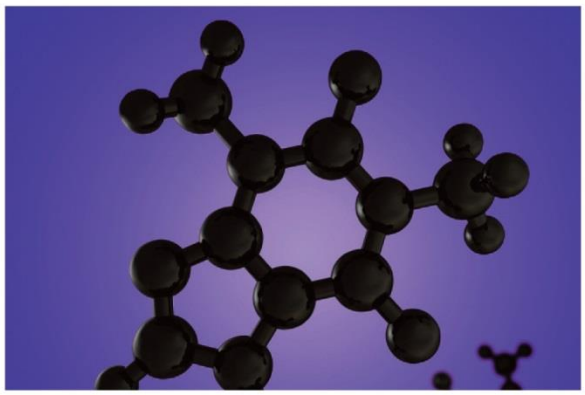
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2012-2013 Targeted Surveys

Allergens



Undeclared Allergens and Gluten in Domestic and Imported Products

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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 domestic and imported prepackaged products such as desserts, snacks, ready to eat meals, spices and flavour packets are available on the Canadian marketplace. Undeclared allergens and/or gluten sources may be present in prepackaged products due to incomplete labelling or cross contamination of an ingredient, or the final product, with an allergen and/or gluten source. This survey gathered information on the levels and prevalence of undeclared allergens and/or gluten in domestic and imported prepackaged products.

The main objectives of the Undeclared Allergens and Gluten in Domestic and Imported Products survey were:

- To obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in domestic and imported prepackaged products.
- To identify potential food safety concerns relating to undeclared allergens and gluten in domestic and imported prepackaged products.

For this survey 594 domestic and 586 imported prepackaged products 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 3705 analyses conducted on the domestic samples, of which 23 products tested positive for one or more undeclared allergens. For samples of imported products, 3739 analyses were conducted, with 50 products being found positive for one or more undeclared allergens. Overall, 3.9% of domestic samples and 8.5% imported samples collected were positive for undeclared allergens or 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's Food Directorate 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 Canada's safety system for food, health and consumer products. 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 12 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 analyse various foods for specific hazards and are meant to complement the CFIA's regular monitoring 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 domestic and imported prepackaged products. Products sampled included desserts, snacks, ready to eat meals, spices and flavour packets. Domestic and imported prepackaged products are consumed by the majority of the Canadian population and there have been some incidents of these products being recalled due to undeclared allergens. Current estimates indicate that food allergies affect as many as 6.0% of young children and 3.0% to 4.0% of adults in westernised countries.[i]

The information gathered will assess the compliance of the domestic and imported prepackaged products sampled with Canadian regulations and will provide an indication as to whether 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 prepackaged 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 prepackaged 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 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 product.

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 continue to encourage industry to declare priority allergens, gluten sources and added sulphites on prepackaged 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.[ii]

2 Allergens and Gluten Survey

2.1 Rationale

The presence of an undeclared allergen or gluten source in a food is not a health 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 imported and domestic prepackaged products available in the Canadian marketplace. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens and gluten in imported and domestic prepackaged products.

2.2 Hazard: Undeclared Allergens and Gluten

Current estimates indicate that food allergies affect as much as 6.0% of young children and 3.0% to 4.0% of adults in westernised countries.[iii] Celiac disease is an autoimmune disorder, 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.[iv]

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, sulphites, tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts and walnuts), mustard seeds, soy, wheat and seafood (fish, shellfish and crustaceans).

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 domestic and imported prepackaged products available in the Canadian marketplace included desserts, snacks, ready-to-eat meals, spices and flavour packets. Samples were collected based on availability in 2012 and 2013 from major retail stores, as well as smaller speciality retailers, across Canada. No specific brands were targeted. A total of 1180 samples were collected. The distribution of samples by product type is listed in Table 1.

Instructions given to samplers for the collection of imported products included collection of samples that did not have the following statements on the labels; Made in Canada, Product of

Canada or Prepared for Company X. Similar instructions were also given for the domestic survey. Samplers were to collect products with Made in Canada, Product of Canada or Prepared for Company X on the label. Products with a "distributed by" statement on the label were assumed to be imported. Some products included in the domestic survey may be products that were packaged in Canada or further processed domestically from imported ingredients.

