



Canadian Food  
Inspection Agency

Agence canadienne  
d'inspection des aliments

# Undeclared gluten in oat products with gluten-free claims – April 1, 2022, to March 31, 2023

## Food allergen – Targeted surveys



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## Executive 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 gluten in oat products with gluten-free claims. Of the 261 samples tested, 18 samples were found to contain undeclared gluten with levels from 6.6 parts per million (ppm) to 240 ppm.

5 positive results for gluten higher than 20 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. 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. None of the products sampled in this survey was found to represent a health risk, and so were not recalled.

## What targeted surveys are

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 the survey was conducted

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 gluten in oat 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 we sampled

All products were sampled between April 2022 and March 2023. Samples were collected from local and regional grocery stores located in 6 major cities across Canada. These cities represented 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 – wheat, barley, oats, rye, triticale, kamut, spelt 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 sample type and origin**

| Sample type        | Domestic | Import | Unspecified <sup>a</sup> origin | Total |
|--------------------|----------|--------|---------------------------------|-------|
| Baked oat products | 24       | 21     | 5                               | 50    |
| Baking Mixes (Oat) | 33       | 10     | 7                               | 50    |
| Granola            | 7        | 10     | 11                              | 28    |
| Oat flour          | 25       | 11     | 6                               | 42    |

|              |            |           |           |            |
|--------------|------------|-----------|-----------|------------|
| Oatmeal      | 36         | 16        | 39        | 91         |
| <b>Total</b> | <b>125</b> | <b>68</b> | <b>68</b> | <b>261</b> |

### Table notes

<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 samples were 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<sup>5</sup>.

## Results of the survey

Over 93% of the oat products with gluten-free claims tested in this survey contained no detectable levels of gluten. The results for 18 positive samples are shown in Table 2 below.

**Table 2: Levels of undeclared gluten in oat products with gluten-free claims in parts-per-million (ppm)**

| Sample type        | Sample description                        | Gluten |
|--------------------|---|--------|
| Baked oat products | Birthday cake bites 6 hunks               | 9.8    |
| Granola            | Organic maple spice crunch granola cereal | 11     |
| Granola            | Organic brownie crunch granola cereal -1  | 6.6    |
| Granola            | Organic brownie crunch granola cereal -2  | 100    |
| Granola            | Organic summer berries crunchy granola    | 18     |
| Granola            | Organic stone age superfood granola       | 12     |
| Oat flour          | Whole grain oat flour -1                  | 28     |
| Oat flour          | Whole grain oat flour -2                  | 16     |

|           |  |     |
|-----------|--|-----|
| Oat flour | Whole grain oat flour -3                       | 12  |
| Oat flour | Whole grain oat flour -4                       | 13  |
| Oat flour | Whole grain oat flour -5                       | 240 |
| Oatmeal   | Oat bran hot cereal                            | 7   |
| Oatmeal   | Rolled oats                                    | 26  |
| Oatmeal   | Organic thick oats                             | 20  |
| Oatmeal   | Organic sprouted rolled oats                   | 36  |
| Oatmeal   | Organic quick rolled Oats                      | 5.8 |
| Oatmeal   | Organic sprouted toasty whole-grain oat cereal | 15  |
| Oatmeal   | Organic creamy coconut superfood oatmeal       | 6.2 |

## What the survey results mean

Of the 261 samples tested in this survey, over 93% did not contain any detectable levels of gluten, while 18 samples were found to contain undeclared gluten with levels from 6.6 ppm to 240 ppm. The best currently available scientific evidence indicates that levels of gluten at and below 20 ppm in gluten-free foods would be protective of the health of the vast majority of people with celiac disease<sup>6</sup>. Therefore, 2 oat flours, 2 rolled oats and 1 granola product were forwarded to 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.

Low levels of undeclared gluten have been known to be present due to cross-contamination as a result of manufacturing practices<sup>6</sup>. These products were assessed as being of no risk to consumers, so no product recall was needed.

### Summary

None of the products sampled in this survey were found to represent a health risk, and therefore none were recalled.

The current survey results (6.90% positive rate) are higher than those found in a similar survey conducted in 2016 by CFIA (2.70% positive rate). In that survey, 300 samples were tested and 8 of the samples were found to contain undeclared gluten.

This survey generated additional information on the presence and levels of undeclared gluten in oat 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

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