# Undeclared Allergens and Gluten in Candies and Chocolate Products - April 1, 2022 to February 28, 2023 

Food allergen - Targeted surveys


Canadà

## 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 candies and chocolate products. Of the 376 samples tested, 46 samples ( 45 samples of chocolate and 1 candy sample) were found to contain undeclared allergens such as beta-lactoglobulin (BLG), casein, hazelnut, peanut, sesame and soy. None of the samples contained undeclared gluten, egg, almond, wheat, barley, oats, rye, or triticale.

All 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. 36 dairy free dark chocolate products sampled in this survey 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 ${ }^{1}$. 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 ${ }^{2}$. 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 ${ }^{3}$.

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 ${ }^{4}$. 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 ${ }^{5}$. 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 candies and chocolate 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 April 2022 and February 2023. 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, 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

| Product type | Domestic | Import | Unspecified $^{\text {a }}$ <br> origin | Total |
| :--- | :---: | :---: | :---: | :---: |
| Candies | 6 | 29 | 14 | 49 |
| Dairy free dark chocolate products | 160 | 106 | 25 | 291 |
| Milk chocolate products | 9 | 17 | 5 | 31 |
| Non-dairy free dark chocolate <br> products | 1 | 4 | 0 | 5 |
| Total | $\mathbf{1 7 6}$ | $\mathbf{1 5 6}$ | $\mathbf{4 4}$ | $\mathbf{3 7 6}$ |

${ }^{\text {a }}$ 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 parts per million (ppm) (due to cross contamination) meet the intent of the Food and Drug Regulations Section B.24.018 for a glutenfree claim.

## What were the survey results

Approximately $87.8 \%$ of all candies and chocolate products in this survey did not contain any detectable levels of allergens and gluten. The results for 46 samples found positive are shown in Table 2.

Table 2: Levels of undeclared allergens and gluten in candies and chocolate products in ppm

| Product type | Sample <br> description | BLG | Casein | HazeInut | Peanut | Sesame | Soy |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Candies | Fruit Juice <br> Blueberries | 0.15 |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Dark All Natural <br> Chocolate | 29.75 | 90.2 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Dark Chocolate <br> Chips 70\% Cocoa | 129.5 | 583 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Crunchy Almond <br> Energy Balls | 147 | 737 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic Coconut <br> Milk Unroasted <br> Dark Chocolate <br> 60\% Cacao |  |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic Dark <br> Chocolate Fig <br> Truffles 64\% Cacao | 2.31 | 10.67 |  | 83.6 |  |  |
| Dairy free dark <br> chocolates <br> products | LC-Mini Dark <br> Chocolate Chips - <br> Organic |  |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Orange cream | 30.8 | 110 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate almonds | 0.67 | 4.51 | 9.3 |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate hazelnuts <br> with chili | 6.3 | 39.6 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Artisanal Belgian <br> dark chocolate 66\% | 66.5 | 330 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate hazelnuts | 3.85 | 25.3 |  |  |  |  |


| Dairy free dark <br> chocolates <br> products | Organic ginger <br> snap unroasted <br> dark chocolate - <br> 70\% cacao |  |  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Dairy free dark <br> chocolates <br> products | Chocolate cashews <br> - Belgium dark <br> chocolate | 1.3 | 9.24 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Dark chocolate <br> enrobed pineapples | 45.5 | 132 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | $80 \%$ dark pumpkin <br> seed butter cups |  |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate almonds | 0.56 | 3.96 | 30 |  |  |  |
| Dairy free dark <br> chocolates <br> products | Guilt-free energy <br> truffle balls of <br> happiness <br> chocolate | 0.46 | 3.19 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate clusters | 0.22 | 1.65 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate almonds <br> with chili | 11.2 | 83.6 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Signature dark <br> chocolate almonds | 0.81 | 2.86 |  |  |  |  |
| Dairy free dark <br> cocolates <br> products |  <br> nibs unroasted dark <br> chocolate bar 75\% <br> cacao |  |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate almonds | 0.67 | 4.84 | 8.85 |  |  |  |
| Dairy free dark <br> chocolates <br> products | LiLo's clusters <br> organic dark <br> chocolate | 4.2 | 24.2 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic hazelnut <br> chocolate bark | 1.68 | 10.01 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark <br> chocolate <br> hazelnuts | 2.45 | 18.7 |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Organic dark 75\% <br> fine chocolate <br> with superfoods <br> raw cacao nibs |  |  |  |  |  |  |
| Dairy free dark <br> chocolates <br> products | Chocolate ginger | 32.2 | 209 |  |  |  |  |


