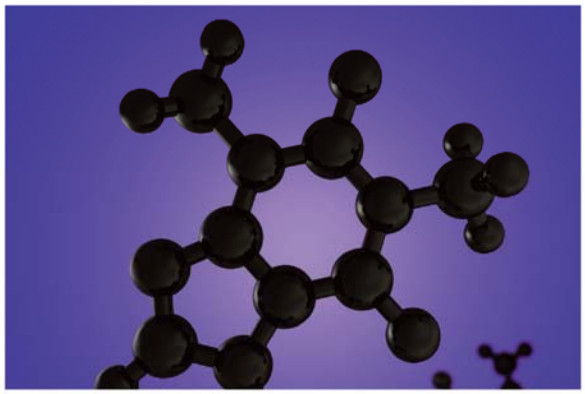
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2012-2013 Targeted Surveys

Allergens



Undeclared Allergens and Gluten in Soup

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RDIMS 4043816

Canada

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 soups, including broths, dried, condensed and ready-to-eat soups are available on the Canadian marketplace. There have been previous incidents of undeclared allergens and gluten sources in soup products which have led to product recalls. Undeclared allergens and/or gluten may be present in a soup product 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 soup products.

The main objectives of the Undeclared Allergens and Gluten in Soup survey were:

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

A total of 499 soup 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 3411 analyses completed on the 499 samples. Some products contained more than one undeclared allergen or gluten source, a total of 22 products contained 26 positive results. Of the 26 positive results (26/3411, 0.8%) there were: 8 milk (7 products were positive; 3 for casein, 3 for beta-lactoglobulin and 1 product tested positive for both proteins), 4 egg, 6 gluten, 1 hazelnut and 7 soy. The majority of the positive results (23/26, 88%) were from dried soups and bouillons. There were no undeclared almond, peanut or sesame 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 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 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 complement 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 soup products. Products sampled included broths, bouillons, dried, condensed and ready-to-eat soups. Soups are consumed by the majority of the Canadian population and there have been some incidents of soup products being recalled due to undeclared allergens. Current estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adults in westernised countries.[i]

The information gathered will assess the compliance of sampled soup 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 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.

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.[ii]

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 soup products available in the Canadian Marketplace. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens and/or gluten in soup.

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.[iii] 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.[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, tree nuts, 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 soup products available in the Canadian Marketplace including bouillons (condensed or dry), dry soup mixes, condensed soups (soups that require the addition of water) and ready-to-eat soups. Samples were collected based on availability in 2012 and 2013 from major retail stores, as well as smaller ethnic retailers. No specific brands were targeted. A total of 499 soup samples were collected. The distribution of samples by product type is listed in Table 1.

Table 1: Sample Distribution

Product Type	Domestic	Imported	Unspecified	Total
Bouillon	9	38	13	60
Broth	21	22	67	110
Condensed	17	2	12	31
Dried	17	37	21	75
Ready-to-eat	70	44	109	223
Total	134	143	222	499

*Unspecified refers to those samples for which the origin (i.e., imported or domestic) could not be determined from the product label.

2.4 Limitations

A total of 499 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 soup 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 in this targeted survey were analyzed by a laboratory under contract with the Government of Canada. This laboratory is accredited by the Standards Council of Canada (SCC) or by the Canadian Association for Laboratory Accreditation Inc. (CALA). The laboratory was required to use analytical methods that met or exceeded the requirements and limits of detection of the equivalent CFIA methods.

