

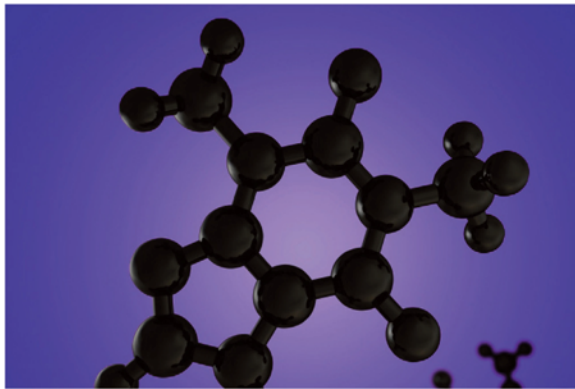


Food Safety Action Plan

REPORT

2010-2011 Targeted Surveys

Allergens



Undeclared Allergens in Flavour Packets

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 flavour packets in Canada has increased because of today's busier lifestyles and the introduction of a wide variety of multi-cultural foods to the population. Flavour packets are premixed in the proper ratios for easy addition to foods.

The main objective of the undeclared allergens in flavour packets survey was:

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

Flavour packets are premixed packages of herbs and/or spices that when blended with other foods infuse or enhance a taste of the finished food. A total of one hundred flavour packets 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 flavour packets sampled for this survey included sauce mixes, drink mixes, seasoning mixes, soup bases and spice mixes.

Positive results were evaluated to determine if the 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 100 samples tested 25 samples were positive for one or more undeclared allergens. The most common undeclared allergen detected was soy (39%), followed by milk (24%) and gluten (21%). There were no undeclared peanuts or tree nuts found in any of the 100 samples of flavour packets 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.

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 six undeclared allergens including: milk, egg, peanut, soy, tree nuts, sesame, as well as gluten, in flavour packets.

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. Health Canada continues 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.ⁱ

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 flavour packets. 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.ⁱⁱ The information gathered will provide an indication of potential food safety concerns relating to undeclared allergens in flavour packets.

2.2 Hazard: Undeclared Allergens and Gluten

Current Canadian estimates indicate that food allergies affect as many as 6% of young children and 3% to 4% of adultsⁱⁱⁱ. 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^{iv}. 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.^v 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 will also be added as a priority allergen in Canada. Sulphites at levels of 10 ppm or higher have also 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.

Flavour packets are a mixture of different ingredients that may contain allergenic components potentially posing a hazard to an allergic individual. For instance, gluten-containing flour or starches are frequently used as ingredients in flavour packets for thickening sauces. If the source of the flour or starch is not specified then there could be a risk to individuals sensitive to the gluten found in wheat, barley, rye, and triticale.

2.3 Sample Distribution

This survey targeted a variety of flavour packets including: bake mixes, dessert mixes, sauce mixes, powdered drink mixes, seasonings, spices mixes and soup bases. 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 100 flavour packet samples were collected. The distribution of samples by product type is listed in Table.1.

Table 1: Sample distribution				
Sample type	Domestic or Imported			Grand Total
	Domestic	Imported	Unknown	
Bake mix	-	3	-	3
Dessert mix	1	2	-	3
Sauce mix	6	6	-	12
Drink mix	1	3	-	4
Seasoning mix	19	27	-	46
soup/bouillon mix	5	17	-	22
Spice mix	-	9	1	10
Grand Total	32	67	1	100

2.4 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			
Method	Analyte	Reporting Limit (ppm)	
		Analyte Level*	Soluble 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

2.5 Limitations

A total of 100 samples of flavour packets were collected and analysed in 2010-2011. 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 are not representative of what is 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.

3. Results and Discussion

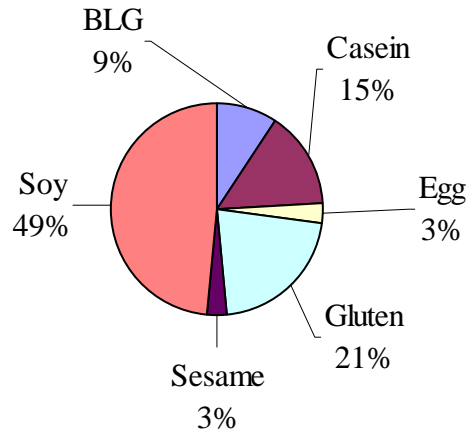
3.1 General Results

One hundred flavour packets (32 domestic products, and 68 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 807 individual allergen tests were completed on the 100 samples collected for this survey. Twenty five samples were positive for one or more of the tested allergens for a total of 33 positive tests. Three samples (9%) which tested positive for soy had hydrolysed soy protein listed on the product label. These samples were tested for soy to establish a baseline value for those product types containing hydrolysed soy protein. Undeclared soy protein was found to be the most prevalent undeclared allergen (39%) in flavour packets followed by milk (24%) and gluten (21%). The distribution of allergens detected is presented in Figure 1 below, nuts have not been included as there were no undeclared peanuts or tree nuts found in the 100 samples of flavour packets analyzed.

