

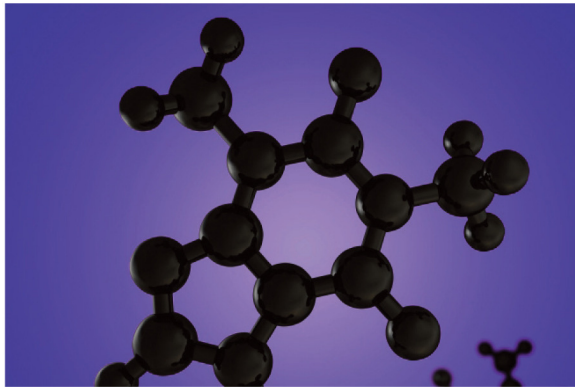


Food Safety Action Plan

REPORT

2011-2012 Targeted Surveys

Allergens



Undeclared Allergens in Protein Substitutes

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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.

Protein substitutes have gained favour with consumers looking to increase their protein consumption for either weight loss or meal replacement purposes. There are a wide variety of protein substitutes available on the Canadian market in ready to consume liquid format or in powdered format that is traditionally added to juice, milk or water.

The main objective of the undeclared allergens in protein substitutes (liquid and powder) survey was:

- To obtain baseline information regarding the presence and levels of undeclared priority allergens and gluten in protein substitutes (liquid and powder).

The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in protein substitutes (liquid and powder).

Two hundred and eighty six protein substitutes (liquid and powder) products were collected between April 2011 and March 2012. Samples were analyzed for the presence of undeclared allergens (soy, egg, milk (beta-lactoglobulin and casein), peanuts, almonds, hazelnuts and sesame) and/or gluten. The majority of the samples were analysed for more than one undeclared allergen and/or gluten, resulting in 1740 analyses completed on the 286 samples. Twenty positive results were obtained. These results were found in 18 samples that were tested for multiple allergens. Three undeclared allergens were detected; almond, gluten, and milk.

All positive results were followed up by CFIA. Follow up actions may involve a food safety investigation, including a health risk assessment conducted by Health Canada and a recall or one of the following: notification to 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 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 (beta-lactoglobulin and casein), egg, peanut, soy, almond, hazelnut, sesame, as well as gluten, in protein substitutes and/or meal replacements.

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 pose 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 the 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 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 protein substitutes and/or meal replacements. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in protein substitutes and/or meal replacements.

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). 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.ⁱ

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 allergen. 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 protein substitutes (liquid and powder) not bearing a Natural Product Number (NPN). If a protein substitute is considered a natural health product then it must have a product licence and clearly indicate the licence number (NPN) on the product label. Products that have an NPN go through a pre-market assessment with Health Canada prior to being allowed for sale in Canada and therefore, were not included in this survey as the risk to the allergic consumer has been evaluated by Health Canada.

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 286 protein substitute samples were collected. The distribution of samples by product type is listed in Table 1.

Table 1: Sample distribution				
Sample type	Domestic or Imported			
	Domestic	Imported	Unknown	Total
Liquid Protein Substitute	50	102	0	152
Powdered Protein Substitute	75	58	1	134
Total	125	160	1	286

2.4 Limitations

A total of 286 samples were 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 protein substitute or meal replacement 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).

The samples were tested for the presence of undeclared 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.

3 Results and Discussion

3.1 General Results

A total of 286 protein substitutes (liquid and/or powder) (125 domestic products, and 160 imported products, 1 of unknown origin) 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 1740 individual tests completed on the 286 samples.

Of the 286 samples analyzed 18 samples tested positive for an undeclared allergen or gluten source. Of the 18 samples 12 samples were domestic and 6 were imported.

Table 2: Positive sample distribution for each allergen		
Analyte	Number of samples tested ¹	Number of positive samples (%) ²
Almond	273	1 (0.37)
Beta-lactoglobulin	33	6 (18.2)
Casein	34	0
Egg	247	0
Gluten	243	13 (5.3)
Hazelnuts	273	0
Peanut	277	0
Sesame	286	0
Soy	80	0

¹The difference between total number of samples (286) and the number of samples with a declaration of the allergen or gluten in the list of ingredients.

² Number of positive samples/Number of samples tested
One sample tested positive for both almond and 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, 243 samples of protein substitutes and/or meal replacements were analyzed for presence of undeclared gluten. Results indicated that 13 of these samples contained undeclared gluten. Six of these samples contained less than 20 ppm gluten, 7 samples had gluten levels ranging from 23 ppm to 540 ppm (Table 5). Health Canada has published a position indicating that levels not exceeding 20 ppm of gluten as a result of cross-contamination are unlikely to cause an adverse health effect in gluten sensitive individuals, when Good Manufacturing Practices are followed. ⁱⁱ The positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 3: Positive gluten results	
Sample description	Gluten (ppm)
Import	
Powdered Protein Substitute	6.9
	7.8
	10
	32
	56
	59
Domestic	
Powdered Protein Substitute	8.5*
	15
	17
	33
	42**
	540
Liquid Protein Substitute	23
* indicates a sample that also tested positive for almond	
** indicates a sample that also tested positive for beta-lactoglobulin	

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 33 samples were tested for the presence of undeclared beta-lactoglobulin and 34 samples were tested for the presence of undeclared casein. Overall, 6 samples were positive for undeclared milk proteins (beta-lactoglobulin). All positive levels of beta-lactoglobulin were very low and may be as a result of cross contamination during production.

Table 4: Positive milk results			
Sample description	Casein (ppm)	BLG¹ (ppm)	Total Milk Protein (ppm)
Domestic			
Powdered Protein Substitute	ND ²	0.14	0.14
	ND	0.26	0.26
	ND	0.27	0.27
	ND	0.31	0.31
	ND	0.51	0.51
	ND	2.8	2.8

¹ BLG= Beta-lactoglobulin

² ND= not detected

3.4 Soy

Soy allergy is often considered to be a childhood allergy, however, older children and adults are also affected by soy 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, none of the 80 protein substitutes (liquid and/or powder) analyzed for presence of undeclared soy protein had detectable levels of soy.

3.5 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%.^{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}

None of the 286 samples analyzed for presence of undeclared sesame had detectable levels of sesame.

3.6 Peanuts and Tree nuts

Peanut and tree nut allergies account for 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} 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 277 samples analyzed for peanut or the 273 samples analyzed for hazelnut were positive. Of the 273 samples analyzed for almond, 1 was positive (Table 5).

Table 5: Positive almond results	
Sample description	Almond (ppm)
Domestic	
Powdered Protein Substitute	2.7

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}

None of the 247 samples analyzed for egg protein had detectable levels of egg.

4 Conclusion

A total of 286 protein substitutes (liquid and/or powder) were analyzed for the presence of undeclared allergens and/or gluten. There were 18 of the 286 products that contained one or more undeclared allergens (~6.3%). Undeclared gluten (13 products) was the most prevalent positive result followed by milk protein (6 products contained undeclared beta-lactoglobulin) and almond (1 product). There were no undeclared peanut, egg, soy or hazelnut found in any of the samples.

There were 12 out of a total of 125 domestic products (~10.4%) and 6 out of a total of 160 imported products (~3.8%) which contained one or more undeclared allergens and/or gluten.

This survey met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in a variety of protein substitutes (liquid and/or powder).

5 References

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