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

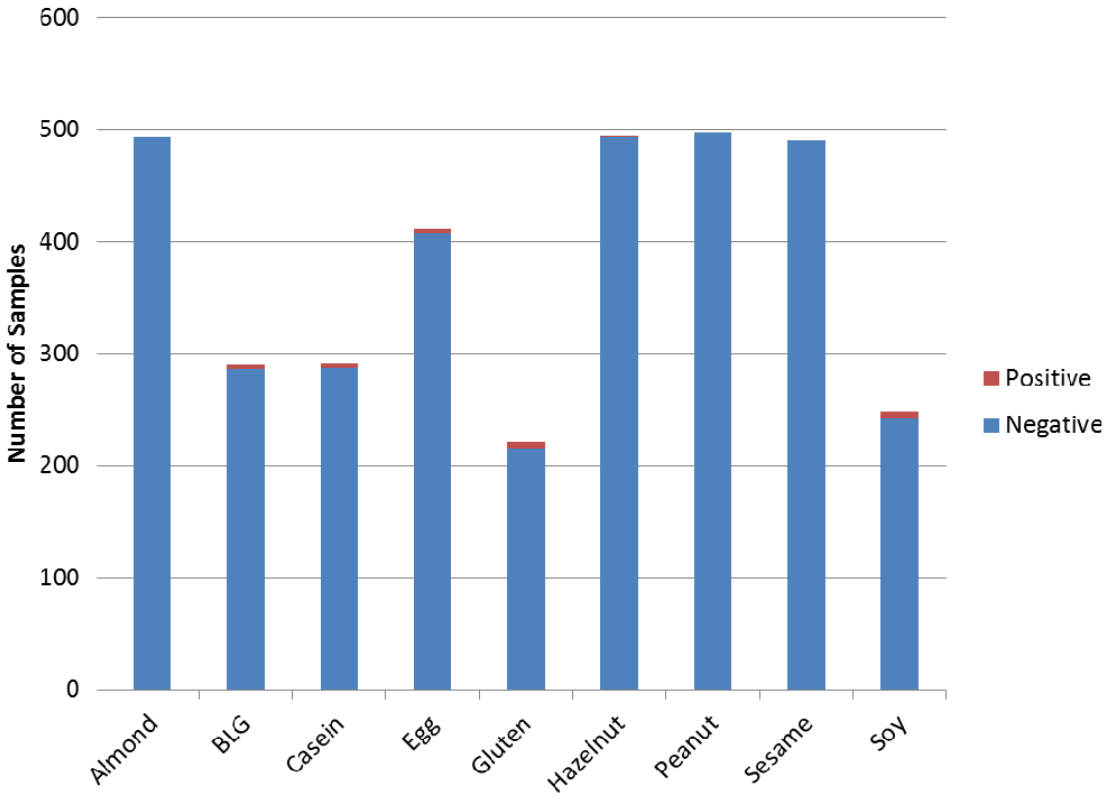
A total of 499 soup products were sampled. Samples were analyzed for the presence of undeclared allergens and/or gluten. Analyses included soy, egg, milk (casein and beta-lactoglobulin separately), peanuts, almonds, hazelnuts, sesame and gluten. There were 3411 individual tests completed on the 499 samples (Table 2, Figure 1). There were 22 products which contained one or more undeclared allergens and/or a gluten source for a total of 26 positive results. The most prevalent undeclared allergen was soy (7 samples), followed by gluten (6 samples), milk (3 samples for BLG, 3 samples for casein and 1 sample for both BLG and casein), egg (4 samples) and hazelnut (1 sample). Products which were positive for more than one allergen and/or gluten included a bouillon sample that was positive for both gluten and soy, a bouillon sample positive for casein, egg and soy and a dried mix sample positive for soy and casein. There was no undeclared sesame, peanuts or almonds found in any of the samples.

There was 1 positive sample out of 134 domestic products analyzed, 13 positive samples out of 143 imported products analyzed and 8 positive samples out of 222 products for which the origin (imported or domestic) was not specified on the label. Further information on these samples can be found in the following sections.

Table 2. Positive sample distribution for each allergen						
Analyte	Number of samples tested*			Number of positive samples		
	Domestic	Imported	Unspecified	Domestic	Imported	Unspecified
Soy	39	87	116	1	4	2
Gluten	37	82	97	0	2	4
Milk (BLG)	80	97	109	0	4	0
Milk (Casein)	81	97	109	0	4	0
Egg	85	129	193	0	2	2
Hazelnut	134	138	221	0	1	0
Almond	134	138	221	0	0	0
Peanut	134	142	221	0	0	0
Sesame	132	140	218	0	0	0

*The difference between total number of samples (499) and the number of samples with a declaration of the allergen or gluten in the list of ingredients.

