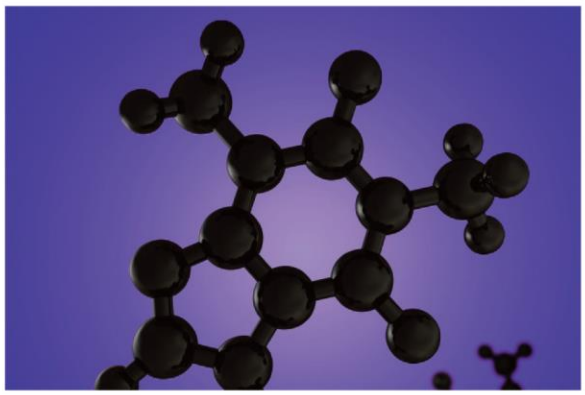
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Food Safety Action Plan

REPORT

2012-2013 Targeted Surveys

Allergens



Soy in Pre-packaged Grain-based Products

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Executive Summary

The Food Safety Action Plan (FSAP) aims to modernize and enhance Canada's food safety system. As part of the FSAP enhanced surveillance initiative, targeted surveys are used to evaluate various foods for specific hazards.

In Canada, and in other countries, as part of normal and long-standing agricultural practices, cereal grains are often grown in close proximity to other types of grains, oil seeds and pulses. In addition, these grains can be harvested, stored and transported using the same equipment and facilities. Therefore, it is extremely difficult to keep all traces of these different crops from getting mixed in with each other at low levels and may lead to the presence of soy protein in other grains such as wheat. The Canadian Food Inspection Agency and Health Canada have advised manufacturers and importers of grain-based products that precautionary labeling for soy is not required on these products when a low level of soy is present due to adventitious presence. Health risk assessments have determined that the low levels of soy due to adventitious presence would not be expected to cause an allergic reaction in the soy allergic community.

Soy may also be present in pre-packaged food products from cross contamination during manufacturing. This type of presence should be reviewed to ensure it is not an indicator of a breakdown in good manufacturing practices.

The main objectives of the soy in grain based foods survey were:

- To obtain baseline information regarding the presence and levels of undeclared soy in single and multiple ingredient grain-based foods.
- To identify potential food safety concerns relating to undeclared soy in grain based foods.

A variety of grain based foods were analysed for the presence of undeclared soy. The foods ranged from single ingredient foods such as flour and whole grains to multiple ingredient foods such as baked goods that contained whole and ground grains. The data collected provided general information around the presence and level of undeclared soy in both starting and finished products such as flours and breads, respectively. Of 368 samples tested, 124 (34%) contained undeclared soy. Wheat flour and baking mixes had the highest percentage of soy positives, 52% and 94%, respectively. Many of the baking mixes contained wheat flour as a primary ingredient.

All positive results were followed up by CFIA. Follow up action may involve a food safety investigation, including a health risk assessment conducted by Health Canada and a recall or one of the following: notification of manufacturer/importer and/or additional sampling.

1 Introduction

1.1 The Food Safety Action Plan

In 2007 the Canadian Government launched a five year initiative in response to a growing number of product recalls and concerns about food safety. This initiative, called the Food and Consumer Safety Action Plan (FCSAP), aims to modernize and strengthen Canada's safety system for food, health and consumer products. The FCSAP initiative unites multiple partners in ensuring safe food for Canadians.

The CFIA's Food Safety Action Plan (FSAP) is one element of the Government's broader FCSAP initiative. The goal of FSAP is to identify risks in the food supply, limit the possibility that these risks occur, improve import and domestic food controls and identify food importers and manufacturers. FSAP also looks to verify that the food industry is actively applying preventative measures.

Within FSAP, there are twelve main areas of activity, one of which is risk mapping and baseline surveillance. The main objective of this area is to better identify, assess and prioritize potential food safety hazards through risk mapping, information gathering and testing foods from the Canadian marketplace. Targeted surveys are one tool that is used to test for the presence and level of a particular hazard in specific foods. Targeted surveys are largely directed towards the 70% of domestic and imported foods that are covered exclusively by the *Food and Drugs Act*, and are generally referred to as non-federally registered commodities.

1.2 Targeted Surveys

Targeted surveys are used to test various foods for specific hazards and are meant to compliment the CFIA's regular programs and inspection activities. The surveys are designed to answer specific questions about hazards in food. Generally, they test for the occurrence and magnitude of defined hazards in targeted foods, often with the testing focusing on a specific segment of the population (i.e. consumers with an allergy or intolerance).

This targeted survey focused on the presence of soy in grain-based products including single grain products such as flour and multiple ingredient products, such as baked goods, which contained grains as the primary ingredient. The sampled foods did not have soy in the list of ingredients or in a precautionary statement.

