Undeclared Allergens and Gluten in Herb and Spice Products – April 1, 2015 to March 31, 2016 and April 1, 2017 to March 31, 2018

Food allergen – Targeted surveys





Summary

Targeted surveys provide information on potential food hazards and enhance the Canadian Food Inspection Agency's (CFIA's) routine monitoring programs. These surveys provide evidence regarding the safety of the food supply, identify potential emerging hazards, and contribute new information and data to food categories where it may be limited or non-existent. We use them to focus surveillance on potential areas of higher risk. Surveys can also help identify trends and provide information about how industry complies with Canadian regulations.

Food allergies can affect people of all ages but are particularly common in children. Food allergens can represent a serious or life threatening health risk for allergic individuals. Additionally, although it is not considered an allergen, undeclared gluten may contribute to chronic health issues for those individuals with celiac disease or gluten sensitivity. Allergens and gluten can be found in food due to their presence in the raw ingredients or they can be accidentally introduced along the food production chain due to cross contamination. Regardless of the source of the allergens, industry must ensure that the food produced is safe for human consumption, either by complying with specific Canadian regulations where applicable or by keeping the levels as low as reasonably possible.

2 surveys were completed to assess the presence of undeclared allergens and gluten in herb and spice products. The initial survey took place from April 1, 2015 to March 31, 2016, in which the main objective was to obtain baseline information regarding the presence and levels of undeclared allergens in ground herbs and spices consisting of only 1 ingredient. 598 samples were tested, and 34% (203) of the samples were found to contain at least 1 undeclared allergen, including the milk protein beta-lactoglobulin (BLG), egg, hazelnut, peanut, sesame, soy, and gluten. These positive results mostly indicated the presence of gluten in imported products. The second, follow-up survey took place between April 1, 2017 and March 31, 2018, and provided more in depth information regarding levels of undeclared allergens and gluten in imported herb and spice products. 359 samples were tested, and 23% (82) of the samples were found to contain at least 1 undeclared allergen, including milk proteins BLG and casein, egg, almond, hazelnut, peanut, sesame, soy, and gluten. These positive results were primarily due to the presence of undeclared gluten.

All positive results were forwarded to the CFIA's Office of Food Safety and Recall (OFSR) to determine if the levels found would pose a health concern to allergic individuals. The extent of the follow-up actions taken by agency is based on the level of the contamination and the resulting health concern as determined by a health risk assessment. In the 2015-16 survey, 3 spice products containing gluten were deemed to represent a health risk and were recalled. Another 3 products were recalled after the 2017-18 survey due to high levels of gluten, milk, and sesame.

What are targeted surveys

Targeted surveys are used by the CFIA to focus its surveillance activities on areas of higher health risk. The information gained from these surveys provides support for the allocation and prioritization of the agency's activities to areas of greater concern. Targeted surveys are a valuable tool for generating information on certain hazards in foods, identifying and characterizing new and emerging hazards, informing trend analysis, prompting and refining health risk assessments, highlighting potential contamination issues, as well as assessing and promoting compliance with Canadian regulations.

Food safety is a shared responsibility. The agency works with federal, provincial, territorial and municipal governments and provides regulatory oversight of the food industry to promote safe handling of foods throughout the food production chain. The food industry and retail sectors in Canada are responsible for the food they produce and sell, while individual consumers are responsible for the safe handling of the food they have in their possession.

Why did we conduct this survey

Approximately 7% of Canadians have self-reported as having at least 1 food allergy, but the actual number of medically confirmed food allergies is expected to be slightly lower¹. It is believed that the rate of food allergies is increasing, particularly among children. Food allergies are estimated to affect up to 5% of adults and up to 8% of children in developed countries². Food allergens are food proteins that can cause a reaction of the body's immune system, and can represent a serious or life threatening health risk for allergic individuals or contribute to chronic health issues for those with pre-existing health conditions like celiac disease. Celiac disease is a chronic reaction where the body reacts to a component of gluten which can damage or destroy certain intestinal cells. Approximately 1% of the total population are affected with celiac disease³.

The priority food allergens are the 10 most common food components associated with severe allergic or allergy-like reactions in Canada. These allergens consist of peanuts, tree nuts, sesame, seafood (fish, shellfish and crustaceans), eggs, milk, soy, mustard, sulphites, and wheat⁴. Gluten, while not a true allergen, is a family of proteins found in certain grains like wheat, rye, barley, kamut, and spelt and is included in this list. Gluten can cause digestive problems and other issues for people with certain health conditions such as celiac disease and gluten sensitivity. This makes proper identification and labeling of allergens in food by the manufacturer essential.

