

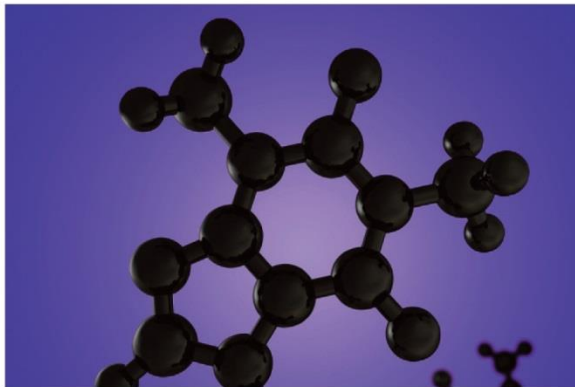


Targeted Surveys

REPORT

2013-2014

Allergens



Undeclared Soy and Gluten in Infant Cereal

RDIMS 6399656

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Executive Summary

Targeted surveys are used by the Canadian Food Inspection Agency (CFIA) to focus its surveillance activities on areas of highest risk. The information gained from these surveys provides both support for the prioritization of the Agency's activities to areas of greater concern and 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 soy and gluten in prepackaged infant cereals, and to identify potential food safety concerns related to undeclared soy and gluten for the allergic and sensitive population.

A wide variety of prepackaged infant cereals are available on the Canadian market. In some cases, undeclared soy and gluten sources 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 an undeclared allergen in a food may represent a serious or life-threatening health risk for allergic or sensitive individuals. In addition, undeclared gluten may contribute to chronic health issues for those individuals with celiac disease or gluten sensitivity.

For this survey, 196 samples of prepackaged infant cereal were collected at retail. Of these, 98 samples were analyzed for undeclared soy and 98 samples for undeclared gluten. Samples targeted in this survey were prepackaged infant cereal (including single and mixed grain as well as flavoured infant cereals).

None of the 196 samples analyzed for soy or gluten were positive. Follow-up actions were not deemed necessary given that none of the samples were positive for soy or gluten. 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). Targeted 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 soy and gluten in prepackaged infant cereals. The sampled foods were not tested for any soy or gluten present in the list of ingredients or in a precautionary statement.

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, 2012¹. 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 allergens that are the result of cross contamination may be contrary to subsection 5 (1) of the FDA², and such food products may therefore be subject to regulatory measures taken by the CFIA.

Health Canada has stated that foods with a gluten-free claim that are prepared under Good Manufacturing Practices and which contain levels of gluten not exceeding 20 parts per million (ppm) as a result of cross-contamination would not pose a health risk to individuals with celiac disease and would meet the intent of B.24.018 of the FDR^{3,4}.

2 Survey Details

2.1 Undeclared Soy and Gluten in Infant Cereal

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 countries⁵. 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.

Soy allergy is most common in infants and typically develops around three months of age⁶. There is little information on prevalence rates for soy allergy; a rate^a of 0.2% in the Canadian population has been reported⁷. Generally, slightly higher rates of soy allergy have been noted in children with eczema⁸. Similar to milk allergy, soy allergy is often outgrown by three years of age⁹.

It is important to distinguish between wheat allergy, celiac disease, and gluten sensitivity/intolerance. Wheat allergy is an immune response to specific proteins found in wheat, and the reaction to wheat is similar to other allergic reactions^{10, 11}. Celiac disease is an autoimmune disorder that causes inflammation of and damage to the small intestine (in turn resulting in the inability to absorb nutrients from food) when gluten (a protein in wheat, barley, and rye) is consumed¹². Celiac disease affects approximately 1% of the population and impacts all age groups¹³. Individuals with celiac disease should avoid all foods containing gluten, which includes wheat-, barley-, and rye-containing products. Gluten sensitivity may be an adverse reaction to gluten which is not caused by an allergic response or by celiac disease.