Table 3 Positive Sample distribution	
Analyte	Number of positive samples
Egg	1
Milk: casein/beta-lactoglobulin	8
Nuts	0
Soy	16*
Gluten	7
Sesame	1
Grand Total	33

* 3 of which were declared on the product label as hydrolysed soy protein.

Figure 1. Distribution of Allergens Detected



Of the 25 positive samples, 17 samples (68%) were imported products and 8 samples (32%) were domestic products.

3.2 Milk

Cows milk allergy is the most common food allergy in children less than three years of age.^{vi} The prevalence of self-declared milk allergy in the Canadian population has been estimated to be 2.09%.^{vii}

Dried milk ingredients 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 food and is commonly used in dried mixes, fillings and in sauces.^{viii} There are two major allergen proteins in cow's milk: casein and beta-lactoglobulin.^{ix} Cow's milk contains approximately 30-35 g of protein per liter^x, of which casein and whey account for 80% and 20%, respectively.^{xi} 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 84 samples were tested for the presence of undeclared milk. Overall, six samples were positive for undeclared milk proteins (casein and/or beta-lactoglobulin). Two samples were positive for both casein and beta-lactoglobulin, five samples were positive for casein, and one sample contained only beta-lactoglobulin.

The levels of undeclared milk (casein + beta-lactoglobulin) found in these samples ranged from 0.36 ppm to 39 ppm (0.0036 mg to 0.277 mg per serving). All six positive samples were evaluated for potential health risk concerns and referred for follow-up as appropriate. The results for one product were 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.

Sample description	Casein	BLG ¹	Casein	BLG ¹	Total Milk Protein	
	ppm		mg/serving ²		ppm	mg/serving ²
Coconut rice mix	1.62	-	0.016	-	1.62	0.016
Chicken gravy mix	1	38	0.007	0.27	39	0.277
Sweet & Sour seasoning mix	1	-	0.007	-	1	0.007
Beef soup mix	0.36	-	0.0036	-	0.36	0.0036
Savoury sauce mix	-	0.4	-	0.014	0.4	0.014
Soya milk mix	5.38	0.38	0.108	0.008	5.76	0.116

¹ BLG= Beta-lactoglobulin

² mg/serving = the amount of protein per serving in mg

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.^{xii, xiii} Gluten sensitivity is an adverse reaction to gluten that is different from celiac disease and wheat allergy.^{xiv}

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

In this survey, 75 samples of flavour packets were analyzed for presence of undeclared gluten. Laboratory results determined that seven of these samples contain undeclared gluten with concentration levels ranging from 8.2 ppm to 14 000 ppm (0.046 mg to 105 mg per serving). All seven positive samples were referred for appropriate follow-up action.

Two of the positive samples had very high levels of undeclared gluten: 7 900 ppm and 14 000 ppm, and were subsequently assessed by Health Canada to determine whether they posed a potential risk to Canadian consumers. The product (a spicy bake mix) containing 14 000 ppm of undeclared gluten was considered to pose a potential health risk and a recall action with a public advisory was initiated. Because of mitigating factors that were present on the product label, the sample containing 7 900 ppm of gluten, was considered unlikely to pose a health risk.

Table 5 Results of Gluten Analysis		
Sample description	Gluten	
	ppm	mg/serving¹
Curry powder seasoning mix	46	0.046
Taco seasoning mix	17	0.119
Chicken gravy mix	7900	55.3
Seafood hot pot seasoning mix	8.2	0.82
Spicy bake mix	14000	105
Chocolate Malt drink mix	360	10.8
Chicken gravy mix	14	0.084

¹ mg/serving = the amount of protein per serving in mg

3.4 Soy

Soy allergy is considered to be a childhood allergy older children and adults are also affected by soy allergy. Soy allergy is most frequently observed in infants^{xxi}, possibly due to the use of soy based infant formulas as a substitute for milk based infant formulas.^{xxii} A study found that 0.4% of young children suffer from an allergy to soy.^{xxiii} However, many of them will outgrow the allergy by the age of 3 years.^{xxiv}

Foods commonly containing soy products such as 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, 70 flavour packet samples were analyzed for presence of undeclared soy protein. The analysis included products declaring modified soy such as hydrogenated or hydrolyzed soy in order to determine the level of potential protein remaining after this type of processing. Low levels of soy protein ranging from 3 ppm to 880 ppm (0.006 mg to 6.6 mg per serving) were found in 16 of the samples analyzed. Three of 16 positive samples contained hydrolyzed soy protein declared on the list of ingredients.

