



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Undeclared Allergens and Gluten in Bakery Products with Gluten-free claims – June 1, 2020 to March 31, 2021

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.

The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared allergens and gluten in bakery products with gluten-free claims. Of the 287 samples tested, 26 samples were found to contain undeclared gluten and/or allergens such as beta-lactoglobulin (BLG), casein, soy, sesame and egg.

26 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 the agency is based on the level of the contamination and the resulting health concern as determined by a health risk assessment. A single dessert product containing BLG and casein, and 1 other bakery product containing gluten were deemed to represent a health risk and were recalled.

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 allergens that are 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 list⁵. 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.

This was the first survey conducted by the agency for undeclared allergens and gluten in bakery products with gluten-free claims. The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared allergens and gluten in bakery products with gluten-free claims.

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

All products were sampled between June 2020 and March 2021. 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 survey:

- products with **all** of the following allergens in the list of ingredients – almond, hazelnut, peanut, sesame, soy/soybean, egg, milk, and wheat, barley, oats, rye, triticale, or gluten
- products with a precautionary statement for all priority allergens
- non pre-packaged products/bulk bin products
- products with no list of ingredients
- products past the best before date

Table 1: Distribution of samples based on product type and origin

Sample type	Domestic	Import	Unspecified ^a origin	Total
Bread	10	12	19	41
Dessert	31	23	39	93
Other ^b	33	54	66	153
Total	74	89	124	287

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

^b other refers to sample types other than bread and dessert, such as bagels, waffles, tortillas, etc.

How were 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 [Food and Drug Regulations Section B.01.010.1](#). 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 [Food and Drug Regulations Section B.24.018](#) for a gluten-free claim.

What were the survey results

Almost 91% of all bakery products with gluten-free claims in this survey did not contain any detectable levels of allergens and gluten. The results for 26 samples found positive are shown in table 2.

Table 2: Levels of undeclared allergens and gluten in bakery products with gluten-free claims in ppm

Sample type	Sample description	BLG	Casein	Egg	Gluten	Sesame	Soy
Bread	7-Grain bread						1.76
Bread	2 organic gluten free baguettines -1					0.81	
Bread	2 organic gluten free baguettines-2					1.54	
Bread	Whole grain sandwich loaf						1.22
Bread	French baguettes						0.95
Bread	Seeds and grains 100% plant based loaf					0.66	
Dessert	Coffee cakes						151.20
Dessert	Goji berries and chocolate cookies	5.95	34.10				
Dessert	Ginger square cookies				69		
Dessert	Gluten free chocolate cake				9200		
Dessert	Allergen friendly brownie bites espresso caramel				5.20		
Other	Whole grain bagels						0.54
Other	100% plant-based buns						1.03
Other	Classic hamburger buns-1						0.53
Other	Classic hamburger buns-2						2.02
Other	Ladyfingers						0.78
Other	Gluten free pizza crust						0.63
Other	Blueberry crumble						0.95
Other	Vegan gluten free par-baked pizza crust			1.24			
Other	Corn wrap				65		
Other	Organic turmeric wrap				160		
Other	Cauliflower tortilla-1						0.66
Other	Cauliflower tortilla-2						1.06
Other	Corn tortillas						1.26
Other	Gluten free breadsticks						1.26
Other	Gluten free buttermilk cheese biscuits						0.47

What do the survey results mean

Of the 287 samples tested in this survey, almost 91% did not contain any detectable levels of allergens or gluten, while 26 samples were found to contain varying levels of undeclared gluten, BLG, casein, soy, sesame and egg.

The best currently available scientific evidence indicates that levels of gluten below 20 ppm in gluten-free foods would be protective of health of the vast majority of people with celiac disease⁵. Accordingly, 4 positive results for gluten with levels of 20 ppm or greater, 1 positive result for both BLG and casein, 1 positive result for egg, 3 positive results for sesame as well as 16 positive results for soy were forwarded to the CFIA's OFSR for follow-up.

The extent of the follow-up actions taken by the CFIA is based on the level of contamination and the resulting health concern as determined by a health risk assessment. Appropriate follow-up actions 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.

Milk

Both undeclared BLG and casein were detected in 1 dessert product. BLG (a whey protein) and casein are major milk proteins. Casein derivatives such as sodium caseinate are often used as emulsifier and thickening agents in processed food including chocolate products⁶. Whey proteins also have excellent emulsifying and foaming properties, so they are widely used in producing desserts, yogurts, etc^{7,8,9}. Low levels of BLG and casein could be introduced into products due to cross contamination on the production line¹⁰. This dessert product was deemed to pose a health risk to consumers, and was recalled¹¹.

