

Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Allergens





Undeclared Allergens in Sauces, Marinades and Dressings

TS-CHEM-10/11



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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.

The use of sauces, marinades and dressings in Canada has increased because of today's busier lifestyles and the introduction of a wide variety of multi-cultural foods in everyday life. Sauces, marinades and dressings are pre-packaged products that allow for easy preparation of foods.

The main objective of the undeclared allergens in sauces, marinades and dressings survey was:

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

Sauces, marinades and dressings are pre-packaged products used to infuse or enhance the taste of the finished food. A total of two hundred and fifty sauces, marinades and dressings were sampled and analyzed for the presence of the following undeclared priority allergens: soy, egg, milk, peanuts, almonds, hazelnuts and sesame, as well as for undeclared gluten. Samples were collected based on retail availability. Examples of sauces, marinades and dressings sampled for this survey included BBQ sauces, vinaigrettes, hot sauces, steak marinades, salad dressings, sweet and sour sauces and dipping sauces.

Positive results were evaluated to determine if the level of undeclared allergen represented a health concern to allergic individuals. 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. Of the 250 samples tested 11 samples tested positive for one or more of the undeclared allergens. In total, there were 5 positive samples for milk protein, 4 for gluten, 1 for hazelnut and 1 for egg. There were no undeclared soy, sesame, peanuts or almonds found in any of the 250 samples of sauces, marinades and dressings analyzed.

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 (FSCAP), aims to modernize and strengthen the food safety regulatory system. The FSCAP 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 FSCAP 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 six undeclared allergens including: milk, egg, peanut, soy, tree nuts, sesame, as well as gluten, in sauces, marinades and dressings.

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* (F&DA) 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* (FDAR).

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 F&DA. These products may therefore be subject to regulatory measures taken by the CFIA.

Health Canada has recently made amendments to the *Food and Drugs Regulations* 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 continue 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 will come into force on August 4, 2012. Further information on these proposed regulations can be found on the Health Canada website.

The products tested in this survey do not have to meet the new regulations coming into force in 2012, however, proactive actions by the manufacturing sector may have occurred to ensure that these products do meet new regulations.

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 sauces, marinades and dressings. Sauces, seasonings, herbs, flavourings, spices, dressings and gravies etc. are listed as other common sources for undeclared allergens on the Canadian Food Inspection Agency's website. The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in sauces, marinades and dressings.

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 countriesⁱⁱⁱ and approximately 7% of Canadians selfreport at least one food allergy. 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 in every 100 - 200 people. Currently 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. The priority allergens in Canada are as follows: milk, eggs, peanut, sesame seeds, tree nuts, soy, wheat and seafood (fish, shellfish and crustaceans). As a result of the Enhanced Allergen Labelling Regulations coming into force on August 4, 2012, mustard seed will be added as a priority allergen in Canada. Sulphites at levels of 10 ppm or higher have been recognized as having the potential to produce serious symptoms similar to an allergen in sensitive individuals and have been added to the Enhanced Allergen Labelling Regulations. 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.

Sauces, marinades and dressings are mixtures of different ingredients that may contain allergenic components that could be a hazard to an allergic individual. For instance, gluten-containing flours or starches are frequently used as ingredients in sauces, marinades and dressings as thickening agents. If the source of the flour or starch is not specified then there could be a risk to individuals sensitive to the gluten.

2.3 Sample Distribution

This survey targeted sauces, marinades and dressings including: BBQ sauces, vinaigrettes, hot sauces, steak marinades, salad dressings, sweet and sour sauces and dipping sauces. Samples were collected based on availability in 2010 from major retail stores as well as smaller ethnic retailers. No specific brands were targeted. A total of 250 sauces, marinades and dressings samples were collected. The distribution of samples by product type is listed in Table.1.