Undeclared allergens can be found in foods due to their presence in the raw ingredients, or can be accidentally introduced along the food production chain through cross contamination. Regardless of the source of the allergens, industry must ensure that the food they produce is safe for human consumption. This can be achieved by complying with specific Canadian regulations where applicable, or by keeping the levels as low as reasonably possible.

The 2015/16 survey was conducted to look for undeclared allergens including BLG, egg, gluten, almond, hazelnut, peanut, sesame, and soy in single ground herb and spice products. The main objective of this survey was to obtain allergen baseline data in spices, and to expand the limited data obtained in a smaller 2010/11 survey, which tested solely for gluten.

After initial evaluation of the data from this 2015/16 survey, a follow-up survey was conducted in 2017/18 to focus on, and to gain more information about imported spices.

All products were tested "as sold," meaning that they were not prepared as per the manufacturer's instructions or as they would typically be consumed.

What did we sample

Ground single herb and spice products were sampled in the 2015-16 survey. Imported powdered and prepared herb and spice products were sampled from 2017-18 survey. Samples were collected from local and regional grocery stores located in 6 major cities across Canada. These cities encompassed 4 geographical areas: Atlantic (Halifax), Quebec (Montreal), Ontario (Toronto, Ottawa) and the West (Vancouver, Calgary). The number of samples collected from these cities was in proportion to the relative population of the respective areas.

The following products were not included in the surveys:

- Products with **all** of the following allergens in the list of ingredients almond, hazelnut, peanut, sesame, soy/soybean, egg, milk, wheat, barley, oats, rye, triticale, or gluten
- Products with a precautionary statement for all priority allergens
- Products with no list of ingredients
- Non-prepackaged spices or from bulk bins
- Fresh, freeze-dried, whole or rubbed herbs and spices, or herbs/spices mixed with salt
- Spice mixtures with more than 1 ingredient (2015/16)
- Products of domestic or unknown origin (2017/18)

Table 1: Distribution of samples based on product origin

	Domestic	Import	Unspecified ^a origin	Total
2015/16 Survey	22	401	175	598
2017/18 Survey	0	359	0	359
Total	22	761	175	957

^aUnspecified refers to those samples for which a country of origin could not be determined from the product label or available sample information.

How were the samples analyzed and assessed

Samples were analyzed by an ISO/IEC 17025 accredited food testing laboratory under contract with the Government of Canada. The samples were tested as sold, meaning that the product was tested as-is and not as prepared according to package instructions.

In Canada, food allergens and gluten must be declared in the list of ingredients if they are present in the prepackaged product in order to comply with the requirements of the <u>Food and Drug Regulations Section B.01.010.1</u>. A prepackaged product will be deemed non-compliant if any level of undeclared allergens and gluten is detected.

Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 parts per million (ppm) (due to cross

contamination) meet the intent of the <u>Food and Drug Regulations Section B.24.018</u> for a gluten-free claim.

What were the survey results

Results from the 2015-16 survey showed over 66% of the samples tested did not contain any detectable levels of undeclared allergens. The remainder of products tested in this survey were found to be positive for at least 1 undeclared allergen. This included 36% of all domestic products, 37% of imported products and 29% of unknown products. These positive results were primarily due to the presence of gluten, but in some cases, sesame and soy. The majority of undeclared allergens found were in imported products, especially herb products including oregano, thyme, fenugreek, and sage. 3 products were recalled based on the results of this survey. These products consisted of a White Pepper Powder product of which 2 samples tested positive for undeclared gluten at levels of 31000 and 120000 ppm, a Black Pepper Powder product that contained undeclared gluten at a level of 48000 ppm, and a Ground Mace product which contained gluten at a level of 16000 ppm. Appendix A contains a table displaying the ranges of each allergen detected in each type of product.

Approximately 23% of all imported powdered and prepared herb and spice products in the 2017-18 survey tested positive for at least 1 undeclared allergen. These positive results were primarily from detection of low levels of gluten in both herbs and spices. The remainder of the samples tested did not contain any detectable levels of undeclared allergens. 4 products were recalled based on the results of this survey. These products consisted of a Black Pepper Powder which contained gluten at a level of 44000 ppm, an Organic Fenugreek Seed Powder product that contained gluten at 310 ppm as well as soy at 18.4 ppm, a mixed seasoning which in which BLG and casein were detected at levels of 190 and 850 ppm respectively, and a mansaf spices mix which contained 9400 ppm of gluten and 270 ppm of sesame. Appendix B contains a table displaying the detected ranges of each allergen in each type of product.

