based) tested positive for mercury. A total of 6 meal replacement samples (13%) and 27 nutritional supplements (27%) tested positive for mercury.

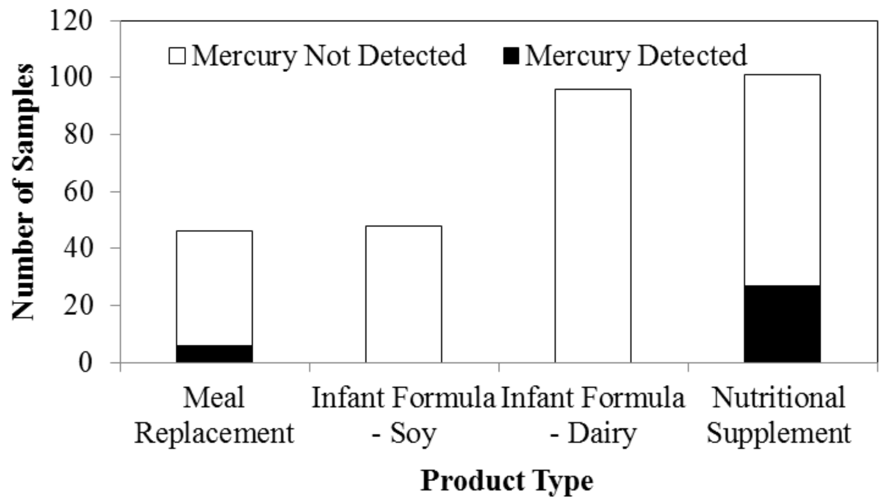
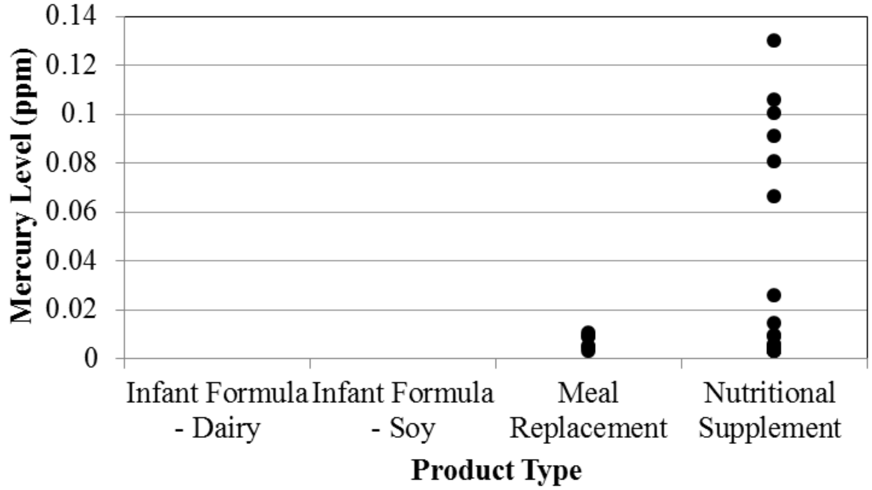


Figure 9. Mercury occurrence by product type (in order of increasing number of samples).

Figure 10 illustrates the distribution of mercury levels detected by product type. As previously mentioned, no samples of infant formula had detectable levels of mercury. Meal replacements had a maximum detected mercury level of 0.0107 ppm, with an average of 0.0069 ppm. Nutritional supplements had the highest occurrence, maximum detected value, and average mercury levels of all the product types tested. The maximum mercury level in nutritional supplements was 0.130 ppm with an average level of 0.026 ppm.



Note: Only values above the limit of detection are displayed.

Figure 10. Distribution of detectable mercury levels by product type (in order of increasing maximum mercury level).

Table 7 summarizes the current FSAP and CFP survey data on mercury levels in infant formulas, meal replacements and nutritional supplements. No samples of infant formulas tested positive for mercury in the current FSAP survey.

Meal replacements had comparable mercury occurrence and maximum levels between FSAP survey years; however, the current year had a higher average. Nutritional supplements had a higher occurrence for mercury in the current FSAP survey compared to the previous study, as well as higher maximum and average levels.

Table 7. Summary of FSAP and CFP survey data on mercury levels in infant formula, meal replacements and nutritional supplements.

Author	Year	Number of Samples	Number (%) of Samples With Detectable Levels	Minimum (ppm)	Maximum (ppm)	Average* (ppm)
Infant Formula - Dairy						
FSAP[20]	2012-2013	96	0 (0)	-	-	-
	2011-2012	116	4 (3)	0.0005	0.0040	0.0016
CFP[19]	2008-2009	26	0 (0)	-	-	-
Infant Formula - Soy						
FSAP[20]	2012-2013	48	0 (0)	-	-	-
	2011-2012	41	2 (5)	0.0006	0.0013	0.0010
CFP[19]	2008-2009	9	0 (0)	-	-	-
Meal Replacement						
FSAP[20]	2012-2013	46	6 (13)	0.0032	0.0107	0.0069
	2011-2012	66	7 (11)	0.0005	0.0093	0.0019
Nutritional Supplement						
FSAP[20]	2012-2013	101	27 (27)	0.0030	0.1298	0.0259
	2011-2012	82	18 (22)	0.0005	0.0098	0.0017

*Average of positive results only

4 Conclusions

This survey expanded upon baseline surveillance data on the levels of arsenic, cadmium, lead, and mercury in infant formulas, meal replacement and nutritional supplement beverages. A total of 291 samples were collected from 11 cities across Canada and analyzed for arsenic, cadmium, lead and mercury.

Overall, the majority (82%) 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- and soy-based formulas, except for cadmium, which was detected in soy-based but not dairy-based formulas. Infant formula samples that did test positive for arsenic, cadmium, lead or mercury generally had very low levels. Health Canada determined that none of the infant formula samples analyzed in this survey containing arsenic, cadmium, lead, or mercury would be considered to be of concern to human health, including infants.

In meal replacement products, the occurrence of metals varied widely, with lead being the most commonly detected metal (87% of meal replacement samples had a detectable level of lead), and mercury having the lowest rate of detection (only 13% 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.

Of the product types investigated in the current survey, nutritional supplements had the highest occurrence and average levels of arsenic, cadmium, lead and mercury. Many nutritional supplement samples (56%) tested positive for all four metals, with cadmium having the highest average level (0.181 ppm). Of the various protein types, rice protein-based nutritional supplements had the highest levels of arsenic, cadmium, lead and mercury. The levels of metals observed in the nutritional supplement products analyzed in this survey would not be expected to pose an unacceptable health risk.

The levels of arsenic, cadmium, lead and mercury were very consistent between FSAP survey years for infant formulas and meal replacements. Nutritional supplements had higher levels of lead and mercury in the current survey year relative to the previous survey, the reason for which is unknown. Health Canada’s BCS did not identify concerns to human health based on the results. No product recalls were warranted given the lack of health concern.

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