



Health
Canada

Santé
Canada

*Your health and
safety... our priority.*

*Votre santé et votre
sécurité... notre priorité.*

Labelling Regulations for Food Allergens in Canada



Prepared by:

*Michael Abbott
FAFIAS*

*Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch*

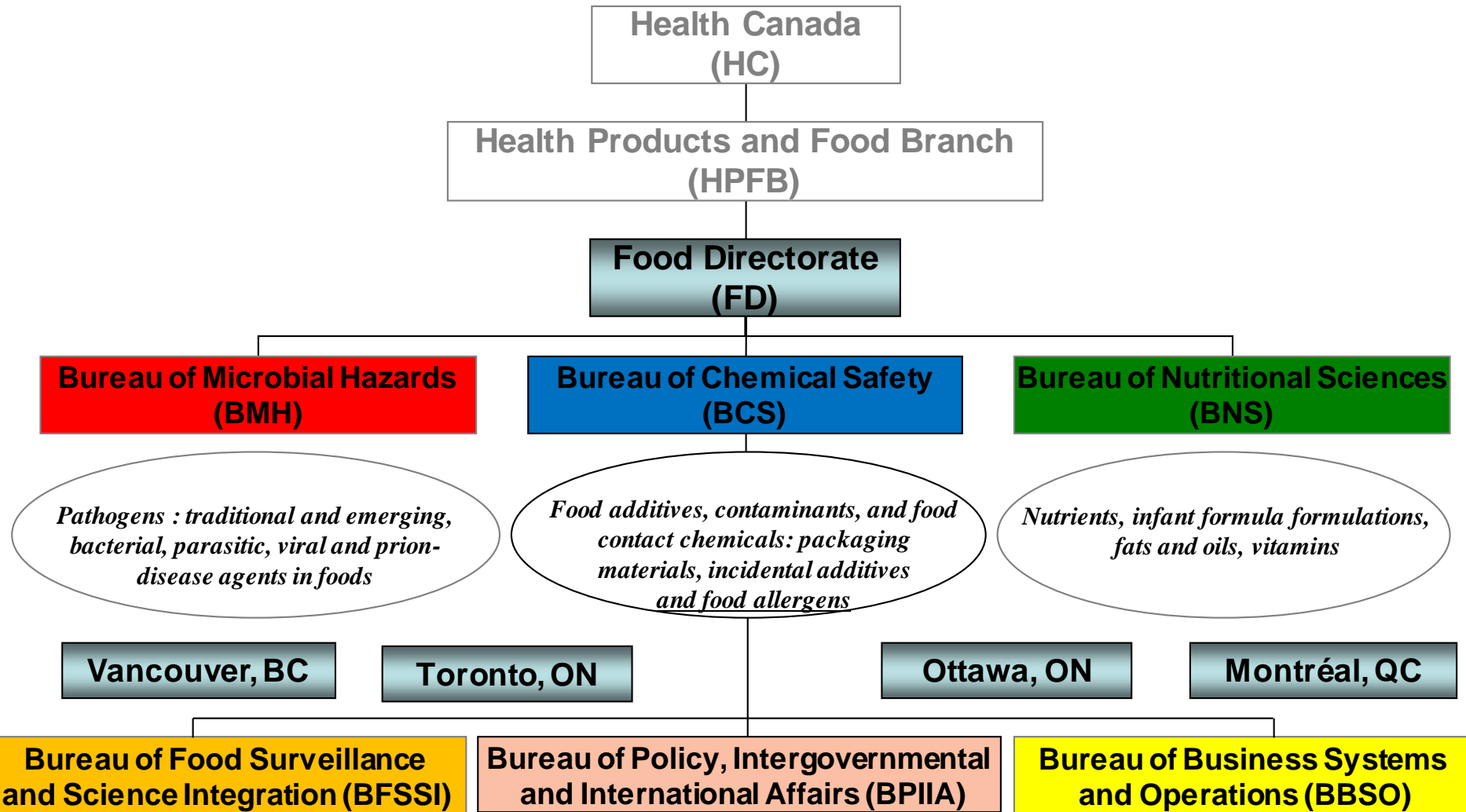
Canada

Overview

- ❑ Organisational structure/roles and responsibilities
- ❑ Background on Food Allergies
- ❑ Policy objectives for food allergen labelling
- ❑ Regulations for enhanced allergen labelling
- ❑ Allergen-free claims
- ❑ Precautionary labelling



Health Canada's Food Directorate



Roles and Responsibilities for Food Allergens

Health Canada

- Development and administration of health and safety policies and standards

Human Health Risk Assessment

Method Development and Evaluation

Establishing regulations, policies and guidelines

Canadian Food Inspection Agency

- Responsible for all federal food inspection service

Investigation / Testing

Risk Management/
Risk Mitigation

Enforcing established
regulations and guidelines



Food Regulatory Framework in Canada

- ❑ Canadian *Food and Drugs Act*
 - General , overarching provisions

- ❑ Canadian *Food and Drug Regulations*
 - Part B is specific to foods
 - It is organized into sections mainly by different types of foods or ingredients



Canadian Food and Drugs Act, Section 5.1

“No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive, or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.”



A High Priority Public Health Issue

- ