

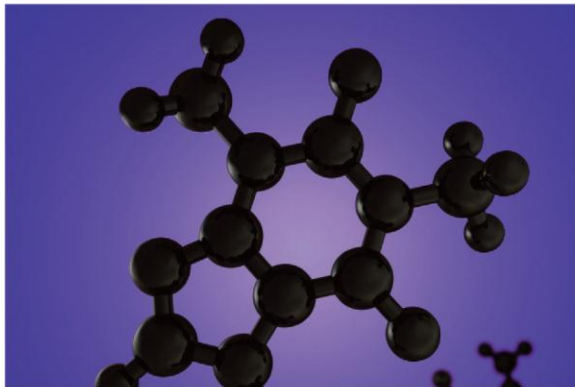


# Food Safety Action Plan

## REPORT

2011-2012 Targeted Surveys

Allergens



*Undeclared Allergens and Gluten in Children's Food*

TS-CHEM-11/12

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## Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As part of the FSAP enhanced surveillance initiative, targeted surveys are used to evaluate various foods for specific hazards.

A wide variety of pre-packaged foods typically consumed by children are available on the Canadian market. These foods include baked goods, cereals, cookies, crackers, granola bars, ready-to-eat meals and puddings.

The main objective of the undeclared allergens in children's food survey was:

- To obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in children's food.
- To identify potential food safety concerns relating to undeclared allergens in children's food.

A total of 304 foods were sampled and analysed for undeclared soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts, sesame and gluten. The majority of the samples were analyzed for more than one undeclared allergen and/or gluten. There were 1846 analyzes completed on the 304 samples. Of the 15 positive results (15/1846, 0.8%) there was; 1 almond, 1 sesame, 2 gluten and 11 soy. There was no undeclared egg, milk (beta-lactoglobulin and casein), peanuts or hazelnuts found in any of the samples.

All positive results were followed up by CFIA. Follow up action may involve a food safety investigation, including a health risk assessment conducted by Health Canada and a recall or one of the following: notification of manufacturer/importer and/or additional sampling.

# 1 Introduction

## 1.1 The Food Safety Action Plan

In 2007 the Canadian Government launched a five year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen the food safety regulatory system. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The 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. FSAP also looks to verify that the food industry is actively applying preventative measures.

Within FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess and prioritize potential food safety hazards through risk mapping, information gathering and testing foods from the Canadian marketplace. Targeted surveys are one tool that is used to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are covered exclusively by the *Food and Drugs Act*, and are generally referred to as non-federally registered commodities.

## 1.2 Targeted Surveys

Targeted surveys are used to test various foods for specific hazards and are meant to compliment the CFIA's regular programs and inspection activities. The surveys are designed to answer specific questions about hazards in food. Generally, they test for the occurrence and magnitude of defined hazards in targeted foods, often with the testing focusing on a specific segment of the population (i.e., consumers with an allergy or intolerance).

This targeted survey focused on the presence of undeclared allergens including: milk, egg, peanut, soy, almond, hazelnut, sesame, as well as gluten, in food typically consumed by children. Current estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adults in westernised countries.<sup>i</sup>

The information gathered will assess the compliance of products typically consumed by children with Canadian regulations and will provide an indication if follow up with industry is required.

### 1.3 Acts and Regulations

The *Food and Drug 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 & Regulations* (FDA and FDR).

If a pre-packaged food product displays a list of ingredients without disclosing potential allergens this may result in a health risk to allergic consumers. Failure to declare allergenic components may be contrary to Subsection 5(1) of the FDA. These products may therefore be subject to regulatory measures taken by the CFIA.

Health Canada made amendments to the FDR to enhance the labelling of priority allergens, gluten sources and sulphites in pre-packaged food sold in Canada. On February 16, 2011 Health Canada published these amendments in the *Canada Gazette*, Part II. The amendments require that food allergen and gluten sources be declared on the labels of pre-packaged 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 product. The amendments also require the labelling of added sulphites.

Due to the complexity of the labelling changes required, and 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 changes required in their labels. CFIA and Health Canada continued to encourage industry to declare priority allergens, gluten sources and added sulphites on pre-packaged food labels to provide Canadians with the information necessary to make informed food choices. Canada's new food allergen labelling regulations came into force on August 4, 2012. Further information on these regulations can be found on the Health Canada website.<sup>ii</sup>

The products analyzed in this survey were sampled prior to these amended regulations coming into force. However, proactive actions by the manufacturing sector may have occurred to ensure that these products did meet the amended regulations.

Gluten free claims are regulated under the FDR as a food for special dietary use. Health Canada has published a position that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of FDR when a gluten-free claim is made.<sup>iii</sup> The CFIA has published information on the compliance and enforcement of gluten free claims.<sup>iv</sup>

## 2 Allergens Survey

### 2.1 Rationale

The presence of an undeclared allergen or gluten source in a food is not a concern for the majority of Canadians. However, undeclared allergens may represent a serious or life threatening health risk for allergic or sensitive individuals. As well, undeclared gluten may contribute to chronic health issues for those individuals with Celiac disease or gluten sensitivity.