Table 1: Sample distribution				
	Domestic or Imported			
Sample type	Domestic	Imported	Total	
Sauces	61	144	205	
Marinades	9	4	13	
Dressings	26	6	32	
Total	96	154	250	

2.4 Limitations

Samples were all purchased in various retail chains in Ottawa, ON. This represents a small sample size in comparison to what is available to Canadian consumers throughout the country. The samples collected in this survey do not guarantee representation of all national availability. 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 Methods of Analysis				
		Reporting Limit (ppm)		
Method	Analyte	Analyte	Soluble	
		Level*	protein**	
Veratox Quantitative Soy Allergen Test	Soy	10	0.5	
Veratox Quantitative Almond Allergen Test	Almond	2.5	0.5	
Veratox Quantitative Hazelnut Allergen Test	Hazelnut	2.5	-	
Veratox Quantitative Egg Allergen Test	Egg	2.5	1.25	
Veratox Quantitative Peanut Allergen Test	Peanut	2.5	0.25	
ELISA Systems Sesame Seed Protein Residue	Sesame	0.5	-	
ELISA Systems Beta-Lactoglobulin	Beta-Lactoglobulin	0.1	-	
ELISA Systems Casein Residue	Casein	1	0.26	
RIDASCREEN Gliadin	Gluten	20	5	

^{*} as defined by manufacturer ELISA kit

^{**}as defined by Allergens Method Committee

3 Results and Discussion

3.1 General Results

Two hundred and fifty sauces, marinades and dressings (96 domestic products, and 154 products of imported origins) were sampled and analyzed for presence of soy, egg, milk (casein and beta-lactoglobulin separately), peanuts, almonds, hazelnuts, sesame and gluten. A total of 2012 individual allergen tests were completed on these 250 samples. Eleven samples were positive for one or more of the tested allergens for a total of 13 positive tests. Undeclared milk protein (casein and beta-lactoglobulin) was found to be the most prevalent undeclared allergen in sauces, marinades and dressings followed by gluten and egg and hazelnut.

Of the 250 samples 11 samples tested positive for undeclared allergens (Figure 1). Peanuts, almonds, sesame and soy have not been included in figure 1 as there were no positive results for these allergens in the tests conducted on the samples of sauces, marinades and dressings analyzed. Of the 11 positive samples, 9 samples (81.8%) were imported products and 2 samples (18.2%) were domestic products.

Table 3 Positive Sample distribution for each allergen			
Analyte	No.	No. of	
	samples	positive	
	tested *	samples	
Egg	238	1	
Milk: casein/beta-lactoglobulin	212	5	
Nuts (Hazelnut)	250	1	
Gluten	183	4	
Total No. of tests run on 250 samples	2012	11	

^{*} The difference between total number of samples (250) and the number of samples with a declaration of allergen in the list of ingredients.

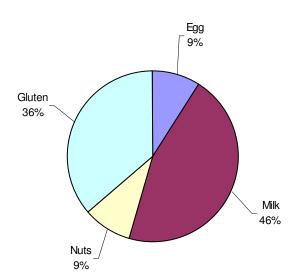


Figure 1. Distribution of Allergens Detected

3.2 Milk

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

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. 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 liter, of which casein and whey account for 80% and 20%, respectively. Betalactoglobulin makes up approximately 50% of the protein found in whey, or approximately 10% of the protein found in cow's milk.

A total of 212 samples were tested for the presence of undeclared milk. Overall, five samples were positive for undeclared milk proteins (casein and/or beta-lactogloblin). Two samples were positive for both casein and beta-lactoglobulin, two samples were positive only for casein, and one sample contained only beta-lactoglobulin.

The levels of undeclared milk (casein + beta-lactoglobulin) found in these samples ranged from 0.21 ppm to 2.91 ppm. All five positive samples were evaluated for potential health risk concerns and referred for follow-up as appropriate.

Table 4 Results of Milk Analysis			
Sample description	Casein	BLG ¹	Total Milk Protein
	ppm		ppm
Coconut chilli sauce	2.1	0.81	2.91
Tamarind Stir-fry Sauce	1	0.15	1.15
Coconut flavoured curry sauce	0.8	ı	0.8
Potatoes & Green Peas in Sauce	0.3	-	0.3
Organic Honey Mustard Dressing	-	0.21	0.21

¹ BLG= Beta-lactoglobulin

3.3 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. Xiii, XiV Gluten sensitivity is an adverse reaction to gluten that is not caused by an allergic response or celiac disease. XV

Celiac disease is an autoimmune disorder that occurs in susceptible individuals and causes inflammation of the small intestine when gluten (from wheat, barley, rye and oats) is consumed. XVI, XVII Celiac disease affects approximately 1% of the population and impacts all age groups although it is more frequent in women than in men. XVIII, XIX Individuals with celiac disease should avoid all foods containing gluten including wheat, barley and rye products. XX, XXII

In this survey, 183 samples of sauces, marinades and dressings were analyzed for presence of undeclared gluten. Laboratory results determined that four of these samples contain undeclared gluten with concentration levels ranging from 6.1 ppm to 920 ppm. All four positive samples were referred for appropriate follow-up action, which can include a food safety investigation.

