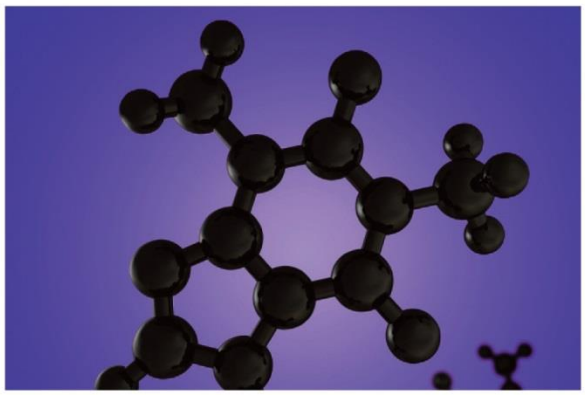
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Targeted Surveys

REPORT

2013-2014

Allergens



Undeclared Milk in Soy-Based Infant Formula

RDIMS 6620703

Canada

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Executive Summary

Targeted surveys are used by the Canadian Food Inspection Agency (CFIA) to both support the prioritization of the Agency's activities to areas of greater concern and provide scientific evidence to address areas of lesser concern. Originally started under the Food Safety Action Plan (FSAP), targeted surveys have been incorporated into the CFIA's regular surveillance activities as a valuable tool for generating essential information on certain hazards in foods, identifying/characterizing new and emerging hazards, informing trend analysis, prompting/refining human health risk assessments, assessing compliance with Canadian regulations, highlighting potential contamination issues, and promoting compliance.

The main objectives of this targeted survey were to obtain baseline information regarding the presence and levels of undeclared milk in soy-based infant formula, and to identify potential food safety concerns related to undeclared milk for the allergic and sensitive population.

A wide variety of soy-based infant formula is available on the Canadian market. In some cases, undeclared milk may be present in these products due to incomplete labelling or cross-contamination prior to or during manufacture of the final product, which may indicate a breakdown in good manufacturing practices or allergen controls. The presence of undeclared milk in a food may represent a serious or life-threatening health risk for allergic or sensitive individuals.

For this survey, 199 samples of soy-based infant formula were collected and analyzed for the milk proteins beta-lactoglobulin and casein. Soy-based infant formula sampled in this survey included powder and liquid concentrate products that did not declare milk in the list of ingredients. All samples contained at least one statement indicating that the product did not contain milk (e.g., free of lactose, no milk products or milk proteins, recommended for babies who cannot consume milk-based products). A precautionary statement indicating that products were manufactured on equipment also used to process dairy was present on 111 (55.8%) of the samples. Two (1.8%) of these samples tested positive for casein; both samples were from the same production lot. None of the remaining 88 samples tested positive for milk.

Both positive results were evaluated by the CFIA, taking into account the fact that not all detectable levels of undeclared milk pose a risk to consumers. The CFIA initiated appropriate risk management actions based on health risk assessments by Health Canada. Actions may include notification to the producer or importer, follow-up inspection, additional directed

sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

The CFIA will continue its surveillance activities and inform the Canadian public and other stakeholders of its findings.

1 Introduction

1.1 Targeted Surveys

The Canadian Food Inspection Agency (CFIA) monitors both domestic and imported foods for the presence of allergenic, microbiological, chemical, and physical hazards. One of the tools used to maintain this oversight are targeted surveys, which are a means to establish baseline information on specific hazards and to investigate emerging risks. Targeted surveys are part of the Agency's core activities along with other surveillance strategies, which include the National Chemical Residue Monitoring Program (NCRMP), the National Microbiological Monitoring Program (NMMP), and the Children's Food Project (CFP). The surveys are complementary to other CFIA surveillance activities in that they examine hazards and/or foods that are not routinely included in those monitoring programs.

Targeted surveys are used to gather information regarding the possible occurrence or prevalence of hazards in defined food commodities. These surveys generate essential information on certain hazards in foods, identify or characterize new and emerging hazards, inform trend analysis, prompt or refine human health risk assessments, assess compliance with Canadian regulations, highlight potential contamination issues, and/or influence the development of risk management strategies as appropriate.

Due to the vast number of hazard and 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, the media, 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.

Some hazards are actually a food itself - food ingredients, which are not a hazard to the majority of the population, can be hazardous to allergic individuals. This targeted survey provides baseline information on the presence and levels of undeclared milk in a range of soy-based infant formula. The sampled formula did not contain milk or dairy ingredients; however, more than half of the samples contained a statement indicating that they were manufactured on equipment also used to process dairy.

1.2 Acts, Regulations, and Codes of Practice

The specific acts and regulations applicable to this survey are described below.

The *Food and Drugs Act* (FDA) is the legal authority that governs the sale of food in Canada. 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 *Food and Drug Regulations* (FDA and FDR).