The main objective of this survey is to obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten sources in children's food. Foods such as baked goods, cookies, crackers, ready-to-eat meals, puddings and granola bars are widely available to Canadian consumers and are increasingly used as convenience foods. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in food typically consumed by children.

### 2.2 Hazard: Undeclared Allergens and Gluten

Current estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adults in westernised countries.<sup>v</sup> Celiac disease is a digestive disease, in which the consumption of gluten (a protein in wheat, rye and barley) leads to damage to the small intestine which in turn results in the inability to absorb nutrients from food. It is estimated that celiac disease affects 1% of the population.<sup>vi</sup> 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, and are sometimes referred to as the priority allergens.<sup>vii</sup> The priority allergens in Canada are as follows: milk, eggs, peanut, sesame seeds, tree nuts, mustard seeds, soy, wheat and seafood (fish, shellfish and crustaceans). Sulphites at levels of 10 ppm or higher have been recognized as having the potential to produce serious symptoms similar to an allergic reaction in sensitive individuals.<sup>i</sup>

There is no cure for a food allergy, and the most important strategy for a person with a food allergy, or a person choosing food for an individual with a food allergy, is avoidance of the allergen or allergens that can trigger an adverse reaction. Allergens and gluten sources should be appropriately labelled to ensure consumers have complete, accurate information when choosing food products.

### 2.3 Sample Distribution

This survey targeted foods typically consumed by children including baked goods, cereal, cookies, crackers, granola bars, ready-to-eat meals and puddings. Examples of baked goods included muffins, small cakes and cake mixes. There were 4 miscellaneous samples; these included canned fruit, marmalade and 2 sauces. Samples were collected based on availability in 2011 and 2012 from major retail stores as well as smaller ethnic retailers. No specific brands were targeted. A total of 304 food samples were collected. The distribution of samples by product type is listed in Table 1.

<b>Table 1: Sample distribution</b>			
<b>Sample type</b>	<b>Domestic or Imported</b>		
	<b>Domestic</b>	<b>Imported</b>	<b>Total</b>
Baked Goods	16	9	25
Cereals	31	44	75
Cookies	20	11	31
Crackers	12	14	26
Granola bars	15	11	26
Miscellaneous	1	3	4
Pudding	1	25	26
Meals	32	59	91
<b>Total</b>	<b>128</b>	<b>176</b>	<b>304</b>

## 2.4 Limitations

A total of 304 samples were all purchased in 2011-2012 at various retail stores in Canada. This represents a small sample size in comparison to what is available to Canadian consumers. The samples collected in this survey do not guarantee representation of all food products typically consumed by children available nationally. The data collected from this survey is meant to provide a snapshot of the targeted commodity and has the potential to highlight problem areas that warrant further investigation.

## 2.5 Methodology

Samples were analyzed by an accredited third party laboratory. Third party laboratories are accredited to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories (or its replacement by the Standards Council of Canada (SCC)).

The samples were tested for the presence of beta-lactoglobulin (BLG - milk protein), casein (milk protein), egg, peanut, almonds, hazelnuts, sesame, soy and gluten proteins. Food allergen proteins were detected and measured in the laboratory using ELISA-based accredited methodology (Table 2).

<b>Table 2: Methods of analysis</b>		
<b>Method</b>	<b>Analyte</b>	<b>Reporting Limit (ppm)</b>
Veratox Quantitative Soy Allergen Test	Soy	10
Veratox Quantitative Almond Allergen Test	Almond	2.5
Veratox Quantitative Hazelnut Allergen Test	Hazelnut	2.5
Veratox Quantitative Egg Allergen Test	Egg	2.5
Veratox Quantitative Peanut Allergen Test	Peanut	2.5
ELISA Systems Sesame Seed Protein Residue	Sesame	0.5
ELISA Systems Beta-Lactoglobulin	Beta-Lactoglobulin	0.1
ELISA Systems Casein Residue	Casein	0.26
RIDASCREEN Gliadin	Gluten	5

## 3 Results and Discussion

### 3.1 General Results

A total of 304 foods that are typically consumed by children were sampled. Samples were analyzed for the presence of undeclared allergens and/or gluten. Tests included soy, egg, milk (casein and beta-lactoglobulin separately), peanuts, almonds, hazelnuts, sesame and gluten. There were 1846 individual tests completed on the 304 samples (Table 3). There were 15 samples that contained an undeclared allergen or gluten source. The most prevalent undeclared allergen was soy (11 samples), followed by gluten (2 samples), almond (1 sample) and sesame (1 sample). There were 5 positive domestic products out of 128 domestic products analyzed and 10 positive imported products out of 176 imported products analyzed. Further information on these samples can be found in the following sections. There was no undeclared egg, milk (beta-lactoglobulin and casein), peanuts or hazelnuts found in any of the samples.