The information gathered provided baseline information on the presence of undeclared soy in grains and pre-packaged grain-based products.

1.3 Acts and Regulations

The *Food and Drug Act* (FDA) is the legal authority that governs the sale of food in Canada. The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing restrictions on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act & Regulations* (FDA and FDR).

If a pre-packaged food product displays a list of ingredients without disclosing potential allergens this may be a health risk to an allergic consumer. Failure to declare allergenic components may be contrary to Subsection 5(1) of the FDA. These products may therefore be subject to regulatory measures taken by the CFIA.

Health Canada made amendments to the FDR to enhance the labelling of priority allergens, gluten sources and sulphites in pre-packaged food sold in Canada. On February 16, 2011 Health Canada published these amendments in the *Canada Gazette*, Part II. The amendments require that food allergen and gluten sources be declared on the labels of pre-packaged foods, having a list of ingredients, whenever the protein, modified protein or protein fractions of the food allergen or gluten source are added to the product. The amendments also require the labelling of added sulphites.

Due to the complexity of the labelling changes required, and the extended shelf-life of some processed foods, Health Canada provided manufacturers with 18 months from the date of registration of the regulatory amendments to implement any changes required in their labels. CFIA and Health Canada continued to encourage industry to declare priority allergens, gluten sources and added sulphites on pre-packaged food labels to provide Canadians with the information necessary to make informed food choices. Canada's new food allergen labelling regulations came into force on August 4, 2012**.** Further information on these regulations can be found on the Health Canada website.[i] The products analyzed in this survey were sampled both prior to and following these amended regulations coming into force.

The CFIA and Health Canada have posted information on the adventitious presence of soy in grain products. [ii, iii] Health risk assessments have determined that the low levels of soy detected during this survey would not be expected to cause an allergic reaction in the soy allergic community.

2 Allergens Survey

2.1 Rationale

The presence of an undeclared allergen in a food is not a concern for the majority of Canadians. However, undeclared allergens may represent a serious or life threatening health risk for allergic or sensitive individuals.

The main objective of this survey was to obtain baseline information regarding the presence and levels of undeclared soy in grains and pre-packaged grain-based products. The adventitious presence of soy in cereal grains can occur due to the manner by which soy and other grains, such as wheat, are grown, harvested, stored and transported. This adventitious presence is not unique to soy, but can occur with other cereal grains and is reflected in the current grain grading standards for quality. This type of presence cannot be completely controlled by good manufacturing practices. Soy may also be present in pre-packaged food products if soy was present in an ingredient but not properly labelled or from cross contamination (ex. products made on equipment that is shared with products that contain soy). This survey tested foods that were grain-based and did not have soy in the list of ingredients or in a precautionary statement. The information gathered provided

an indication of the levels of soy in single grain products as well as potential food safety concerns relating to undeclared soy in grains and grain-based products.

2.2 Hazard: Undeclared Soy

Soy allergy is most frequently observed in infants and typically develops around 3 months of age.[iv] There is little information on prevalence rates for soy allergy; a rate of 0.3-0.4% has been noted, with higher rates in children with eczema[v]. Soy allergy is often outgrown by 3 years of age.[vi, vii]

There is no cure for a food allergy, and the most important strategy for a person with a food allergy, or a person choosing food for an individual with a food allergy is avoidance of the allergen that can trigger an adverse reaction. Allergen sources should be appropriately labelled on products to ensure consumers have complete, accurate information when choosing food.

2.3 Sample Distribution

This survey targeted grain-based foods that contained wheat, rye, barley and/or oats. Products included single and multiple ingredient foods such as flours, breakfast cereals, baking mixes and baked goods. Examples of baking mixes included pancake and cookie mixes, examples of baked goods included muffins, breads and cookies. A total of 368 food samples were collected in 2012 and 2013 from major retail stores as well as smaller ethnic retailers. No specific brands were targeted. The distribution of samples by product type is listed in Table1. Samples that indicated 'prepared for' with a Canadian address or which only had a Canadian address were counted with the domestic products, samples that did not have any clear indication of origin on the label were noted as unknown.

Table 1: Sample distribution

	Domestic	Imported	Unknown	Total
Baked Goods	93	13		106
Baking Mixes	18	15	3	36
Cereals	10	12		22
Wheat Bran	17	5		22
Wheat Flour	79	6		85
Oat, Grain	17	5		22
Oat Flour	11	0		11
Barley, Grain	15	5		21
Barley Flour	11	3		13
Rye, Grain	7	1		8
Rye Flour	21	1		22
Total	299	66	3	368

2.4 Limitations

A total of 368 samples were purchased in 2012-2013 at various retail stores in Canada. This represents a small sample size in comparison to what is available to Canadian consumers. The samples collected in this survey do not guarantee representation of all grain-based products available nationally. The data collected from this survey is meant to

provide a snapshot of the targeted commodity and has the potential to highlight problem areas that warrant further investigation.

