



Canadian Food
Inspection Agency

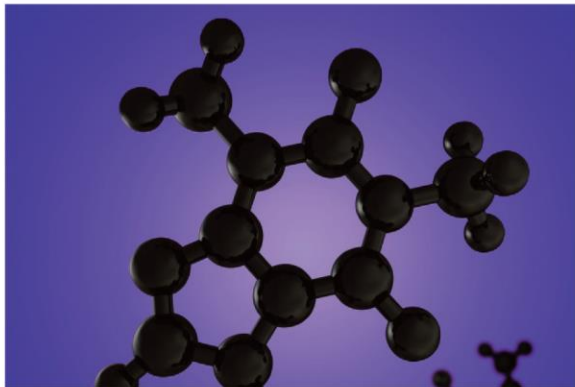
Agence canadienne
d'inspection des aliments

Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Allergens



***Undeclared Allergens in Snack Foods with an
Allergen Free and/or Gluten Free Claim***

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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 snack foods are available on the Canadian market. Snack foods include baked goods, cereals, cookies, crackers, granola bars and puddings. Some snack foods have allergen free and/or gluten free claims on their labels. Allergen free and gluten free claims imply that measures have been taken by a company to ensure that the claim is accurate, and provides a measure of reassurance to an allergic or gluten sensitive individual.

The main objectives of the undeclared allergens in snack foods survey were:

- To obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in snack foods which have an allergen free and/or gluten free claims on their labels.
- To identify potential food safety concerns relating to undeclared allergens in snack foods which have an allergen free and/or gluten free claims on their labels.

Each of the 487 snack food products sampled in the survey had one or more allergen free claims (eg. peanut free) and or a gluten free claim on the label. Samples were analyzed for the presence of allergens and/or gluten that were the subject of a free claim on the label as well as for allergens and gluten that were not declared in the list of ingredients. The allergen analyses consisted of: soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts and sesame. The majority of the samples were analysed for more than one allergen and/or gluten. There were 2810 analyses completed on the 487 samples. Twenty nine (6%) of the 487 samples of snack foods sampled were found to be positive for the presence of an undeclared allergen(s) or gluten. Some of the 29 samples were positive for more than one undeclared allergen; there were a total of 43 positive results. Of the 43 positive results (43/2810, ~1.5%) there was: 1 almond, 18 milk (8 beta-lactoglobulin and 10 casein), 18 gluten, 2 sesame and 4 soy. Of the 18 samples that were positive for undeclared gluten 4 samples had levels above 20 ppm, levels below 20 ppm are unlikely to cause adverse health effects. There were no undeclared peanut, egg or hazelnut found in any of the samples.

Over half of the undeclared allergens and gluten detected, 23 out of 43, were found in products with a corresponding allergen free and/or gluten free claim. The positives were: 3 soy, 18 gluten and 2 milk (1 beta-lactoglobulin and 1 casein). These 23 positive results were found in 20 products. Two products contained an allergen (soy, milk) as well as gluten. There was a claim on each label indicating the product was free of the allergen and gluten.

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 snack foods. All snack food samples had one or more allergen free claims and/or a gluten free claim on the label.

The information gathered will assess the compliance of these products 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 be a health risk to an allergic consumer. 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.ⁱ

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.ⁱⁱ The CFIA has published information on the compliance and enforcement of gluten free claims.ⁱⁱⁱ

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 was to obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten sources in snack foods that have an allergen free and/or gluten free claim on their labels. Snack foods such as baked goods, cookies, crackers and granola bars are widely available to Canadian consumers and are increasingly used as convenience foods. Some snack foods have claims on their labels indicating that the product is free of one or more allergens and/or that the product is gluten free. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in snack foods which have an allergen free and/or gluten free claim on their labels.

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.^{iv} 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.ⁱⁱ 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.^v 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).

There is no cure for a food allergy or gluten sensitivity, and the most important strategy for a person with a food allergy or gluten sensitivity, or a person choosing food for an individual with a food allergy or gluten sensitivity, is avoidance of the allergen(s) or gluten 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. Additionally, products that have a claim on their label indicating that they are free of an allergen or gluten are targeted specifically to sensitive individuals and it is vital that the claim is accurate.