Egg

A single product in this survey tested positive for undeclared egg. Low levels of egg in the product could be a result of cross-contact of mislabeled or contaminated raw ingredient¹². Inadequate cleaning of shared processing and/or packaging equipment between each run could introduce low level allergens in products¹³. This product was deemed not to present a risk to consumers.

Sesame

Undeclared sesame was found in 3 bread products. Sesame seeds have long been used in the food industry to produce sesame oils, salad dressing, bakery products, etc. Cross-contamination from processing and handling on the shared production line may be the reason of the low level of sesame in the tested bread product¹³. All 3 samples were assessed as being of no risk to consumers.

Gluten

5 dessert products were found to contain varying level of undeclared gluten (5.2, 65, 69, 160 and 9200 ppm). Lower detected levels of gluten 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 foods¹⁴. Further investigation performed by OFSR on the dessert product containing high level of undeclared gluten (9200 ppm) indicated that this product was put in the wrong packaging sleeve, and none of such product was left on the market, so this sample wasn't deemed to be a health risk. Therefore, only 1 positive sample was deemed to pose a health risk to consumers, and was recalled¹⁵.

Soy

Undeclared soy was found in 16 products. The presence of low level of soy in cereal grains product may be due to cross contamination during normal agricultural activities, such as the growth, the harvest, the transport and the storage of grains¹⁶. The levels found were low and deemed not to pose a risk to consumers.

Summary

A single dessert product containing BLG and casein, and 1 other bakery product containing gluten were deemed to represent a health risk and were recalled. No published literature could be found on the similar topic for results comparison.

This survey generated baseline information on the background level of undeclared allergens and gluten in bakery products with gluten-free claims collected from 6 cities across Canada. Information gathered in this survey, 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 the 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 non-compliant products.

References

1. Soller, L., Ben-Shoshan, M., Harrington, D. W., Fragapane, J., Joseph, L., Pierre, Y. S., Clarke, A. E. (2012). Overall prevalence of self-reported food allergy in Canada. *Journal of Allergy and Clinical Immunology*, 130(4), 986-988.
2. Sicherer, S. H., & Sampson, H. A. (2014). Food allergy: Epidemiology, pathogenesis, diagnosis, and treatment. *Journal of Allergy and Clinical Immunology*, 133(2), 291-307.e5.
3. [Celiac disease foundation](#); (2018). United States. Celiac Disease Foundation.
4. [Common food allergens](#); (2018, May 14). Canada. Health Canada.
5. [Codex Alimentarius Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten - Codex Stan 118-1979](#). (2008). United States. Food and Agriculture Organization of United Nations & World Health Organization.
6. Applications and uses of sodium caseinate; (2015, July 3). China. Newseed Chemical Co., Limited.

7. Day, Li. (2016). Encyclopedia of Food and Health. Palmerston North, New Zealand. AgResearch Ltd. Pages 530-537
8. [U.S. Whey Products and Lactose in Confectionery Applications](#); (1999, January). United States. U.S. Dairy Export Council.
9. G. Masson, R. Jost. (1986). A study of oil-in-water emulsions stabilized by whey proteins. *Journal of Colloid and Polymer Science*, Volume 264, Issue 7, pp 631–638
10. Vierk, K., Falci, K., Wolyniak, C., Klontz, K. (2002). Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999. *Journal of Allergy and Clinical Immunology*, 109(6), 1022-1026
11. [Food Recall Warning \(Allergen\)\(Reference #14250\)](#); (February 25, 2021). Canada. Canadian Food Inspection Agency.
12. Khuda, S., Sharma, G., Gaines, D., Do, A., Pereira, M., Chang M., Ferguson, M., Williams, K. (2016). Survey of undeclared egg allergen levels in the most frequently recalled food types (including products bearing precautionary labelling). *Food Additives & Contaminants: Part A*, 33(8), 1265-1273
13. Lauren S. Jackson, Fadwa M. Al-taher, Mark Moorman, Jonathan W. Devries, Roger Tippett, Katherine M.J. Swanson, Tong-Jen Fu, Robert Salter, George Dunaif, Susan Estes, Silvia Albillos, Steven M. Gendel (2008). Cleaning and Other Control and Validation Strategies To Prevent Allergen Cross-Contact in Food-Processing Operations. *Journal of Food Protection*, 71(2), 445–458
14. [Health Canada's Position on Gluten-Free Claims](#); (2012). Canada. Government of Canada.
15. [Food Recall Warning \(Allergen\)\(Reference #14157\)](#); (December 30, 2020). Canada. Canadian Food Inspection Agency.
16. [Information for Canadians with Soy Allergy](#); (2013, January 25). Canada. Health Canada.