



# Undeclared Allergens and Gluten in Protein Substitute/Vegetarian Meat Products – 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 additional information regarding the presence and levels of undeclared allergens and gluten in protein substitute/vegetarian meat products. Of the 290 samples tested, 12 samples were found to contain undeclared gluten or allergens such as beta-lactoglobulin (BLG), casein, egg, peanut, sesame and soy.

Of the positive samples, 11 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. 2 protein substitute ready-to-eat (RTE) meal products and 2 meat alternative products 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 lower<sup>1</sup>. 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 countries<sup>2</sup>. 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 disease<sup>3</sup>.

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 wheat<sup>4</sup>. 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<sup>5</sup>. 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 main objective of this survey was to obtain additional information regarding the presence and levels of undeclared allergens and gluten in protein substitute/vegetarian meat products.

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)
- West (Vancouver and 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 <sup>a</sup> origin	Total
Dairy alternative	22	16	3	41
Meat alternative	33	65	31	129
Other	2	0	0	2
Protein substitute RTE meal	10	29	6	45
Tempeh/Tofu	32	22	19	73
<b>Total</b>	<b>99</b>	<b>132</b>	<b>59</b>	<b>290</b>

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

# 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 96% of all protein substitute/vegetarian meat products in this survey did not contain any detectable levels of allergens and gluten. The results for 12 samples found positive are shown in Table 2.

**Table 2: Levels of undeclared allergens and gluten in protein substitute/vegetarian meat products in ppm**

Sample type	Sample description	BLG	Casein	Gluten	Egg	Peanut	Sesame	Soy
Dairy alternative	Fresh cultured cashew spread					2.31		
Dairy alternative	Cultured cashew soft cheese -1	0.42	1.21					
Dairy alternative	Cultured cashew soft cheese -2	0.42	1.21			1.3		
Dairy alternative	Cheese alternative					1.04		
Meat alternative	Veg-o-mix fish flavour				9.55			
Meat alternative	Simulated sausage							1.76
Meat alternative	Beet balls			12				
Meat alternative	Vege meatball			39000				
Protein substitute RTE meal	Vegan kung pao				0.42			
Protein substitute RTE meal	Mexican plate		2.2					
Protein substitute RTE meal	Power bowls	0.42	2.75					
Tempeh/Tofu	Soy kasha tempeh						0.32	

## What do the survey results mean

Of the 290 samples tested in this survey, almost 96% did not contain any detectable levels of allergens or gluten, while 12 samples were found to contain varying levels of undeclared gluten, BLG, casein, egg, peanut, sesame and soy. The best currently available scientific evidence indicates that levels of gluten below 20 ppm in gluten-free foods would be protective of the

health of the vast majority of people with celiac disease<sup>5</sup>. Therefore, 11 positive samples 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 2 dairy alternative and 1 protein substitute RTE meal products, while single undeclared casein was detected in 1 protein substitute RTE meal product. BLG (a whey protein) and casein are major milk proteins. Casein derivatives such as sodium caseinate are used as emulsifier and thickening agent in processed foods including chocolate products<sup>6</sup>. Whey proteins also have excellent emulsifying and foaming properties, so they are widely used in producing chocolate, desserts, yogurts, etc<sup>7,8,9</sup>. Low levels of BLG and casein found in this survey could also be introduced into the product due to cross contamination on the production line<sup>10</sup>. 2 protein substitute RTE meal products (Mexican plate and power bowls) were deemed to pose a health risk to consumers, and were recalled<sup>11,12</sup>.

## **Gluten**

2 of the meat alternative products tested were found to contain varying levels of undeclared gluten (12 and 39000 ppm). Lower detected levels of undeclared gluten have been known to be present due to cross-contamination as a result of manufacturing practices<sup>13</sup>. Only 1 product (Vege meatball) was considered to represent a health risk to consumers, and was recalled<sup>14</sup>.

## **Soy**

Undeclared soy was found in 1 product. The level detected was likely due to cross contamination or cross contact in the manufacturing process<sup>15</sup>. This could result in the presence of a small amount of allergen in the final product. The level found was low and deemed not to pose a risk to consumers.

## **Egg**

2 products 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 ingredient<sup>16</sup>. Inadequate cleaning of shared processing and/or packaging equipment between each run could introduce low level allergens in products<sup>15</sup>. 1 product (Veg-o-mix fish flavor) was assessed as being a health risk to consumers and was recalled<sup>17</sup>.

## **Peanut**

Undeclared peanut was detected in 3 dairy alternative products. The low levels of undeclared peanut may have been due to incomplete cleaning of the production line leading to cross-contamination during the manufacturing process<sup>10</sup>. All products were deemed not to present a risk to consumers.



## Sesame

Undeclared sesame was found in 1 tempeh/tofu product. Sesame seeds have long been used in the food industry to produce sesame oils, 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 tempeh/tofu product<sup>15</sup>. This product was assessed as being of no risk to consumers.

## Summary

2 protein substitute RTE meal products and 2 meat alternative products resulted in product recalls, while all other positive allergen findings in this survey were determined not to pose a risk to consumers. The results are higher than those found in a similar survey which was conducted in 2013 by the agency to obtain baseline information regarding the presence and levels of undeclared allergens and gluten in meat alternative products. In that survey, 597 products were tested and 11 samples tested positive for one or more undeclared allergens and/or gluten.

This survey generated additional information on the background level of undeclared allergens and gluten in protein substitute/vegetarian meat products 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., and 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 and 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 \(Allergen\)\(Reference #14056\)](#); (October 9, 2020). Canada. Canadian Food Inspection Agency.
12. [Food Recall Warning \(Allergen\)\(Reference #14292\)](#); (March 19, 2021). Canada. Canadian Food Inspection Agency.
13. [Health Canada's Position on Gluten-Free Claims](#); (2012). Canada. Government of Canada.
14. [Food Recall Warning \(Allergen\)\(Reference #14243\)](#); (February 20, 2021). Canada. Canadian Food Inspection Agency.
15. Lauren S. Jackson, Fadwa M. Al-taher, Mark Moorman, Jonathan W. Devries, Roger Tippet, 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
16. 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
17. [Food Recall Warning \(Allergen\)](#); (March 23, 2021). Canada. Ministry of Agriculture, Fisheries and Food of Quebec.