2.4 Limitations

A total of 1180 samples were purchased in 2012-2013 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 domestic and imported prepackaged 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 ISO 17025 accredited laboratory under contract with the Government of Canada. 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. Samples were not tested for the presence of other priority allergens (e.g., mustard, fish), as these substances were outside the scope of this survey. Food allergen proteins were detected and measured in the laboratory using ELISA-based methodology.

3 Results and Discussion

3.1 General Results

Samples (1180) of domestic and imported prepackaged products were collected and analyzed for the presence of undeclared allergens and/or gluten. Analyses included soy, egg, milk (casein and beta-lactoglobulin separately), peanuts, almonds, hazelnuts, sesame and gluten. There were 3705 individual tests completed on the 594 domestic samples and 3739 individual tests completed on the 586 imported samples (Table 1).

There were 26 positive results (on 23 products) out of 594 domestic products analyzed and 53 positive analyses (on 50 products) out of 586 imported products analyzed. Further information on these samples can be found in the following sections.

Table 1: Positive sample distribution for each allergen and gluten				
Analyte	**# Tests Domestic**	**# Tests Imported**	**# positive Domestic (%)**	**# positive Imported (%)**
Almond	528	483	1 (0.19)	0 (0)
BLG	320	330	1 (0.31)	4 (1.2)
Casein	320	332	5 (1.6)	2 (0.60)
Egg	461	484	1 (0.22)	1 (0.21)
Gluten	181	239	7 (3.9)	22 (9.2)
Hazelnut	535	494	0 (0)	0 (0)
Peanut	549	510	0 (0)	1 (0.20)
Sesame	566	551	1 (0.18)	3 (0.54)
Soy	245	316	10 (4.1)	20 (6.3)
Total	**3705**	**3739**	**26* (0.70)**	**53** (1.4)**

* There were 26 positive analyses on 23 samples as some samples contained multiple allergens

**There were 53 positive analyses on 50 samples as some samples contained multiple allergens

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 certain other grains.[vi] Gluten sensitivity is an adverse reaction to gluten that is not caused by an allergic response or celiac disease.

Celiac disease is an autoimmune disorder affecting approximately 1% of the population and impacts all age groups.[viv] When gluten (from wheat, barley, rye and oats) is consumed by an individual with celiac disease it causes inflammation of the small intestine. [vii] Individuals with celiac disease should avoid all foods containing gluten including wheat, barley and rye products.

In this survey, 181 domestic samples and 239 imported samples were tested for undeclared gluten. Table 2 shows the product types that were positive for undeclared gluten and the results associated with those samples. Of the domestic samples analyzed, 6 out of 181 (3.3%; 39 to 120 ppm) samples were positive for undeclared gluten at a level greater than 20 ppm. Of the 239 imported samples analyzed, 15 samples (6.3%; 24 to 460 ppm) were positive for undeclared gluten in levels greater than 20 ppm.

From a general health and safety perspective, Health Canada's Food Directorate 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 gluten-free claim on the label would not pose a health risk to individuals with celiac disease and would meet the intent of the FDR.[iv] One domestic sample (8 ppm) and 7 imported samples (9.2 to 18 ppm) were below 20 ppm. All positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 2: Positive results of gluten analysis		
Sample description	**Sample type**	**Gluten (ppm)**
Domestic		
Cereal	Maple and Brown Sugar Oatmeal	65
Ready to eat meal	Carrot and Orange Soup*	58
	Curry chicken with Rice	71
	Leek and Tomato Soup	47
	Pickled Sausage	120
Flavour Packet - Dried	Montreal Style Chicken Spice Mix	39
	Organic Curry Culinary Mix	8
Import		
Flavour Packet - Dried	Beef Spice***	27
	Chinese Special Spice	13
	Chow Mein Seasoning Mix	25
	Chunky Chat Masala**	9.2
	Gravy Mix	75
	Louisiana Cajun seasoning	57
	Naturally Flavoured Brown Gravy Mix	17
	Oriental Gravy Mix	91
	Palabok Oriental Gravy	50
	Palabok Oriental Gravy Mix	97
	Poultry Seasoning	25
	Poultry Seasoning	26
	Poultry Seasoning	45
	Spice Mix for Bombay Biryani	24
	Spice Mix for Chicken with Vegetables	18
	Spice Mix for Delhi Nihari	15
	Spice Mix for Murgh Cholay	57
	Spice Mix for Shahi Daal	10
	Spice Mix for Punjabi Chana	17
	Steak seasoning rub	40
	Sweet & Sticky Chicken Seasoning	460
	Texan steakhouse seasoning	270
	Sweet & Sticky Chicken Seasoning	460