2.3 Sample Distribution

This survey targeted snack foods including baked goods, cereal, cookies, crackers, granola bars and puddings. Examples of baked goods included muffins, small cakes and fruit filled bars. There were 3 miscellaneous samples, these included frozen desserts. 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 487 snack food samples were collected. The distribution of samples by product type is listed in Table 1.

Table 1: Sample distribution			
Sample type	Domestic or Imported		Total
	Domestic	Imported	
Baked Goods	12	22	34
Cereals	34	31	65
Cookies	64	50	114
Crackers	31	69	100
Granola bars	75	57	132
Miscellaneous	2	1	3
Pudding	5	34	39
Total	223	264	487

2.4 Limitations

A total of 487 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 snack food products 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).

Table 2: Methods of analysis		
Method	Analyte	Reporting Limit (ppm)
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 protein	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 487 snack foods which had one or more allergen free claims and/or a gluten free claim on the label (223 domestic products, and 264 imported products) were sampled. Samples were analyzed for the presence of undeclared allergens and/or gluten, including allergens that were the subject of a free claim. Tests consisted of soy, egg, milk (casein and beta-lactoglobulin separately), peanuts, almonds, hazelnuts, sesame and gluten. There were 2810 individual tests completed on the 487 samples.

Twenty nine samples were positive for one or more of the tested allergens and/or gluten for a total of 43 positive results (Table 3). Six samples were found to contain more than one undeclared allergen (Table 4). Undeclared gluten was the most prevalent positive result in the snack foods analysed, followed by milk protein (casein and beta-lactoglobulin), soy, sesame and almond (Table 3). There were no undeclared peanuts, egg or hazelnuts found in the samples analyzed.

Over half of the undeclared allergens and gluten detected, 23 out of 43, were found in products with a corresponding allergen free and/or gluten free claim (Table 5). These 23 positive results were found in 20 products. Two products contained an allergen as well as gluten; there was a claim on each label indicating the product was free of the specified allergen and gluten. One imported granola bar contained both soy and gluten (<20 ppm) and an imported cookie product contained milk and gluten (<20 ppm). Positive samples that had a corresponding free claim are noted in tables throughout the results section.

There were 8 out of a total of 223 domestic products (~4%) and 21 out of a total of 264 imported products (~8%) that contained one or more undeclared allergens and/or gluten. Of the 20 products that had a positive result(s) for an allergen and/or gluten for which there was a corresponding free claim on the label, 17 were imported (85%) and 3 (15%) were domestic products.

Analyte	Number of samples tested ¹	Number of positive samples
Milk: casein	238	10
Milk: beta-lactoglobulin	238	8
Gluten	309	18
Soy	123	4
Sesame	360	2
Almond	389	1

¹The difference between total number of samples (487) and the number of samples with a declaration of the allergen or gluten in the list of ingredients or in a precautionary statement. Samples were only tested for the presence of an allergen(s) and/or gluten if it was not indicated as present, or may be present, on the label.

Table 4: Samples with more than one undeclared allergen			
Sample	Domestic/Import	Allergen	Result (ppm)
Granola bar	Import	Gluten ¹	14
		Soy ¹	37
Cookie: Chocolate chip	Import	Gluten ¹	8.9
		BLG	0.89
		Casein	69
Cookies: Chocolate orange	Import	Gluten ¹	6.4
		BLG ¹	0.67
		Casein ¹	48
Cookies: Pistachio	Domestic	Almond	9.7
		BLG	0.44
		Casein	41
Cookies: Chocolate chip	Import	Gluten ¹	7.6
		BLG	1.4
		Casein	130
Cookies: Chocolate chip	Import	Gluten ¹	5.2
		Casein	0.38

¹Product had a corresponding free claim

Table 5: Positive sample distribution for allergens and gluten that were the subject of a free claim on the label						
Product type	Number of positive samples				Sample Origin	
	Gluten ¹	BLG	Casein	Soy	Domestic	Imported
Cookies	7	1	1	1	0	10
Baked Goods	1	-	-	-	0	1
Cereal	3 ²	-	-	-	2	1
Crackers	4 ³	-	-	-	0	4
Granola	3	-	-	2	1	4
Total	18	1	1	3	3	20

¹All gluten results were <20 ppm except 4 samples, as noted.