Currently, there is no cure for food allergies or celiac disease. 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 and gluten sources 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 prepackaged foods, including infant cereals, are available to Canadians. In some cases, a soy or gluten source 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. Some common foods have allergen-free claims on

^a Based on self-reported allergies

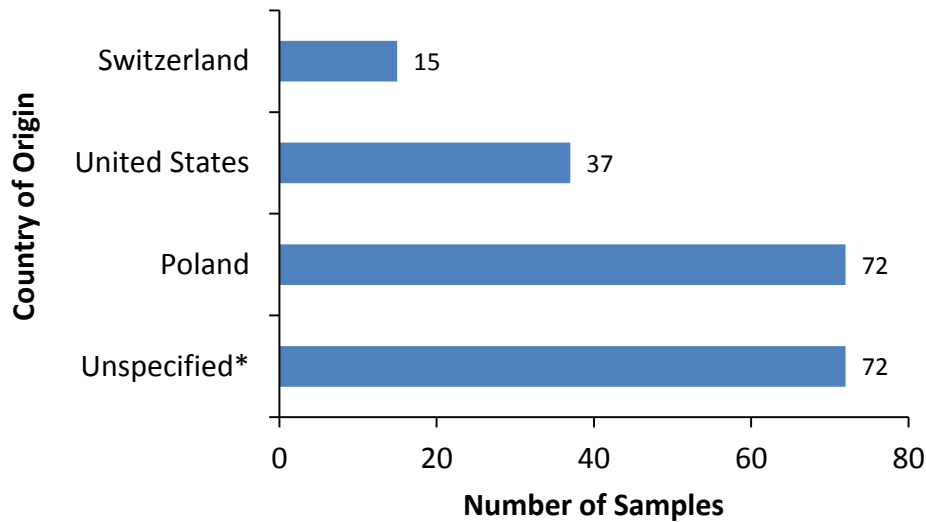
the labels, implying that measures have been taken by the company to ensure that the claim is accurate and the product is truly allergen-free, which provides a degree of reassurance to an allergic or sensitive individual or their caregiver. Prepackaged infant cereals were targeted as a food commodity due to their widespread feeding to infants, who are a more allergen-sensitive population.

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

2.3 Sample Selection

A total of 196 samples of prepackaged infant cereal were collected nationally from retail stores in six Canadian cities between July 2013 and March 2014. Specific brands were not targeted.

The 196 survey samples were all imported products, although the country of origin of these products was often unspecified. An unspecified country of origin refers to those samples for which the origin was 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 Figure 1.



* Unspecified refers to those samples for which the country of origin could not be determined from the product label

Figure 1. Distribution of prepackaged infant cereal samples by country of origin

2.4 Limitations

This targeted survey was designed to provide a snapshot of the presence and levels of undeclared soy and gluten in selected prepackaged infant cereals available to Canadian consumers, and highlight commodities that warrant further investigation. 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.

3 Results and Discussion

3.1 Overview of Survey Results

Samples in the Undeclared Soy and Gluten in Infant Cereal 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. These kits are manufactured by various companies who may use different materials to calibrate and

standardize their tests. Consequently, when data is generated by these different kits, the results cannot necessarily be directly compared to one another. To eliminate this issue, the CFIA usually converts the results to a common unit of measurement (i.e., concentration of soluble allergen protein in parts per million [ppm]) by applying a conversion factor.

Samples were tested for either soy or gluten that was not declared on the label, either in the list of ingredients or in a precautionary statement.

None of the 196 prepackaged infant cereal samples analyzed were positive for undeclared soy (98 samples) or gluten (98 samples). The distribution of samples by product type and country of origin is detailed in Tables 1 and 2. Product types sampled encompassed single and mixed grain infant cereals (including fruit, vegetable and yoghurt flavoured infant cereals). Follow-up actions were not deemed necessary given that none of the samples were positive for soy or gluten.

Table 1. Distribution of samples tested for soy by product description and country of origin

Product Type	Country of Origin	Number of Samples Tested
Barley Cereal	USA	4
Mixed Grain Cereal	Poland	6
	Switzerland	6
	Unspecified	5
	USA	5
Oat Cereal	Poland	4
	Switzerland	3
	Unspecified	8
	USA	11
Rice Cereal	Poland	10
	Switzerland	4
	Unspecified	7
	USA	4
Wheat Cereal	Switzerland	2
	Unspecified	18
	USA	1
Total		98

Table 2. Distribution of samples tested for gluten by product description and country of origin

Product Type	Country of Origin	Number of Samples Tested
Corn-Based Cereal	Poland	11
Rice and Corn-Based Cereal	Poland	8
Rice-Based Cereal	Poland	33
	Unspecified	34
	USA	12
Total		98

4 Conclusion

This targeted survey obtained baseline information regarding the presence and levels of undeclared soy and gluten in prepackaged infant cereals available to consumers on the Canadian market.

In total, 196 samples were collected and analyzed for the presence of either soy (98 samples) or gluten (98 samples). None of the samples were positive for gluten or soy. Follow-up actions were not deemed necessary given that none of the samples were positive for gluten or soy.

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

5 References

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