Table 5 Results of Gluten Analysis		
Sample description	Gluten	
Sample description	ppm	
BBQ sauce	920	
Oyster flavored sauce	240	
Onion and Yogurt Sauce	28	
Biryani cooking sauce	6.1	

3.4 Soy

Soy allergy is 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^{xxii}, possibly due to the use of soy based infant formulas as a subsitute for milk based infant formulas. ^{xxiii} 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. ^{xxiv}

Foods commonly containing soy products are dressings, marinades, seasonings, spices, thickening agents, Monosodium Glutamate (MSG) and hydrolyzed vegetable protein (HVP). Given that flavour packets usually contain seasonings, spices and thickening agents these were a product type chosen to explore the potential for undeclared soy.

In this survey, 184 sauces, marinades and dressings samples were analyzed for presence of undeclared soy protein. Soy was not found in any of the samples tested.

3.5 Sesame

Sesame is a priority allergen in Canada and can cause a severe allergic reactions. According to a population-based study on a number of allergens in Canada, the prevalence of sesame allergy in Canada is 0.09%. 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 Mediterranean diet. Sesame components have also been widely used in salad dressings in Oriental, Chinese, and South American cuisines. Since herbs, seasonings, flavourings and spices are considered other possible sources for sesame these were tested in this survey.

Of the 250 samples collected and analyzed 238 samples of sauces, marinades and dressings were analyzed for presence of undeclared sesame. Sesame was not found in any of the samples tested.

3.6 **Egg**

Egg allergies are considered one of the most common allergies in the population, with between 1.6% and 3.2% of the population estimated as being affected. It is particularly common in children, however, it has been reported that ~2/3 of children will outgrow this allergy by the age of 7. Both egg whites and egg yolk contain allergenic proteins, with a much higher concentration found in egg whites. **xxviii*

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, 238 sauces, marinades and dressings were analyzed for presence of undeclared egg. One sample (a sauce) was found to contain undeclared egg protein at a concentration of 5.3 ppm.

Table 6 Results of Egg Protein Analysis		
Sample description	Egg	
Sample description	ppm	
Maple, Apple and Beer Sauce	5.3	

3.7 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%. **xix** Prevalence of peanut allergy in young children was found to be much higher than that of adults and estimated at 1.03% confirmed allergy and 1.63% probable allergy. **xx**

There were no positive results for peanut in the 248 samples analyzed. 247 samples were analyzed for almond and none were positive. One marinade sample tested positive for hazelnut (550 ppm). The positive sample was evaluated for potential health risk concerns and referred for follow-up as appropriate. This product was evaluated by Health Canada and a Health Risk Assessment was conducted. It was necessary to recall the product based on Health Canada's assessment that this product represented a health risk to sensitive individuals.

Table 7 Results of Hazelnut Protein Analysis		
Sample description	Hazelnut	
Sample description	ppm	
Marinade sauce	550	

4 Conclusion

Two hundred fifty samples of a variety of sauces, marinades and dressings were collected and analysed for undeclared allergens. Eleven samples were found to contain one or more of undeclared allergens, with a total of 13 positive allergen results. This survey, even with limited samples size (250 samples), met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in a variety of sauces, marinades and dressings.

Of the 11 samples that tested positive for undeclared allergens, 5 were positive for milk protein, 4 were positive for gluten, 1 was positive for egg and 1 was positive for hazelnut. There were no undeclared peanuts, almonds, soy or sesame found in the 250 hundred samples of sauces, marinades and dressings analyzed. This survey also indicated that closer attention should be paid to undeclared milk and gluten in sauces, marinades and dressings type products.

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