Health Canada has made amendments to the FDR to enhance the labelling of priority allergens, gluten sources, and sulphites on prepackaged foods sold in Canada. Some of these amendments require that food allergen and gluten sources be declared on the labels of prepackaged foods having a list of ingredients whenever the protein, modified protein, or protein fractions of the food allergen or gluten source are added to the food product. Due to the complexity of the labelling changes required, and given the extended shelf-life of some processed foods, Health Canada provided manufacturers with 18 months from the date of registration of the regulatory amendments to implement any necessary label changes. Thus, manufacturers were required to comply with Canada's amended food allergen labelling regulations when they came into force on August 4, 2012[1]. The food products analyzed in this survey were sampled after these amended labelling regulations came into force and therefore were required to comply with these new regulations.

In addition, failure to declare the possible presence of food allergens that are the result of cross contamination may be contrary to subsection 5 (1) of the FDA[2], and such food products may therefore be subject to regulatory measures taken by the CFIA.

2 Survey Details

2.1 Undeclared Milk in Soy-Based Infant Formula

While the presence of undeclared allergens in foods is not a health concern for the majority of Canadians, it may represent a serious or life-threatening health risk for allergic or sensitive individuals. Current estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adults in westernised countries[3]. In Canada, a specific list of food allergens have been identified by Health Canada as being responsible for causing the majority of severe allergic reactions. These are sometimes referred to as the priority allergens: eggs, milk, mustard, peanuts, seafood (fish, crustaceans, shellfish), sesame, soy, sulphites, tree nuts

(almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts), and wheat.

Milk allergy (which is not the same as lactose intolerance) is also one of the most common food allergies in children[4]. There are two major allergenic proteins in cow's milk: casein and beta-lactoglobulin (BLG; found in whey). These proteins are similar to those found in milk from other animals (e.g., goat, sheep, buffalo), thus people who are allergic to cow's milk may also experience allergic reactions to other types of milk[5]. The prevalence of self-reported milk allergy in the Canadian population is estimated to be approximately 2%[6], and this allergy is often outgrown by children within a few years[4].

Currently, there is no cure for food allergies. The most important strategy for a person with a food allergy or sensitivity, or a person choosing food for such an individual, is avoidance of the allergen that can trigger an adverse reaction. Allergens must be appropriately labelled on prepackaged food products to ensure consumers have complete, accurate information when choosing food.

2.2 Rationale

A wide variety of soy-based infant formula is available to Canadians. In some cases, undeclared milk may be present in such food products as a result of cross-contamination prior to or during manufacturing, which may indicate a breakdown in good manufacturing practices or allergen controls. Soy-based formula products available on the market may have allergen-free claims on the labels, implying that measures have been taken by the company to ensure that the claim is accurate and the product is truly allergen-free, which provides a degree of reassurance to the caregiver of an allergic or sensitive individual. Soy-based infant formula was targeted as a food commodity as it is often used as a primary or sole food source for infants with milk allergy or lactose intolerance.

This survey complements previous undeclared allergen targeted surveys and provides baseline information regarding the presence and levels of undeclared milk in soy-based infant formula available in the Canadian marketplace. The information gathered will provide an indication of potential food safety concerns relating to undeclared milk in soy-based infant formula.

2.3 Sample Selection

In total, 199 soy-based infant formula samples were collected nationally from retail stores in six Canadian cities between August 2013 and March 2014. Specific brands were not targeted.

The 199 survey samples included 161 imported products and 38 products for which the origin (i.e., domestic or imported) was unspecified. Of the 161 imported products, 129 were from the United States and the remaining 32 did not specify the country of origin (Table 1). An unspecified country of origin refers to those samples for which the origin is not indicated on the product label. It is important to note that the products sampled often contained the statement "packaged 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 distribution of samples collected in this survey with respect to the country of origin (as indicated on the product label) is depicted in Table 1.

Table 1. Distribution of soy-based infant formula samples by type and country of origin

Type of Formula	Imported or Domestic	Country of Origin	Total
Liquid Concentrate	Imported	United States	75
Powder	Imported	United States	54
		Unspecified	32
	Unspecified	Unspecified	38
Total			199

*Unspecified refers to those samples for which the country of origin could not be determined from the product label. Of the 70 unspecified samples, 32 were labelled as imported.

2.4 Limitations

This targeted survey was designed to provide a snapshot of the presence and levels of undeclared milk in selected soy-based infant formula available to Canadian consumers. The limited number of samples analyzed represents a small fraction of the products available to consumers. Therefore, care must be taken when interpreting and extrapolating these results. Few inferences or conclusions were made regarding the data with respect to country of origin (refer to Section 2.3).