2.5 Methodology

The samples were tested for the presence of soy proteins using ELISA-based methodology. Samples were analyzed by an accredited third party laboratory. Third party laboratories are accredited to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories (or its equivalent by the Standards Council of Canada (SCC)).

3 Results and Discussion

A total of 124 of the 368 samples analysed contained a detectable level of soy (34%). The distribution of results by product type is shown in Figure 1 and 2. The information provided by these samples can only be viewed in a general sense as the foods were not followed from raw material through the production chain, i.e. the flour that was analysed was not used for production of the baking mixes and/or baked goods which were analysed.

There were 8 single ingredient product types sampled, of which half were whole or partially whole grains and half were flours of wheat, barley, rye and oats. In all cases the flours contained a higher percentage of samples with detectable soy in comparison to the grain sample. Neither rye nor oats had detectable soy in the grains.

Wheat flour and baking mixes had the highest percentage of positive results, 52% and 94%, respectively. The high percentage of soy positives in the wheat flour samples indicates that this grain may have had soy present from adventitious presence, for example from shared harvesting equipment. It was expected that the baking mixes could contain soy as many contained wheat flour as a primary ingredient. It is also possible that some of the baking mixes contained soy from cross contamination during manufacturing. A lower percentage (19%) of the baked goods was positive for soy.

The percentage of positives in the domestic (96/299, 32%) and imported (25/66, 37%) products was similar.