²One sample contained >20 ppm gluten.

³Three samples contained >20 ppm gluten.

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.^{vi, vii} Gluten sensitivity is an adverse reaction to gluten that is not caused by an allergic response or celiac disease.^{vi}

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

In this survey, 309 samples of snack foods were analyzed for presence of undeclared gluten, all other samples had a gluten source in the list of ingredients or in a precautionary statement. Laboratory results indicated that 18 of these samples contained undeclared gluten. All 18 products with a positive gluten result had a gluten free claim on the label. Fourteen of these samples contained less than 20 ppm gluten, 4 samples had gluten levels ranging from 22 ppm to 150 ppm (Table 6). 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.ⁱⁱ The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Sample description	Gluten (ppm)	Domestic/Imported
Baked good: Caramel bars	23	Imported
Cereal	12	Domestic
Cereal	8.5	Domestic
Cereal	5.4	Imported
Cookies: Chocolate chip	5.2	Imported
Cookies: Chocolate orange	6.4	Imported
Cookies: Vanilla	6.6	Imported
Cookies: Double chocolate	6.9	Imported
Cookies: Chocolate chip	7.6	Imported
Cookies: Chocolate chip	8.9	Imported
Cookies: Chocolate chip	10	Imported
Crackers	10	Imported
Crackers	22	Imported
Crackers	22	Imported
Crackers	150	Imported
Granola bars: Very berry	5.2	Imported
Granola bars: Wild berry	10	Domestic
Granola bars: Seeds	14	Imported

3.3 Milk

Cow's milk allergy is the most common food allergy in children less than three years of age.^x The prevalence of self-declared milk allergy in the Canadian population is estimated to be 2.09%.^{xi}

Dried milk components are widely used in processed food products. Dried whey can be used as an emulsifier, a gelling agent and as a taste enhancer in foods. It is one of the least expensive ingredients that can be used in manufactured food and is commonly used in dried mixes, fillings and in sauces.^{xii} There are two major allergen proteins in cow's milk: casein and beta-lactoglobulin.^{xiii} Cow's milk contains approximately 30-35 g of protein per litre^{xiv}, of which casein and whey account for 80% and 20%, respectively.^{xv} Beta-lactoglobulin makes up approximately 50% of the protein found in whey, or approximately 10% of the protein found in cow's milk.

A total of 238 samples were tested for the presence of undeclared milk. Overall, 10 samples were positive for undeclared milk proteins (casein and/or beta-lactoglobulin). Eight samples were positive for both casein and beta-lactoglobulin, 2 samples were positive only for casein (Table 7). Of the 10 positive samples, 9 were cookie products and one positive sample was a cracker product. Two samples, 1 cookie and 1 cracker, were positive for only 1 milk protein, casein. Only 1 positive sample, a cookie sample, had a milk free claim on the label.

The levels of undeclared milk (casein + beta-lactoglobulin) found in these samples ranged from 0.3 ppm to 550.66 ppm (Table 7). All 10 positive samples were referred for follow-up as appropriate.

Sample description	Casein (ppm)	BLG ¹ (ppm)	Domestic/Imported
Cookie: Chocolate Orange	26	0.6	Imported
Cookie: Almond	46	0.4	Domestic
Cookie: Chocolate chip	0.38	-	Domestic
Cookie: Chocolate chip	130	1.4	Imported
Cookie: Pistachio	41	0.44	Domestic
Cookie: Chocolate chip	69	0.89	Imported
Cookie: Punjabi	550	0.66	Domestic
Cookie: Ginger	0.72	0.38	Domestic
Cookie: Chocolate orange ²	48	0.67	Imported
Cracker	0.3	-	Imported

1 BLG= Beta-lactoglobulin

2 This sample had a 'Milk Free' claim on the label.

3.4 Soy

Soy allergy is often considered to be a childhood allergy, however, older children and adults are also affected with this allergy. Soy allergy is most frequently observed in infants^{xvi}, possibly due to the use of soy based infant formulas as a substitute for milk based infant formulas.^x 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.^x

In this survey, 123 snack foods were analyzed for presence of undeclared soy protein. Soy was found in 4 of the samples tested (Table 8).