Analysis was completed on products as available on the Canadian retail market. Samples were tested as sold, meaning that the concentrated formula was not prepared as per the package instructions.

3 Results and Discussion

3.1 Overview of Survey Results

Samples in the Undeclared Milk in Soy-Based Infant Formula Targeted Survey were analyzed by an ISO 17025 accredited food testing laboratory under contract with the Government of Canada. Commercially available ELISA-based allergen testing kits were used for analysis. A conversion factor was applied to the results to allow for comparison between kits. Sample concentration has been reported as soluble protein in parts per million (ppm). Details relevant to interpretation of the results of this survey can be found in sections below.

None of the soy-based infant formula samples tested contained milk in the list of ingredients. All samples contained at least one statement indicating that the product did not contain milk (e.g., free of lactose, no milk products or milk proteins, recommended for babies who cannot consume milk-based products). A precautionary statement indicating that products were manufactured on equipment also used to process dairy was present on 111 (55.8%) of the samples; two (1.8%) of these samples tested positive for casein (Tables 2 and 3). None of the remaining 88 samples tested were positive for milk.

The two positive samples were the same brand and type of powdered formula from the same production lot. The labels for these samples indicated that they were free of milk protein and contained no dairy ingredients. In addition, both samples contained a precautionary statement indicating that the product was manufactured on equipment used to also process dairy. Neither sample tested positive for beta-lactoglobulin.

Table 2. Distribution of soy-based infant formula, by product type and presence of dairy precautionary statement

Product Type	Powder	Liquid concentrate	Total
No dairy precautionary statement	63	25	88
Dairy precautionary statement	61	50	111
Total	124	75	199

Table 3. Concentration of soluble milk proteins (beta-lactoglobulin and casein) detected in soy-based infant formula samples

			Soluble Milk Protein (ppm)	
Product Type	**Sample Description**	**Country of Origin**	**Beta-lactoglobulin (BLG)**	**Casein**
Powder	Soy Infant Formula with Iron, 0-12 months	United States	0	0.8
Powder	Soy Infant Formula with Iron, 0-12 months	United States	0	1.0

Both positive results were evaluated by the CFIA, taking into account the fact that not all detectable levels of milk pose a risk to consumers. The CFIA initiated appropriate risk management actions based on health risk assessments by Health Canada. Actions may include notification to the producer or importer, follow-up inspection, additional directed sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

Given the levels of casein found in these products, it is difficult to infer the source of the milk. The presence of a statement indicating that the product was manufactured on equipment used to also process dairy would be considered a precautionary statement for the presence of milk. Potential sources of undeclared milk in products are cross-contamination prior to or during manufacturing or intentional addition.

4 Conclusion

This targeted survey obtained baseline information regarding the presence and levels of undeclared milk in soy-based infant formula available to consumers on the Canadian market.

In total, 199 samples of soy-based infant formula were collected and analyzed for the presence of two milk proteins (beta-lactoglobulin and casein). Samples included powder and liquid concentrate forms for various ages and stages and all samples contained at least one statement indicating that the product did not contain milk (e.g., free of lactose, no milk products or milk proteins, recommended for babies who cannot consume milk-based products). A precautionary statement for dairy was present on 111 (55.8%) of the samples; two (1.8%) of these samples tested positive for casein. None of the remaining 88 samples were positive for milk.

Both positive results were evaluated by the CFIA, taking into account the fact that not all detectable levels of milk pose a risk to consumers. The CFIA initiated appropriate risk management actions based on health risk assessments by Health Canada. Actions may include notification to the producer or importer, follow-up inspection, additional directed sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

5 References

1. Health Canada. *Health Canada's Modifications to Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites*. 2010 [cited March 9 2015]; Available from: http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/proj1220-modifications-eng.php.

2. Department of Justice Canada. *Food and Drugs Act (R.S.C., 1985, c. F-27) Part I. Food. 5(1).* [cited March 9 2015]; Available from: http://laws-lois.justice.gc.ca/eng/acts/f-27/index.html.

3. Health Canada. *Food Allergies and Intolerances*. [cited March 11 2015]; Available from: http://www.hc-sc.gc.ca/fn-an/securit/allerg/index-eng.php.

4. S.H. Sicherer and H.A. Sampson, *Food Allergy.* J Allergy Clin Immunol, 2006. **117**(2): p. S470-S475.

5. Health Canada. *Milk - One of the ten priority food allergens*. 2012 [cited March 9 2015]; Available from: http://www.hc-sc.gc.ca/fn-an/pubs/securit/2012-allergen_milk-lait/index-eng.php.

6. L. Soller, et al., *Overall prevalence of self-reported food allergy in Canada.* J Allergy Clin Immunol, 2012. **130**(4): p. 986-988.