



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments



Food Allergens And Sensitivities: An Overview of CFIA Experience

FSIS Public Meeting on Allergens, March 16, 2017

Jennifer Miner, Technical Specialist

Canadian Food Inspection Agency



Prevalence of Food Allergies/Sensitivities

- **Recent Estimate - An estimated 3.5 to 4% of adults, and 6 to 8% of children¹, are allergic to certain foods.**
- **Evidence that the incidence is increasing, especially in children²**
- **Food allergies, celiac disease and sulphite sensitivity affect approximately 1.75 million Canadians.³**

•1. J. Agric. Food Chem. 2013, 61, 5624–5633

•2, Summary of the ACS Symposium on Advances in Food Allergen Detection - J. Agric. Food Chem. 2013, 61, 5621–5623

•3. Government of Canada 2011. <http://www.gazette.gc.ca/rp-pr/p2/2011/2011-02-16/html/sor-dors28-eng.html>

Canadian Approach to Allergens

- **Joint Collaborative Approach – Health Canada and CFIA**
- **International Collaboration and Standard Setting e.g. Codex**
- **Labelling Regulations**
- **Method Development**
- **Compliance Promotion for Industry**
- **Consumer Education**
- **Targeted Surveys, Sampling, Inspections**
- **Recalls and Investigation**

History

- **Regulatory framework for allergens developed – 1990's**
- **Canada Published first list of allergens - 1999**
- **Enhanced labelling regulation and policy development**
 - **Establishing New Priority Food Allergens - 2010**
 - **Enhanced Labelling Regulations - 2012**
 - **Position of Gluten Free Claims - 2012**
 - **Position on Precautionary Statement – 2012**
 - **Regulations further amended – Dec 2016**
- **Monitoring and Assessment moved from presence/absence to ingested level**
- **Extensive methods development by HC/CFIA/industry**
- **Investigations and Recalls – more complex**

Food Allergens - A Different Hazard

- A food allergen hazard is more difficult to manage than microbial pathogens.
- Food allergen hazard results from improper labeling or cross contamination.
- **Primary risk management option is to ensure allergic consumers are provided accurate, clear, consistent information on food labels.**

International Collaboration

- Health Canada makes every effort to harmonize with other countries which have developed similar food labelling laws, i.e. the United States, Australia/ New Zealand, and the European Union.
- Balance between regulating the priority food allergens that form a significant health risk within their country and adapting the particularities of their own national and federal statutes.
- Priority allergens may vary from country to country based on cultural component on impact to health depends on population's diet. – **Celery in Europe not in Canada.**

Regulations – Overall Objectives

The overall objectives are to:

- **minimize risks** associated with inadvertent consumption of undeclared food allergens, gluten sources and added sulphites in food; and
- **maximize choice** of safe and nutritious foods for consumers with dietary restrictions.

Canadian Priority Allergens

Food and Drug Regulations (B.01.010.1(1))

Any protein from any of the following foods, or any modified protein, including any protein fraction, that is derived from any of the following foods:



Eggs	Peanuts	Soybeans
Milk	Mustard Seeds	Crustaceans
Sesame seeds	Wheat or triticales	Shellfish
Fish	Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts	

Regulations – Gluten

Canadian Food and Drug Regulations

B.01.010.1(1))

Definition: Any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals:

- Barley
- Oats
- Rye
- Triticale
- Wheat (all species, including kamut & spelt)



Regulations – Sulphites

Food and Drug Regulations (B.01.010.2 (1))

•Sulphites - means one or more of the following food additives;

- Potassium bisulphite
- Potassium metabisulphite
- Sodium bisulphite
- Sodium dithionite
- Sodium metabisulphite
- Sodium sulphite
- Sulphur dioxide
- Sulphurous acid



Regulations – A Labelling Example

How to **label** allergens:

Within the **ingredients** list

Ingredients: Apples, Pie crust [Flour (wheat), Shortening, Liquid albumen (egg), Salt], Sugar, Flour, Lemon juice, Whole milk, Cinnamon.
May contain pecans.

OR

Using a **contains** statement

Ingredients: Apples, Pie crust [Flour, Shortening, Liquid albumen, Salt], Sugar, Flour, Lemon juice, Whole milk, Cinnamon.
Contains: Wheat, Egg, Milk.
May contain pecans.

Added food allergens, gluten and sulphites (10 ppm or higher) must be declared either:

- in the list of ingredients, OR
- in the statement: “Contains”

While many ingredients are exempt from component declaration, all allergens and gluten or added sulphites (above 10ppm) are not exempt.

Precautionary Statements

- The use of precautionary statement is voluntary.
- To be used when the presence of allergens in the food is unavoidable, despite all reasonable precautions.
- **Cannot be used in lieu of GMP's.**
- While several precautionary statements are seen in the marketplace, Health Canada strongly recommends that companies use:
 - **“May contain [X]” where X is the name of the allergen.**
- In December 2016, the Food and Drug Regulations were amended to require that a precautionary statement, if used, must appear immediately after List of Ingredients or “Contains” Statement.
- If a precautionary statement is used, it must not be false or misleading.

“Free” Claims

- Manufacturers must ensure there is **no amount of the named food allergen** source present in the product, whether through intentional or inadvertent means.
- Any representation (statement, image or advertising) that states, suggests or implies that **a food allergen source is not present when it is present** would be considered false and misleading information under subsection 5.(1) of the Food and Drugs Act.
- Regulated parties may be asked by the CFIA to **demonstrate that production systems or process controls** are in place to substantiate that the claim does not mislead the consumer as to the safety of the food for consumers.