What do the survey results mean

In the 2015/16 survey of 598 samples of single herb and spice products, undeclared allergens were found in approximately 34% of the samples, primarily due to the presence of gluten. Undeclared allergens were most frequently present in imported herb and spice products. For this reason, a follow-up survey was designed to obtain more data about undeclared allergens and gluten in imported herb and spice products. In the survey completed in 2017/18, approximately 23% of the 359 samples of prepared herb and spice products contained undeclared allergens, again mainly gluten.

The extent of the follow-up actions taken by CFIA is based on the level of contamination and the resulting health concern as determined by a health risk assessment. Appropriate follow-up actions can include additional sample testing, facility inspection and product recall. The health risk assessment is based on exposure to the allergens and gluten through consumption. The exposure is calculated by using the typical serving sizes for each food. Assessment based on serving size means not all detectable levels of undeclared allergens and gluten in food will cause a reaction in an allergic individual.

Gluten

Gluten was the most frequently detected undeclared allergen present in foods in both surveys. It was found in 149 (25%) samples in the 2015-16 survey at levels ranging from 5 to 120000

ppm and in 63 (18%) from the 2017-18 survey at levels as high as 44000 ppm. Lower detected levels have been known to be present due to cross-contamination as a result of manufacturing or distribution practices, as grains containing gluten are widely used in the production of many pre-packaged foods⁵. Contamination may also be because of agriculture co-mingling; spices are often sourced from small farming establishments in rural areas at which other crops such as wheat are also grown⁶. Higher levels of gluten have been known to be indicative of undeclared introduction during formulation or for economic gain. The specific reason for the elevated levels can only be assessed through a trace-back investigation which can be complicated with imported commodities. An economically motivated act is defined as ingredient additions or substitutions used while manufacturing the product to decrease processing costs and increase profit⁷.

A total of 5 of the products found to contain gluten were assessed as presenting a risk to consumers and were subsequently recalled^{8,9,10,11,12}.

Soy

A low level of soy was detected in 51 (9%) of the products in the 2015-16 survey, compared to 17 (5%) from the 2017-18 survey. The low levels could have been the result of cross contamination or cross contact in the manufacturing process, or were present in 1 of the ingredients. This could result in the presence of an allergen in the final product. A white pepper sample tested during the 2017-18 survey reported a high level of soy at 16600 ppm (1.66 %). However, given the small serving size associated with the use of spices, none of the products were identified as presenting a health risk to consumers in either survey.

Sesame

Sesame was found in 46 (8%) of the single ground herb and spice products tested in the 2015-16 survey and in 6 (2%) of the imported prepared herb and spice products tested in the 2017-18 survey. Of the products in the 2017-18 survey, 1 product that contained sesame was recalled for high levels of undeclared gluten but not for sesame¹¹.

Peanut

Peanut was found in 19 (3%) products in the 2015-16 survey and 15 (4%) from the 2017-18 survey. Since the levels detected were low, it is possible that contamination occurred through inadvertent exposure to peanut products. None of the products were assessed as presenting a risk to consumers.

Egg

Egg was present in 3 (0.5%) products tested in the 2015-16 survey, and in 2 (0.6%) in the 2017-18 survey. All of the positive results for undeclared egg in the 2015-16 survey were found in paprika. The source of the egg protein could not be determined. The detected levels were low and were assessed as not posing a risk to consumers.

Milk

BLG was found in 2 (0.3%) products in the 2015-16 survey, both in ground fenugreek. Products in this survey were not tested for the presence of casein. In the 2017-18 survey, BLG was found in 2 (0.6%) products. Casein was detected in 1 (0.3%) product in this survey. The levels of BLG and casein in 1 product in the 2017-18 survey were high enough to present a risk to consumers,

and this product was recalled¹³. All other results were below what might be expected to be of any functional value as an additive. The source of the milk proteins could not be determined.

Hazelnut

Of the products tested in the 2015-16 survey, 1 (0.2%) was found to contain a low level of hazelnut. In the 2017-18 survey, 1 (0.3%) product contained a low level of undeclared hazelnut. Neither result was assessed as having a level of protein high enough to present a health risk to consumers.