These results indicate that a significant portion of products containing hydrolysed soy protein have some soy protein remaining. However, the level of soy protein remaining is minimal and unlikely to cause an adverse reaction in soy allergic individuals. All samples found to contain measurable levels of soy, which did not have any mention of soy on the label, were evaluated by Health Canada and considered unlikely to result in any adverse effects for soy allergic individuals.

Table 6 Results of Soy Protein Analysis		
Sample description	Soy	
	ppm	mg/serving¹
Curry powder seasoning mix	6.2	0.006
Pepper spice soup mix	3	0.06
Burger seasoning mix	150	0.945
Spicy Bake mix	880	6.6
Masala Spice mix for salads	12	0.06
Masala spice mix for chick peas	3.2	0.016
Mushroom sauce mix	13	0.078
Shepherds pie seasoning mix	30	0.234
Chicken gravy mix	6.5	0.039
Brown gravy mix	17	0.119
Spicy chilli seasoning mix	18	0.081
Yorkshire pudding mix	80	0.6
Broccoli soup mix	24	0.312
Beef soup mix	14	0.14
Fish spice mix	7.9	0.039
Chicken soup mix	38	0.456

¹ mg/serving = the amount of protein per serving in mg

3.5 Sesame

Sesame is a priority allergen in Canada and can cause 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%.^{xxv} 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 oil has also been widely used in salad dressings in Oriental, Chinese, and South American cuisines.^{xxvi} As well, herbs, seasonings, flavourings and spices are considered other possible sources for sesame.^{xxvii}

Ninety five flavour packets were analyzed for presence of undeclared sesame. One sample, a seasoning mix, was found to contain low levels of undeclared sesame (4.6 ppm). This product was evaluated by Health Canada, which determined that this product did not pose a health risk for sesame allergic individuals.

Table 7 Results of Sesame Protein Analysis		
Sample description	Sesame	
	ppm	mg/serving¹
Balsamic chicken seasoning mix	4.6	0.032

¹ mg/serving = the amount of protein per serving in mg

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, 99 flavour packets were analyzed for presence of undeclared egg.

One sample (a spicy bake mix) was found to contain undeclared egg protein at a concentration of 250 ppm. This product was referred to Health Canada for a Health Risk Assessment. The level of undeclared egg protein present was considered to pose a potential health risk and appropriate recall action was taken. It should be noted that this same sample also contained high level of undeclared gluten (14000 ppm, as mentioned in section 3.3) as well as undeclared soy (880 ppm, as mentioned in section 3.4).

Table 8 Results of Egg Protein Analysis		
Sample description	Egg	
	ppm	mg/serving¹
Spicy Bake mix	250	1.875

¹ mg/serving = the amount of protein per serving in mg

3.7 Peanuts and Tree nuts

Peanut and tree nut allergies account for the majority of severe allergic reactions in Canada. The prevalence of probable peanut and tree nut allergy is respectively 0.93% and 1.14%. 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 1.68% probable allergy. ^{xxix}

There were no positive results for tree nuts nor for peanut in any of the 100 samples collected and analyzed.

4. Conclusion

One hundred samples of a variety of flavour packets were collected and analysed for undeclared allergens. Twenty five samples were found to contain one or more of undeclared allergens, with a total of 33 positive allergen results. This survey was limited in the number of samples tested, however, it met the objective of gathering baseline information on the occurrence of undeclared priority allergens and gluten in a variety of flavour packets.

Based on the results, the most common undeclared allergens in flavour packets were found to be soy, milk and gluten representing, 39, 24 and 21 percent of total positive results respectively. Only one sample tested positive for undeclared egg and one sample tested positive for undeclared sesame. There were no undeclared peanuts, almonds, and hazelnuts found in the 100 samples of flavour packets analyzed. Products with hydrolyzed soy protein and hydrogenated soy oil were also analysed to obtain some information on how much if any soy protein remains after these processes.

Three samples with hydrolyzed soy protein declared on the label were found to contain low levels of soy protein. There were no traces of soy protein found in products containing hydrogenated soy oil. From these results it can be concluded that hydrolysis of soy protein can leave intact or partially intact protein in the product. However, a larger survey on products containing hydrolyzed and hydrogenated soy protein would need to be done to obtain better data on how often and how much intact protein remains in these food products. This survey also indicated that closer attention should be paid to undeclared soy, milk and gluten in flavour packet type products.

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