Gluten Free Claims

- **While there is no regulatory threshold, Health Canada considers that levels of gluten protein below 20 ppm generally do not represent health risks to consumers with celiac disease.**
- **Specially produced products with less than 20ppm can be labelled as gluten-free.**
- **In 2015, Health Canada registered a Marketing Authorization (MA) permitting use of gluten-free claims for gluten free oats and foods that contain them as ingredients.**

Industry Responsibilities

All federally inspected meat and poultry establishments must have an allergen control program.

Must have documented procedures and/or policies for:

- proper control of new or modified product formulations
- purchasing of ingredients to ensure proper control and identification of allergens for incoming ingredients
- proper control of new or modified labels
- receiving of ingredients and externally printed labels
- weighing/blending/mixing/formulation to ensure that the correct ingredient is added to the correct product as indicated in the formula
- the use of rework
- labelling of finished product
- disposal of obsolete materials e.g. labels
- control of cross-contamination of undeclared allergens in the food products.

Food Allergens – Testing

Most commonly used in Canada are ELISA methods that use antibodies to detect protein(s) from a food allergen.

Canada uses commercial available test kits for many different food allergens including:

- Neogen
- Elisa Systems
- R-Biopharm
- Romer Labs

Detection limits are usually in 1-5 ppm of protein range.

Common concern with private testing is use of insufficient/high detection and/or quantification limits.

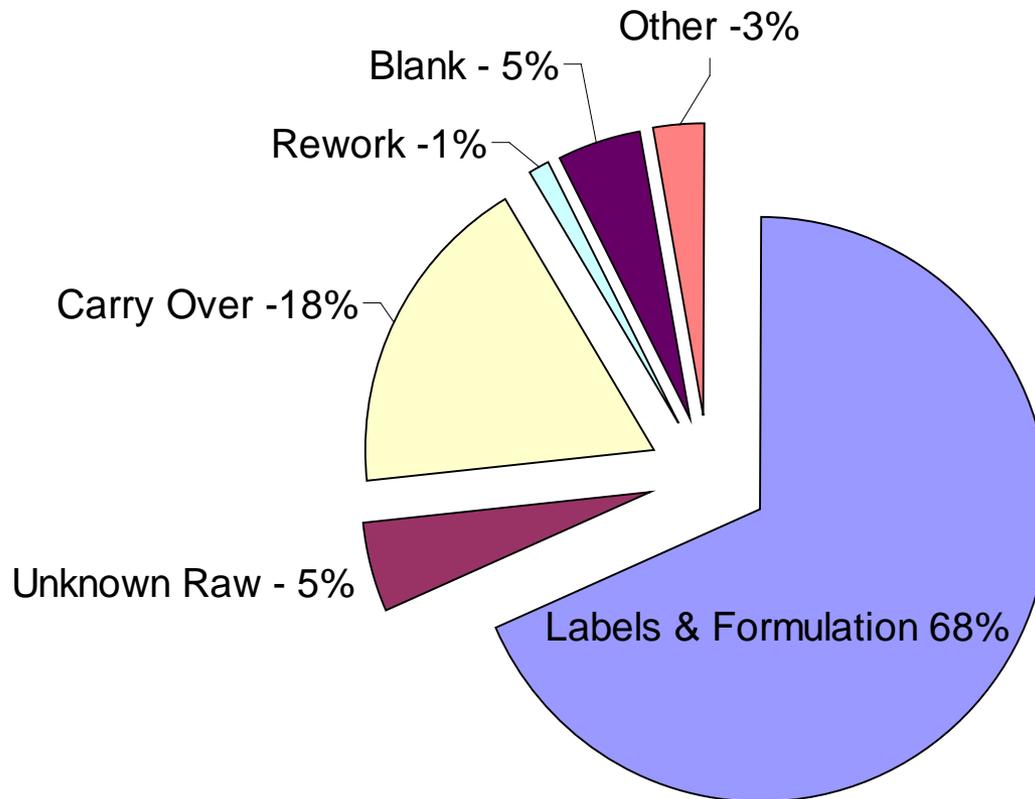
CFIA Surveillance Testing

- ~ 3150 samples collected / year under various sampling plans (single sulphite and multiple allergens)
- More than 40 % of all food recalls conducted by CFIA are allergen related and require supportive laboratory analysis
- Overall purpose is to **detect and correct** specific as well as sector wide issues

Food Safety Investigation and Recalls

- **Issues related to priority allergen/gluten/sulphites are considered high priority issues**
- **If a reaction is reported, undeclared presence of a non-priority allergen is also investigated and could lead to a recall**
- **Proper testing with quantification is conducted**
- **Investigation and assessment always focus on -**
 - Level of ingested substance**
 - Cause of presence – formula vs cross-contamination**
 - Distribution and mitigations (visual or indirect)**

**Allergen/Gluten/Sulphites –
Causes of Recalls (2001-2006)***



Information for Industry and Consumers

Industry

- Checklists
- Model allergen programs (for non-registered plants)
- Infographics
- Guidance documents and toolkits

Consumers

- Fact sheets
- Interactive labels
- Reference materials
- Recall alerts

In Closing

Undeclared food allergens, gluten and sulphites represent a health risk and are priority food safety issues in Canada.

The overall objective is to minimize risks while maximizing choice.

In Canada, the health risk from food allergens and sensitivities is managed by:

- **Research**
- **Testing and Surveillance**
- **Enhanced Regulations**
- **Labelling Compliance Promotion**
- **Industry Guidance**
- **Inspections**
- **Food Safety Investigation and Recalls**

Canada