Figure 1: Distribution of Results by Product Type, Single Ingredient Products

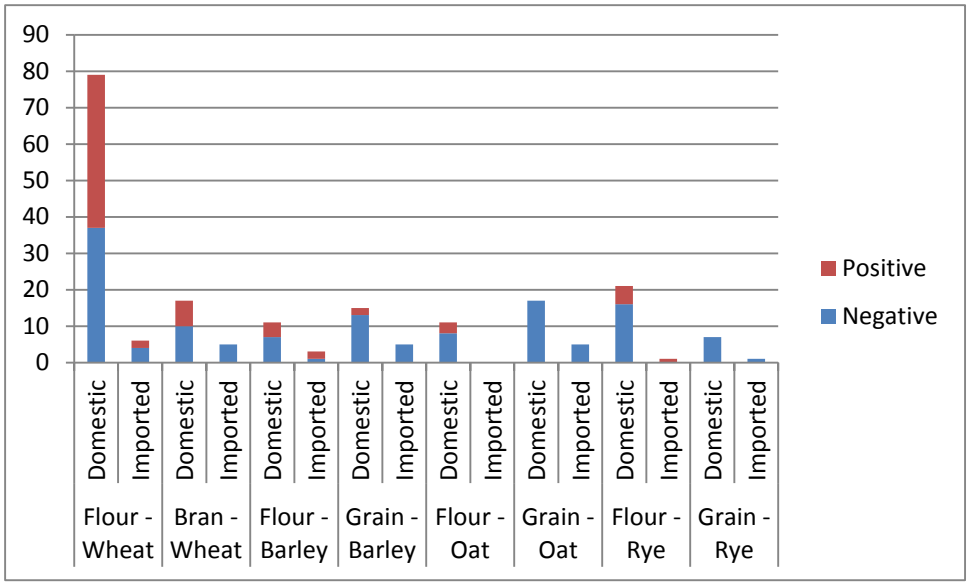


Figure 2: Distribution of Results by Product Type, Multiple Ingredient Products

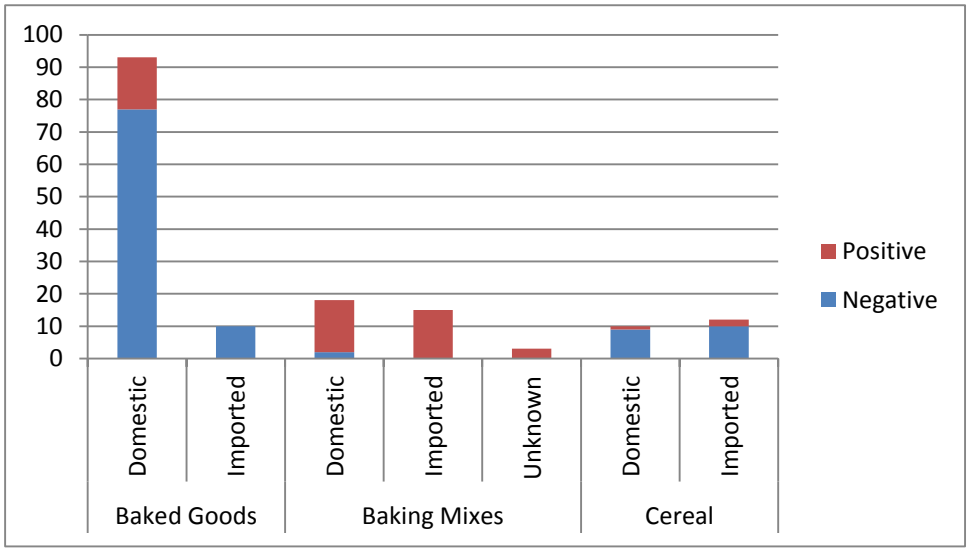
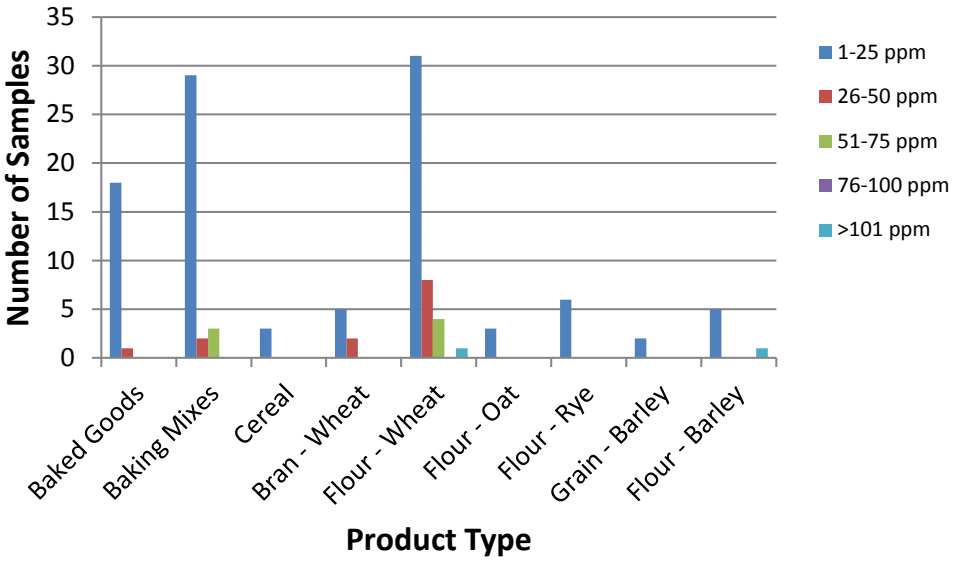


Figure 3 shows the amount of soy, in a range, by product type. The levels of soy detected generally support that the presence of soy was from either adventitious presence or from a cross contamination. The levels do not indicate that soy was intentionally added.

Figure 3: Distribution of Positive results by Product type and Amount of Soluble Soy Protein Detected



4 Conclusion

This survey met the objective of gathering information, over one year, on the occurrence of undeclared soy in single and multi-ingredient grain-based products. The information gathered indicated that soy may be present at low levels in flours, in particular wheat flour, which is a primary ingredient of baking mixes and baked goods. Based on the levels detected, it is likely that this presence is adventitious from the normal growth, harvesting, storage and processing of the grains or from cross contamination during processing or manufacturing.

Further data would be required to complete a comprehensive baseline of levels in grain-based products to determine if the low level presence is static over time and in a variety of products.

5 References

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[ii] CFIA. Adventitious Presence of Soy in Grain Products. [online]. 2013. Accessed June 25, 2013, http://www.inspection.gc.ca/food/labelling/core-requirements/ingredients/allergen-labelling/adventitious-presence-of-soy-in-grain-products/eng/1360691333452/1360691654497.

[iii] Health Canada. Co-Mingling in Agricultural Grain Products as a Possible Source of Food Allergens. 2013. Accessed June 25, 2013. http://hc-sc.gc.ca/fn-an/securit/allerg/fa-aa/co-mingling-melange-eng.php

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[v] EFSA. Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies [NDA] on a request from the Commission Relating to the Evaluation of Allergenic Foods for Labelling Purposes. 2004. EFSA 2004.32

[vi] Kabourek, J.L. Soyfoods and Allergies: Separating Fact from Fiction. Soy Connection Newsletter. Accessed June 25, 2013. http://www.soyconnection.com/newsletters/soy-connection/health-nutrition/articles/Soyfoods-And-Allergies-Separating-Fact-From-Fiction

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