Undeclared Allergens and Gluten in Processed Fish and Seafood – April 1, 2015 to March 31, 2016





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 baseline information regarding the presence and levels of undeclared beta-lactoglobulin (BLG) (one of the milk proteins), egg, soy and gluten in prepackaged processed fish and seafood products. Of 600 samples tested, approximately 26 were found to contain undeclared allergens. The most prevalent allergens in the dried fish products were BLG and gluten while egg and soy were more common in frozen fish products.

All positive results obtained during the course of these surveys 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. 14 products from this survey containing undeclared gluten or egg 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 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 for undeclared allergens and gluten in processed fish and seafood products. The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared allergens including egg, soy, BLG, and gluten in these 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 May 2015 and April 2016. 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 products were not included in the survey:

- products with all of the following allergens in the list of ingredients 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
- products with no list of ingredients
- products past the best before date

Table 1: Distribution of products based on product type and origin

Sample type	Domestic	Imported	Unspecified ^a origin	Total
Fish/seafood canned	18	181	1	200
Fish/seafood dried	26	47	2	75
Fish/seafood frozen or refrigerated	72	163	15	250
Fish/seafood pickled or marinated	33	42	0	75
Total	149	433	18	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

Tests were assigned sample by sample after label review. If the presence of allergens (soy/soybean, egg, milk, and wheat, barley, oats, rye, triticale, or gluten) were indicated by inclusion in the list of ingredients or by way of a precautionary statement, analysis for these allergens were not carried out.

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 <u>Food and Drug Regulations Section B.01.010.1</u>. 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 <u>Food and Drug Regulations Section B.24.018</u> for a gluten-free claim.

What were the survey results

Over 95% of all processed fish and seafood products sampled in this survey did not contain any detectable levels of undeclared allergens. 26 samples were positive for BLG, gluten, egg or soy. Details the types of food from the survey where undeclared allergens were found are shown in Table 2 as well as which allergen was detected and at what level.

Table 2: Levels of undeclared allergens and gluten in processed fish and seafood products in ppm

Sample type	Sample description	BLG (ppm)	Gluten (ppm)	Egg (ppm)	Soy (ppm)
Fish/seafood canned	Fish salad		2200		
Fish/seafood dried	Japanese style anchovy		4500		
Fish/seafood dried	Spicy crispy anchovies		3200		
Fish/seafood dried	Honey roasted cod		3500		
Fish/seafood dried	Wild pacific regular salmon jerky	0.1			
Fish/seafood dried	Fish maw	0.6			
Fish/seafood dried	Dry seasoned squid	0.9			
Fish/seafood dried	Premium squid	0.1			
Fish/seafood frozen or refrigerated	Battered Alaska pollock fillets				0.98
Fish/seafood frozen or refrigerated	Salt & pepper calamari	1.9			
Fish/seafood frozen or refrigerated	Fried dace fish ball			190	
Fish/seafood frozen or refrigerated	Fish ball - 1			880	4.6
Fish/seafood frozen or refrigerated	Fried shrimp balls			160	
Fish/seafood frozen or refrigerated	Fish balls with black moss				5.4
Fish/seafood frozen or refrigerated	Fish fingers			240	
Fish/seafood frozen or refrigerated	Seafood pancake			2700	
Fish/seafood frozen or refrigerated	Surimi chunks			6000	
Fish/seafood frozen or refrigerated	Frozen pre-fried fish cake			2	
Fish/seafood frozen or refrigerated	Fish ball - 2				8.6
Fish/seafood frozen or refrigerated	Fried fish cake sushi			0.7	

Fish/seafood frozen or			2000	
refrigerated	Fried fish balls			
Fish/seafood frozen or				
refrigerated	Fish tofu	1.6		
Fish/seafood frozen or			33	
refrigerated	Shrimp flavoured ball			
Fish/seafood frozen or			933	
refrigerated	Seafood pancake			
Fish/seafood frozen or				1.84
refrigerated	Blue hake cutlet			
Fish/seafood frozen or			118	
refrigerated	Vegetable fish sausage			

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 in this survey, over 95% did not contain any detectable levels of allergens and gluten, while 26 samples were found to contain varying levels of BLG, gluten, egg or soy.

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

There are two milk proteins that cause allergic reactions. These are BLG and casein. BLG is a major component of whey protein. Whey protein can be used as either a stand-alone protein, a partial replacement of meat proteins, or as partial or total replacement of soy protein products or other non-meat binders such as modified starches⁶. 6 products tested positive for BLG, but at levels below what might be expected to be a functional level for an additive. Based on previous risk assessments conducted by the CFIA, these levels might possibly represent an indication of cross contamination in an ingredient or the final product. None of these samples were deemed to present a risk to consumers.

Casein, a protein found in whole milk, was not analyzed in this survey because of concerns over low analyte recovery with certain fish species. The CFIA, in consultation with Health Canada, determined it would be possible to provide a health risk assessment based on the BLG test results only. However, it was noted the BLG results alone might underestimate the quantity of milk present, especially if contamination was from whole milk powder, skim milk powder or caseinates.

Gluten

Gluten was present in 4 samples at levels well above what would be expected for cross contamination. According to the food safety investigation conducted on these positive results, these levels may be present from sub-components or added ingredients. 3 gluten positive samples were assessed to represent a health risk and were recalled^{7,8,9}.

Egg

Egg protein was present in 12 products tested. 11 of the positive samples were assessed to represent a health risk and were recalled 10,11,12,13,14,15,16,17,18,19.20.

Soy

Undeclared soy was found in 5 of the products tested. These soy results were also below a functional level for an additive and might represent cross contamination in an ingredient or the final product. All of them were determined to be safe for consumers.

Summary

All positive results were forwarded to the CFIA's OFSR to determine if the levels of undeclared allergens found would pose a health concern to allergic individuals. There were 14 samples which resulted in product recalls, and all other positive allergen findings were determined not to pose a risk to consumers.

This survey generated additional information on the background level of undeclared allergens in processed fish and seafood 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 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.

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