| Dairy free dark chocolates products | Chocolate hazelnuts Belgium dark chocolate | 63 | 385 |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Dairy free dark chocolates products | Guilt-free, energy truffle chocolate balls | 57.5 | 330 |  |  |  |  |
| Dairy free dark chocolates products | Chocolate cashews Belgium dark chocolate | 0.4 | 4.18 |  |  |  |  |
| Dairy free dark chocolates products | Dark chocolate chickpea snacks | 300 | 1540 |  |  |  |  |
| Dairy free dark chocolates products | Dark chocolate coffee beans | $\begin{aligned} & 11.7 \\ & 5 \end{aligned}$ | 56.1 |  | 1.56 |  |  |
| Dairy free dark chocolates products | Almond bark no sugar added dark 55\% cacao | 35 | 198 |  |  |  |  |
| Dairy free dark chocolates products | Organic coconut dark chocolate bark | 8.25 | 42.9 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate pitaya bites | $\begin{aligned} & 20.2 \\ & 5 \end{aligned}$ | 165 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate pineapple bites | 17.5 | 132 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate banana clusters | 3.25 | 31.9 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate dipped peanuts | 2.5 | 29.7 |  |  |  |  |
| Dairy free dark chocolates products | Signature chocolate almonds | 7.75 | 74.8 | 1.8 | 1.64 |  |  |
| Dairy free dark chocolates products | Dark NFLD wildberry bark | 95 | 759 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate covered pineapple 70\% Peruvian cacao | 5.75 | 26.4 |  |  |  |  |
| Dairy free dark chocolates products | Organic dark chocolate almonds with chili | 10 | 74.8 | 3.75 |  |  |  |
| Dairy free dark chocolates products | 60\% dark chocolate with hazelnuts | $\begin{aligned} & 22.2 \\ & 5 \end{aligned}$ | 121 |  |  |  |  |


| Dairy free dark <br> chocolates <br> products | Organic <br> goldenberry dark <br> chocolate clusters | 137. <br> 5 | 880 |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Dairy free dark <br> chocolates <br> products | Orange dark <br> chocolate | 24 | 101.2 |  |  |  |  |

## What do the survey results mean

Of the 376 samples tested in this survey, approximately $87.8 \%$ did not contain any detectable levels of allergens or gluten, while 46 samples were found to contain varying levels of undeclared BLG, casein, hazelnut, peanut, sesame or soy. All 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

BLG (a protein found in whey) and casein are major milk proteins. Casein derivatives such as sodium caseinate are used as emulsifiers and thickening agents in processed foods including chocolate products ${ }^{6}$. Whey proteins also have excellent emulsifying and foaming properties, so they are widely used in producing chocolate, desserts, yogurts, etc ${ }^{7,8,9}$. Both undeclared BLG and casein were detected in 39 dairy free dark chocolates products, while undeclared BLG was detected in 1 candy product. The BLG and casein found in this survey were most likely introduced into the products due to cross-contamination on the production line. Other possible sources of milk proteins could be undeclared ingredients or components of ingredients. 35 dairy free dark chocolates products were deemed to pose a health risk to consumers, and were recalled ${ }^{10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30 \text {. The other } 4 \text { products were deemed not to }{ }^{1} \text {. }}$ present a risk to consumers.

## Hazelnut

Undeclared hazelnut was detected in 6 dairy free dark chocolate products. The low levels of undeclared hazelnut may have been due to incomplete cleaning of the production line leading to cross-contamination during the manufacturing process ${ }^{31} .4$ products positive for hazelnut were also positive for milk and were deemed to present a risk to consumers, and were recalled ${ }^{16,17}$. The level of Hazelnut in one of the remaining products was assessed as safe to consumers, however was recalled due to undeclared milk ${ }^{27}$.

## Peanut

2 of the dairy free dark chocolates products tested were found to contain undeclared peanut. Lower detected levels of undeclared peanut have been known to be present due to cross-
contamination as a result of manufacturing practices ${ }^{32}$. Both products were deemed not to present a risk to consumers with the presence of undeclared peanut, but both products were recalled due to undeclared milk ${ }^{24,27}$.