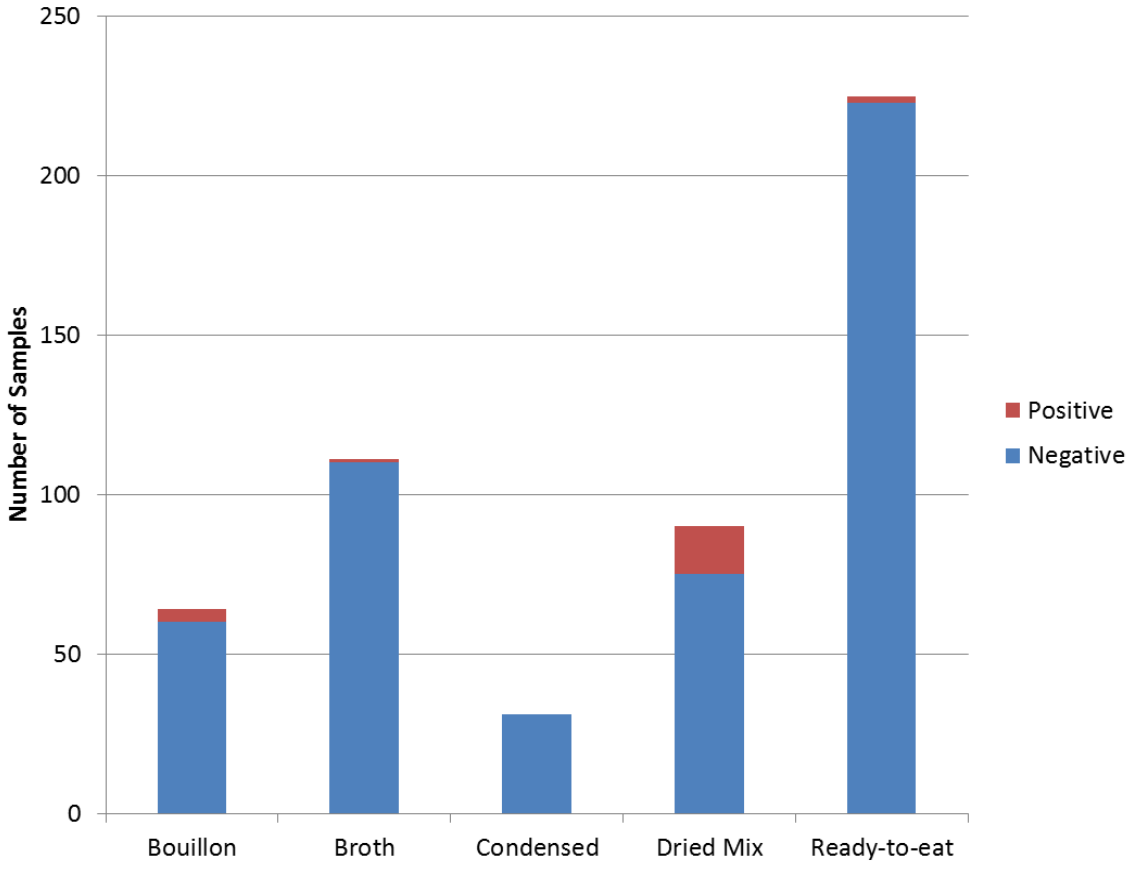
Figure 1: Distribution of results by allergen test



Dried soup mixes and bouillon contained the highest percentage of undeclared allergens and/or gluten (Figure 2). The samples are not prepared as they would be for consumption, therefore, the dried mixes and the bouillons are the most concentrated of the soup products.

In some cases the allergen would be diluted below the detection limit in the products ready-to-eat form.

Figure 2: Distribution of results by product type



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] 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 that causes inflammation of the small intestine when gluten (from wheat, barley and rye) is consumed.[vii] Celiac disease affects approximately 1% of the population and impacts all age groups.[iv] Individuals with celiac disease should avoid all foods containing gluten including wheat, barley and rye products.