* This sample also tested positive for soy, ** This sample also tested positive for peanut, *** This sample also tested positive for soy

3.3 Soy

Soy allergies are most frequently observed in infants and [viii] are often considered to be a childhood allergy, however, older children and adults can also be affected. A study found that 0.40% of young children suffer from an allergy to soy, however, many of them will outgrow the allergy by the age of three years. [ix]

In this survey, 245 domestic and 316 imported samples were tested for undeclared soy. Table 3 shows the product types that were positive for undeclared soy and the results associated with those samples. Of the domestic samples analyzed, 10 samples (4.1%) were positive for undeclared soy with levels ranging from 0.8 to 36 ppm. Of the 316 imported samples analyzed, 20 samples (6.3%) were positive with a range of 0.56 to 18.6 ppm soy.

Table 3: Positive results of soy analysis		
Sample description	**Sample type**	**Soy (ppm)**
Domestic		
Flavour Packet - Dried	Béchamel Sauce Mix	11.5
	Béchamel Sauce Mix	22
	Gravies - Sauce Turkey	0.80
	Onion Toasted Garlic	1.75
	Onion Toasted Garlic	0.92
	Sweet & Sour Chicken Sauce	6
Cookies	Strawberry Tarts, Coconut Cookies with Strawberry Filling	1.3
Cereal	Breakfast Cereal*	36
Ready to eat meal	Carrot & orange RTE soup **	0.88
	Hawaiian Pizza Pops	13
Imported		
Baking Mixes	Baking Mix	0.62
Cereal	Wheat based hot cereal	5
	Wheat based hot cereal	18.6
	Wheat based hot cereal	6
	Wheat based hot cereal	3
	Wheat based hot cereal	11.4
	Hot Cereal	12.2
	Hot Cereal	8
	Hot cereal	8.2
	Wheat based hot cereal	2
	Wheat based hot cereal	50
Flavour Packet - Dried	Beef spice	0.80
	Fried chicken spice mix	17.6
	Oriental spice blend***	22
	Roasted garlic with sea salt	0.56
	Shrimp Sauce Mix	0.76
Ready to eat meal	Blueberry toaster strudel	0.74
	Cream Cheese filled bagels	2
	Flatbread Morning Sandwich	0.64
	Flatbread Morning Sandwich	0.68

* This product also tested positive for sesame, ** This product also tested positive for gluten, *** This product also tested positive for gluten

3.4 Milk

Cow's milk allergy is the most common food allergy in children.[x] The prevalence of self-declared milk allergy in the Canadian population is estimated to be 2.09%.[xi]

There are two major allergenic proteins in cow's milk: casein and beta-lactoglobulin. Cow's milk contains approximately 30-35 grams of protein per litre, of which casein and whey (containing beta-lactoglobulin) account for 80% and 20%, respectively.

In this survey, 320 domestic and 332 imported samples were tested for undeclared milk. Table 4 shows the product types that were positive for undeclared milk and the results associated with those samples. Of the domestic samples analyzed, 5 samples (1.6%) were positive for undeclared milk. Four (4) samples were positive for casein only, at levels ranging from 0.40 to 0.44 ppm and 1 sample was positive for both casein and beta-lactoglobulin (0.77 and 0.90 ppm respectively). Of the 332 imported samples analyzed, 6 samples (1.8%) were positive for undeclared milk. Four (4) samples were positive for beta-lactoglobulin at levels ranging from 0.28 to 0.48 ppm and 2 were positive for casein with levels of 0.30 and 0.34 ppm.