## Sesame

Undeclared sesame was found in 3 dairy free dark chocolates products. Sesame seeds have long been used in the food industry to produce dressing, sauce, bakery products, dessert etc. Cross-contamination from processing and handling on the shared production line may be the reason for the low level of sesame in the tested dairy free dark chocolates products ${ }^{32}$. Only 1 product was assessed as being of risk to consumers, and was recalled ${ }^{33}$.

## Soy

Undeclared soy was found in 2 dairy free dark chocolates products. The level detected was likely due to cross contamination or cross contact in the manufacturing process ${ }^{15}$. 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.

## Summary

Of the 376 samples tested in this survey, 46 samples were found to contain undeclared allergens. 36 dairy free dark chocolate products sampled in this survey were deemed to represent a health risk and were recalled. The remaining samples contained detectable levels of allergens but the levels found did not pose a risk to human health.

The results are higher than those found in 2 similar surveys which were conducted in 2018 by CFIA to obtain baseline information regarding the presence and levels of undeclared allergens and gluten in candies and chocolate products. In one survey, 345 products were tested, 10 samples tested positive for one or more undeclared allergens and/or gluten. In the other survey, 356 products were tested, 10 were found to contain undeclared allergens, specifically betalactoglobulin (BLG) and casein.

This survey generated additional information on the background level of undeclared allergens and gluten in candies and chocolate 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., \& 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. Food Recall Warning (Allergen)(CFIA ID: 15474); (2023-04-06). Canada. Canadian Food Inspection Agency.
11. Food Recall Warning (Allergen)(CFIA ID:15048); (2022-06-21). Canada. Canadian Food Inspection Agency.
12. Food Recall Warning (Allergen)(CFIA ID:15046); (2022-06-23). Canada. Canadian Food Inspection Agency.
13. Food Recall Warning (Allergen)(CFIA ID:15049); (2022-06-23). Canada. Canadian Food Inspection Agency.
14. Food Recall Warning (Allergen)(CFIA ID:15060); (2022-07-05). Canada. Canadian Food Inspection Agency.
15. Food Recall Warning (Allergen)(CFIA ID:15077); (2022-07-15). Canada. Canadian Food Inspection Agency.
16. Food Recall Warning (Allergen)(CFIA ID:15089); (2022-07-22). Canada. Canadian Food Inspection Agency.
17. Food Recall Warning (Allergen)(CFIA ID:15101); (2022-07-26). Canada. Canadian Food Inspection Agency.
18. Food Recall Warning (Allergen)(CFIA ID: 15097, 15105); (2022-07-28). Canada. Canadian Food Inspection Agency.
19. Food Recall Warning (Allergen)(CFIA ID: 15251); (2022-11-04). Canada. Canadian Food Inspection Agency.
20. Food Recall Warning (Allergen)(CFIA ID: 15287); (2022-11-19). Canada. Canadian Food Inspection Agency.
21. Food Recall Warning (Allergen)(CFIA ID: 15296); (2022-12-14). Canada. Canadian Food Inspection Agency.
22. Food Recall Warning (Allergen)(CFIA ID: 15294); (2022-11-25). Canada. Canadian Food Inspection Agency.
23. Food Recall Warning (Allergen)(CFIA ID: 15340); (2022-12-24). Canada. Canadian Food Inspection Agency.
24. Food Recall Warning (Allergen)(CFIA ID: 15341); (2022-12-24). Canada. Canadian Food Inspection Agency.
25. Food Recall Warning (Allergen)(CFIA ID: 15158); (2022-08-29). Canada. Canadian Food Inspection Agency.
26. Food Recall Warning (Allergen)(CFIA ID: 15424); (2023-02-25). Canada. Canadian Food Inspection Agency.
27. Food Recall Warning (Allergen)(CFIA ID: 15432); (2023-03-09). Canada. Canadian Food Inspection Agency.
28. Food Recall Warning (Allergen)(CFIA ID: 15457); (2023-03-24). Canada. Canadian Food Inspection Agency.
29. Food Recall Warning (Allergen)(CFIA ID: 15469); (2023-04-01). Canada. Canadian Food Inspection Agency.
30. Food Recall Warning (Allergen)(CFIA ID: 15479); (2023-04-06). Canada. Canadian Food Inspection Agency.
31. Food Recall Warning (Allergen)(CFIA ID: 15474); (2023-04-06). Canada. Canadian Food Inspection Agency.
32. 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
33. 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
34. Food Recall Warning (Allergen)(CFIA ID: 15052); (2022-06-24). Canada. Canadian Food Inspection Agency.
