



Undeclared Gluten in Products Containing Gluten-Free Oats - April 1, 2016 to March 31, 2017

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. They are often used by the CFIA 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 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 gluten in products containing gluten-free oats. 300 samples were tested and 2.7% (8) of the samples were found to contain undeclared gluten. Most positive results for undeclared gluten were associated with cereal products.

1 positive result was forwarded to the CFIA's Office of Food Safety and Recall (OFSR) for follow-up and it was determined that this product did not represent a health risk to consumers. The extent of all follow-up actions taken by CFIA is based on the seriousness of the contamination and the resulting health concern as determined by a health risk assessment.

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 CFIA 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. Approximately 1% of the total population are affected with celiac disease³. Celiac disease is a chronic reaction where the body reacts to a component of gluten which can damage or destroy certain intestinal cells.

The priority food allergens are the 10 most common food components 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 included in this list. Gluten is a family of proteins found in certain grains like wheat, rye, barley, kamut, and spelt. Gluten can cause digestive problems and other issues for people with certain health conditions such as celiac disease and gluten sensitivity. This report presents the results of a survey conducted to look at the levels of undeclared gluten in products containing gluten-free oats.

Undeclared allergens and gluten can be found in food 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 their levels as low as reasonably possible.

Food allergens 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. Reactions to food allergens depend on the individual's sensitivity and can range from mild to severe or life threatening. This makes proper identification and labeling of allergens in food by the manufacturer essential. The following types of products were sampled for this

survey: baked goods, baking mixes, cereal, oat bran, oat flour and oat grain. All products were tested “as sold,” meaning that they were not prepared as per manufacturer’s instructions or as they would typically be consumed.

This was the first survey conducted by the CFIA for undeclared gluten in products containing gluten-free oats. The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared gluten in products containing gluten-free oats.

What did we sample

All types of products containing gluten-free oats were sampled from April 2016 and March 2017. Samples were collected from local/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:

- gluten-free products without oats
- oat products without a gluten-free claim
- products missing required list of ingredients
- products packaged instore or bulk products
- products past the “use by” or “best before” date

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

Product type	Domestic	Import	Unspecified origin ^a	Total
Baked goods	7	21	7	35
Baking mixes	31	4	0	35
Oat bran	21	0	13	34
Cereal	13	76	11	100
Oat flour	19	0	17	36
Oat grain	18	9	33	60
Total	109	110	81	300

^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 International Standards Organization (ISO) 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 ingredient if they are present in the prepackaged product in order to comply with the requirements of *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

Over 97% of all products containing gluten-free oats sampled in this survey did not contain any detectable levels of gluten. 8 samples were positive for gluten, and this includes 1.2% of all samples with unspecified origin, 2.8% of all domestic products and 3.6% of all imported products tested. The majority of gluten positive results were found in cereals product. 7 of the positive samples contained levels of gluten not exceeding 20 ppm thereby meeting Health Canada's definition of a gluten free food.

Table 2. Levels of gluten in positive sample of products containing gluten-free oats in mg/kg or ppm

Sample	Gluten ppm
Cereal	
Oatmeal, cinnamon pumpkin seed	6
Quinoa granola, dark chocolate	16
Instant oatmeal	30
Quinoa spiced pumpkin granola hot & cold cereal	9
Creamy coconut oatmeal	8
Hot & fit cereal superfood blueberry chia	10
Breakfast cereal Canadian blend plus	14
Oat flour	
Whole grain oat flour	9

What do the survey results mean

Of the 300 samples tested, over 97% did not contain any detectable levels of undeclared gluten. The 8 positive results were found in cereal products with levels ranging from 6 to 30 ppm.

A Swedish study published in 2003 investigated the presence of gluten in oat products and products naturally free from gluten. A total of 88 oat products and 22 products based on maize, rice, millet or buckwheat were sampled and analysed. The study found that 50 % of the oat products and 41% of products naturally free from gluten contain level of gluten exceeding 20 ppm. The study also found that 13% of the oat products and 14% of naturally gluten-free products contain level of gluten over 200 ppm⁵.

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 can be present in a food due to cross-contamination during manufacturing or because of the adventitious presence of gluten containing grains in other bulk grain products. 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 disease⁶. As a result, only positive results higher than 20 ppm (per serving) are typically forwarded to the CFIA's OFSR for follow-up. None of the products sampled in this survey were found to present a health risk.

This survey generated new information on the background level of undeclared gluten in products with gluten-free oats 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

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