Almond

None of the products tested in the 2015-16 survey contained detectable levels of almond. The 2017-18 survey had 3 (0.8%) products which tested positive for undeclared almond. These results were deemed not to pose a risk to consumers.

Summary

When comparing the 2 surveys, the number of low level undeclared allergen results is similar. This is possibly indicative of low level cross contamination during manufacture/packaging of the product. Furthermore, since the products are imported, it is not possible to determine if the results indicate a localized or systemic issue. It is more difficult to attribute the cause of the 5 higher gluten level results to cross contamination.

All positive results were forwarded to the CFIA's OFSR to determine if the levels found would pose a health concern to allergic individuals. With the exception of the 6 samples which resulted in product recalls, all other positive allergen findings were determined to be safe for consumption.

These surveys generated new information on the background level of undeclared allergens in herb and spice products collected from 6 cities across Canada. Information gathered in these surveys, in conjunction with other data including the Canadian Total Diet Study, and Statistics Canada's Canadian Health Measures Survey food consumption data, are critical in assessing the health risk that our food supply poses to Canadian consumers. The results of CFIA's surveillance activities are also used to inform the Canadian public and stakeholders by raising consumer awareness and help build public confidence in their food supply by removing noncompliant products.

References

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Appendices

Appendix A. Ranges of levels of allergens and gluten in products in the 2015/16 survey

Sample type	Total samples tested	Almond ppm*	BLG ppm	Egg ppm	Gluten ppm			Sesame ppm	Soy ppm
Cilantro/ Coriander	30				5 to 280		4.5 to 11	1.2 to 7.6	0.6 to 40
Marjoram	3				6				
Oregano	28				7 to 210				
Rosemary	9				7 to 11	0.9			
Sage	27				6 to 45				
Thyme	29				5 to 69				
Allspice	28							0.8 to 1800	
Anise	25				45 to 86		1.6 to 3.2	1 to 2	0.52 to 2.2
Cardamom	28				6		1.6	0.6 to 7	
Cayenne	27						8.9		0.66
Cinnamon	41				6		10 to 18		
Cumin	29				27 to 120		1.4 to 9.6	0.9 to 15	0.56 to 1.94
Fenugreek/Methi	25		0.5		6 to 410			1.4 to 4.3	0.54 to 84
Ginger	40							0.5 to 1.1	0.92 to 0.98
Mace	25				7 to 16000			0.6 to 0.7	
Mustard	34				22 to 58			4.1	
Nutmeg	31							0.5 to 1	1.3 to 7.6
Paprika	37			1.47 to 4.67					
Pepper – Black	40				5 to 48000			0.6	0.8 to 2.6
Pepper – White	26				11 to 120000			1.4	0.54 to 3.2
Turmeric	36				10		6	3	0.64 to 14.2
Total positive results		0	2	3	149	1	19	46	50

Note: All samples were tested for a variety of allergens dependant on the ingredients in the food. Only positive results for allergens were included in the table.

Appendix B. Ranges of levels of allergens and gluten in products in the 2017/18 survey

Sample type	Total samples tested	Almond ppm*	BLG ppm	Casein ppm	Egg ppm	Gluten ppm	Hazelnut ppm	Peanut ppm	Sesame ppm	Soy ppm
Cilantro/ Coriander	10					10 to 53				5.6
Sage	10					6 to 27				
Thyme	10					6 to 17				
Mixed herbs	60		0.3 to 190	850	0.99	5 to 6300	6.27		2.1 to 160	1.4 to 5.8
Allspice	9									
Anise	4									
Cardamom	11							1.6		
Cayenne	11							0.45		
Cinnamon	11									
Cumin	11					8 to 130			1.2	
Fenugreek/ Methi	6					29 to 310				18.4
Garlic	11				0.77	64		0.3 to 21		150
Ginger	11							0.76		
Mace	8					250				
Mustard	11									
Nutmeg	11									1.92
Onion	11									
Paprika	11									
Pepper – Black	11					44000				14
Pepper – White	11					510			1.5	16600
Turmeric	10									4.3 to 7.8
Mixed spices	100	0.94 to 1.13				6 to 9400		0.3 to 2.1	3.3 to 270	0.52 to
Total positive results		3	2	1	2	63	1	2.1 15	6	22 18

Note: All samples were tested for a variety of allergens dependant on the ingredients in the food. Only positive results for allergens were included in the table.