



Undeclared Gluten in Infant Foods - 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 to 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 allergen levels as low as reasonably possible.

The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared gluten in gluten-free infant foods. Of 600 samples tested, 10 samples were found to contain undeclared gluten. 8 out of these 10 samples were an infant cereal and was the same product with different lot numbers.

5 positive results for gluten higher than 20 parts per million (ppm) 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. All lot numbers of 1 infant cereal product containing undeclared gluten in this survey were deemed to represent a health risk and 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 diagnosed 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 to investigate the occurrence of undeclared gluten in gluten-free infant foods. The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared gluten in gluten-free infant foods.

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 April 2017 and March 2018. 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 types of products were not included in the survey:

- Products with any of the following allergens in the list of ingredients - wheat, rye, barley, triticale, kamut, spelt or gluten
- Products with oat in the list of ingredients, but without a “Gluten free” claim
- Products with no list of ingredients
- Products with a precautionary statement for wheat, rye, barley, triticale, kamut, spelt or gluten
- Products for infants older than 12 months

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

Product type	Domestic	Import	Unspecified origin ^a	Total
Infant cereal	0	201	0	201
Infant puree	111	96	0	207
Infant snacks	0	190	2	192
Total	111	487	2	600

^a 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 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

Over 98% of all gluten-free infant foods tested in this survey did not contain any detectable levels of gluten. 10 samples were positive for undeclared gluten, and 8 of them were the same product with different lot numbers, but purchased at different locations in 4 different cities. All of the gluten positive results were found in infant cereals. The results for the 10 samples found positive are shown in table 2.

Table 2. Levels of undeclared gluten in gluten-free infant foods in ppm

Sample type	Sample description	Gluten (ppm)
Infant cereal	Buckwheat + Chia Organic Infant Cereal -1	6
Infant cereal	Buckwheat + Chia Organic Infant Cereal -2	8
Infant cereal	Buckwheat + Chia Organic Infant Cereal -3	17
Infant cereal	Buckwheat + Chia Organic Infant Cereal -4	20
Infant cereal	Buckwheat + Chia Organic Infant Cereal -5	57
Infant cereal	Buckwheat + Chia Organic Infant Cereal -6	77
Infant cereal	Buckwheat + Chia Organic Infant Cereal -7	110
Infant cereal	Buckwheat + Chia Organic Infant Cereal -8	160
Infant cereal	Sprouted Whole Grain Brown rice cereal	460
Infant cereal	Organic buckwheat cereal	20

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.

What do the survey results mean

Of the 600 samples tested, over 98% did not contain any detectable levels of gluten. The 10 positive results were all found in infant cereals with levels ranging from 6 to 460 ppm.

The best currently available scientific evidence indicates that levels of gluten at or below 20 ppm in gluten-free foods would be protective of the health of the vast majority of people with celiac disease⁵. Therefore, 5 positive results for gluten higher than 20 ppm 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.

Lower detected levels of undeclared 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 foods⁶. A single product recall was issued as a result of this survey⁷.

This survey generated new information on the background level of undeclared gluten in gluten-free infant foods 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 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. [Health Canada's Position on Gluten-Free Claims](#); (2012). Canada. Government of Canada.
7. [Food Recall Warning \(Allergen\) \(Reference #11715\)](#); (September 14, 2017). Canada. Canadian Food Inspection Agency.