In this survey, 6 of 216 samples of soup contained an undeclared gluten source (wheat, barley, rye) (Table 3). 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.[iv] Three of the 6 positive samples were below 20 ppm. All positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 3: Positive results of gluten analysis

Sample Description	Sample Type	Gluten (ppm)	Domestic/Imported
Lentil	Ready-to-eat	8.3	Unspecified
Chicken	Broth	13	Unspecified
Cream of Asparagus	Dried	16	Unspecified
Carrot	Ready-to-eat	27	Unspecified
Vegetable	Dried	80	Import
Beef*	Bouillon	9500	Import

* This product also tested positive for soy

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[viii]. 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. [ix]

In this survey, 242 soups were analyzed for presence of undeclared soy protein. Soy was found in 7 of the samples tested (Table 4). The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 4: Positive results of soy analysis

Sample Description	Sample Type	Soy (ppm)	Domestic/Imported
Matzo Ball	Dried	0.8	Imported
Tomato Vegetable	Dried	1.2	Unspecified
Chicken Noodle *	Dried	1.2	Imported
Chicken Base	Bouillon	1.6	Domestic
Chicken **	Bouillon	2.8	Imported
Cream of Vegetable	Dried	6.6	Unspecified
Beef ***	Bouillon	15.5	Imported

* This product also tested positive for casein
** This product also tested positive for casein and egg
*** 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 allergen proteins in cow's milk: casein and beta-lactoglobulin. Cow's milk contains approximately 30-35 g of protein per litre, of which casein and whey account for 80% and 20%, respectively.[x] Beta-lactoglobulin is a protein found in the whey.

A total of 287 samples were tested for the presence of undeclared milk. Overall, 7 imported samples were positive for undeclared milk proteins (casein and/or beta-lactoglobulin). One sample was positive for both casein and beta-lactoglobulin, 3 samples were positive only for casein and 3 samples were positive only for beta-lactoglobulin (Table 5). All 7 positive samples were referred for follow-up as appropriate.

Table 5: Positive results of milk analysis

Sample Description	Sample Type	Casein (ppm)	BLG* (ppm)
Onion soup	Dried		0.12
Chicken Noodle	Dried	1	0.15
Beef	Bouillon		0.28
Chicken Noodle	Dried	0.38	
Chicken **	Bouillon	0.42	
Chicken flavour instant noodles	Dried		0.47
Chicken Noodle ***	Dried	0.59	

* BLG = Beta-lactoglobulin

** This product also tested positive for soy and egg

*** This product also tested positive for soy

3.5 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.[xii] 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.[xiii] Both egg whites and egg yolk contain allergenic proteins, with a much higher concentration found in egg whites.[xiv xv]

A total of 407 soup samples were tested for the presence of undeclared egg. Of the 4 positive results 3 were in dried soups and 1 bouillon (Table 6). The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 6: Positive results of egg analysis

Sample Description	Sample Type	Egg (ppm)	Domestic/Imported
Lobster flavour soup	Dried	0.6	Imported
Julienne	Dried	1.3	Unspecified
Chicken *	Bouillon	2.2	Imported
Chicken Noodle	Dried	2.9	Unspecified

* This product also tested positive for soy and casein

3.6 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%.[xi]

None of the 497 samples analyzed for peanut, or the 493 samples analyzed for almond, tested positive. Of the 493 samples analyzed for hazelnut, 1 sample, an eleven bean soup was positive (0.5 ppm). This sample was referred for follow-up as appropriate.

4 Conclusion

Of the 499 soup products sampled and analysed, 22 products (4.5%) contained one or more undeclared allergens and/or gluten sources. The most prevalent undeclared allergen was gluten (6/216), followed by soy (7/242), milk (4/286 for BLG, 4/287 for casein), egg (4/407) and hazelnut (1/493). There was no undeclared sesame, almond or peanut found in any of the samples tested.

This survey met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in soup products available on the Canadian marketplace.

5 References

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