Table 8: Results of Soy Analysis		
Sample description	Soy (ppm)	Domestic/Imported
Cookie: Oat cookies	11 ¹	Domestic
Cookie: Chocolate chip	21 ¹	Imported
Granola bar: Very berry	11 ¹	Imported
Granola bar: Seeds	37 ¹	Imported

¹Sample had a ‘soy free’ claim on the label

3.5 Sesame

Sesame is one of the priority allergens in Canada. According to a population-based study on allergens in Canada, the prevalence of sesame allergy in Canada is 0.09%.^{xvii} 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.^{xviii}

Of the 487 samples collected and analyzed, 360 samples of snack foods were analyzed for presence of undeclared sesame. Sesame was found in 2 of the samples tested (Table 9). These samples did not have a sesame free claim on the label; however, sesame was not in the list of ingredients or in a precautionary statement. The positive samples were referred for follow-up as appropriate.

Table 9: Results of Sesame Analysis		
Sample description	Sesame protein (ppm)	Domestic/Imported
Cereal	0.5	Imported
Granola bar : Peanut	2.1	Imported

3.6 Peanuts and Tree nuts

Peanut and tree nut allergies account for the majority of severe and anaphylactic allergic reactions in Canada. Estimates of the prevalence of peanut and tree nut allergies in the Canadian population range between ~0.6% and 1%.^{xi} The 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.^{xvii}

None of the 407 samples analyzed for peanut or the 394 samples analyzed for hazelnut, tested positive. Of the 389 samples analyzed for almond, 1 was positive (Table 10). This sample did not have an almond free claim on the label, however, almond was not in the list of ingredients or in a precautionary statement. This sample was referred for follow-up as appropriate.

Table 10: Results of Almond Protein Analysis		
Sample description	Almond (ppm)	Domestic/Imported
Cookies: Pistachio	9.7	Domestic

3.7 Egg

Egg allergies are considered one of the most common allergies in children, with 0.2% to 1.6% of this population estimated as being affected.^{xix} According to Soller et al, 2012, in Canada, self-reported prevalence rates are estimated at 1.2% in children and 0.8% in the general population.^{xx} Both egg whites and egg yolk contain allergenic proteins, with a much higher concentration found in egg whites.^{xxi xxii}

Eggs and egg by-products are often used in processed products as food additives for the following purposes: binder, emulsifier, coagulant, preservative, or used to give baked goods a shiny coating.

In this survey, 352 snack foods were analyzed for presence of undeclared egg. None of the analysed samples contained undeclared egg protein.

4 Conclusion

A total of 487 snack food samples that had one or more allergen free claims and/or a gluten free claim on the label were analyzed for the presence of undeclared allergens and/or gluten. There were 29 products that contained one or more undeclared allergens out of a total of 487 products tested (~6%). Undeclared gluten (18 products) was the most prevalent positive result in the snack foods followed by milk protein (10 products contained undeclared casein and/or beta-lactoglobulin), soy (4 products), sesame (2 products) and almond (2 products). There were no undeclared peanut, egg or hazelnut found in any of the samples. Of the 43 positive results 23 (~53% of the positive results and ~1% of all 2810 results) were found in products with a corresponding allergen free or gluten free claim.

There were 8 out of a total of 223 domestic products (~4%) and 21 out of a total of 264 imported products (~8%) which contained one or more undeclared allergens and/or gluten. The majority of the products that had a positive result with a corresponding free claim were imported (17/20, ~85%).

This survey met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in a variety of snack foods that had an allergen free and/or gluten free claim(s) on their labels. The information gathered indicated that there may be a need for a further focus on products, in particular those of imported origins, which make an allergen free and/or gluten free claim.

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