Table 4: Positive results of milk analysis

Sample description	Sample type	Casein (ppm)	BLG* (ppm)
Domestic			
Cereal	Oat bran	0.40	-
Cookies	Anisetti sponge biscuits	0.43	-
Flavour Packet - Dried	Lemon Pepper Seasoning	0.44	-
Cakes	Coffee Cake	0.77	0.90
Ready to eat meal	Rigatoni Pomodoro	0.41	-
Import			
Flavour Packet - Dried	Instant thickener for brown gravies	-	0.47
	Instant thickener for brown gravies	-	0.48
	Mix For Brown Gravy	-	0.40
	Pad Thai Seasoning Mix	-	0.28
C**e**real	Wheat based hot cereal **	0.34	-
	Fritter Breakfast Mix	0.30	-

* BLG= Beta-lactoglobulin, **This product also tested positive for soy and egg

3.5 Egg

Egg allergies are considered one of the most common allergies in children, with 0.20% to 1.6% of this population estimated as being affected. [xii] According to Soller et al, 2012, in Canada, self-reported prevalence rates are estimated at 1.2% in children and 0.80% in the general population.[xiii] Both egg whites and egg yolk contain allergenic proteins, with a much higher concentration found in egg whites.[xiv xv]

In this survey, 461 domestic and 484 imported samples were tested for undeclared egg. Table 5 shows the product types that were positive for undeclared egg and the results associated with those samples. Of the domestic samples analyzed, 1 out of 461 (0.22%) samples were positive for undeclared egg. Of the 484 imported samples analyzed, 1 sample (0.21%) was positive for undeclared egg.

Table 5: Positive results of egg analysis

Sample description	Sample type	Egg (ppm)	Domestic/Imported
Ready to eat meal	Seafood pie	2.2	Domestic
Ground spice	Chili powder	2.2	Imported

3.6 Tree nuts

Tree nut allergies are one of the major causes of severe and anaphylactic allergic reactions in Canada. Current estimates of the prevalence of tree nut allergies in the Canadian population range between ~0.60% and 1.0%.[xi]

In this survey, 535 and 528 domestic samples were tested for hazelnut and almond, respectively. Of these domestic samples only one sample (0.19%) was positive for undeclared almond. As well, 494 and 483 imported samples were tested for hazelnut and almond, respectively. None of these imported samples were positive for undeclared tree nuts. Table 6 shows the product types that were positive for undeclared almond and the result associated with that sample.

Table 6: Positive results of tree nut analysis

Sample type	Sample description	Result (ppm)	Domestic/Imported
Cakes	Caramel and Cinnamon Pudding Cake	3.52	Domestic

3.7 Peanuts

Peanut allergies are one of the major causes 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 ~0.60% and 1.0%.xi

In this survey, 549 domestic samples were tested for peanut. None of these domestic samples were positive for undeclared peanut. As well 510 imported samples were tested for peanut. Of these imported samples only one sample (0.20%) was positive for undeclared peanut. Table 7 shows the product type that was positive for undeclared peanut and the result associated with that sample.

Table 7: Positive results of peanut analysis

Sample type	Sample description	Result (ppm)	Domestic/Imported
Flavour Packet - Dried	Chunky chat Masala*	0.39	Imported

*This sample also tested positive for gluten

3.8 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%.[xvi] Sesame seeds are available in three colors: white, brown and black. The seeds are widely used as garnishing items in fast food industries, in baking and are very common in the Mediterranean diet. Sesame components have also been used as an ingredient in many cracker products. [xvii]

In this survey, 566 domestic and 551 imported samples were tested for undeclared sesame. Table 8 shows the product types that were positive for undeclared sesame and the results associated with those samples. Of the domestic samples analyzed, 1 sample (0.18%) was positive for undeclared sesame with a level of 2.9 ppm. Three (3) samples (0.54%) were positive for undeclared sesame with levels of 0.95, 1.0 and 1.8 ppm.

Table 8: Positive results of sesame analysis		
Sample description	**Sample type**	**Sesame (ppm)**
Domestic		
Cereal	Breakfast Cereal*	2.9
Import		
Flavour Packet - Dried	Achar/Pickle Seasoning	1.8
	Curry Powder	0.95
	Gourmet Seasoning	1

* This product also tested positive for soy

4 Conclusion

Of the 594 domestic and 586 imported samples of prepackaged products collected and tested, there were 23 domestic and 50 imported products found positive for undeclared allergens and/or gluten. Three domestic as well as three imported samples were found to be positive for more than one allergen. Overall, 3.9% of domestic and 8.5% imported samples collected were found to be positive for undeclared allergens or gluten.

This survey met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in domestic and in imported prepackaged food available in the Canadian market.

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