Analyte	Number of samples tested <sup>1</sup>	Number of positive samples
Soy	152	11
Sesame	285	1
Almond	266	1
Gluten	60	2
Milk (BLG and Casein)	312	0
Peanut	279	0
Egg	222	0
Hazelnut	270	0

<sup>1</sup>The difference between total number of samples (304) and the number of samples with a declaration of the allergen or gluten in the list of ingredients.

### 3.2 Gluten

It is important to distinguish wheat allergy from gluten sensitivity and celiac disease. Wheat allergy is an immune response to specific proteins found in wheat whereas celiac disease is an autoimmune disorder that is triggered by the gluten found in wheat and other grains.<sup>viii, ix</sup> Gluten sensitivity is an adverse reaction to gluten that is not caused by an allergic response or celiac disease.<sup>vii</sup>

Celiac disease is an autoimmune disorder that causes inflammation of the small intestine when gluten (from wheat, barley, rye and oats) is consumed.<sup>x</sup> Celiac disease affects approximately 1% of the population and impacts all age groups although it is more frequent in women than in men.<sup>vii, xi</sup> Individuals with celiac disease should avoid all foods containing gluten including wheat, barley, oats and rye products.

In this survey, 60 samples of foods typically consumed by children were analyzed for presence of an undeclared gluten source (wheat, barley, rye and oats) (Table 4). Currently, products sold in Canada, which contain wheat, barley, rye, or oats cannot make a gluten free claim. One product that contained oats had a wheat free claim as well as a statement



that the product was produced in a dedicated gluten free facility. These statements could lead a consumer to believe the product was gluten free, therefore, it was analyzed for gluten. This product contained 17 ppm gluten. One other product, a corn cereal contained 23 ppm of gluten. From a general health and safety perspective, Health Canada has published a position indicating that at levels not exceeding 20 ppm of gluten as a result of cross-contamination, when Good Manufacturing Practices are followed; a claim suggesting the food is gluten-free would not pose a health risk to individuals with celiac disease and would meet the intent of the FDR.<sup>v</sup> The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

<b>Sample description</b>	<b>Gluten (ppm)</b>	<b>Domestic/Imported</b>
Corn cereal	23	Imported
Mixed grain cereal	17	Domestic

### 3.3 Soy

Soy allergy is often considered to be a childhood allergy, however, older children and adults are also affected. Soy allergy is most frequently observed in infants<sup>xii</sup>. A study found that 0.4% of young children suffer from an allergy to soy, however, many of them will outgrow the allergy by the age of three years.<sup>xi</sup>

In this survey, 152 foods typically consumed by children were analyzed for presence of undeclared soy protein. Soy was found in 11 of the samples tested (Table 5). The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

<b>Sample description</b>	<b>Soy (ppm)</b>	<b>Domestic/Imported</b>
Green tea cake	12	Imported
Red velvet cake mix	25	Domestic
Chocolate cake mix	460	Domestic
Cereal: oats	2.6	Imported
Cereal: wheat	85	Imported
Cereal: mixed	340	Imported
Cereal: mixed	600	Domestic
Cereal: wheat	1200	Imported
Cookies: chocolate	52	Imported
Cookies: shortbread	500	Domestic
Crackers: seed	3	Imported

### 3.4 Sesame

Sesame is a priority allergen in Canada and can cause a severe allergic reaction. According to a population-based study on allergens in Canada, the prevalence of sesame allergy in

Canada is 0.09%.<sup>xiii</sup> Sesame seeds are available in three colors: white, brown and black. The seeds are widely used as garnishing items in Western fast food industries, in the baking industry, and are very common in the Mediterranean diet. Sesame components have also been used in many cracker products.<sup>xiv</sup>

Of the 304 samples collected and analyzed, 285 samples food typically consumed by children were analyzed for presence of undeclared sesame. Sesame was found in 1 of the imported ready-to-eat meal samples tested (0.84 ppm). This sample was referred for follow-up as appropriate.

### **3.5 Peanuts and Tree nuts**

Peanut and tree nut allergies account for majority of severe and anaphylactic allergic reactions in Canada. Current estimates of the prevalence of peanut and tree nut allergies in the Canadian population range between ~0.6% and 1%.<sup>xii</sup> Prevalence of peanut allergy in young children was found to be higher than that of adults and estimated at 1.03% confirmed allergy and 1.63% probable allergy.<sup>xvii</sup>

None of the 279 samples analyzed for peanut, or the 270 samples analyzed for hazelnut, tested positive. Of the 266 samples analyzed for almond, 1 sample, an imported chocolate snack cake was positive (190 ppm). This sample was referred for follow-up as appropriate.

## **4 Conclusion**

A total of 304 foods typically consumed by children were analyzed for the presence of undeclared allergens and/or gluten. There were 1846 analyzes completed on the 304 samples. Of the 15 positive results (15/1846, 0.8%) there was; 1 almond, 1 sesame, 2 gluten and 11 soy. Five out of a total of 128 domestic products (~4%) and 10 out of a total of 176 imported products (~6%) contained and undeclared allergens or gluten source.

This survey met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in a variety of foods typically consumed by children.

## 5 References

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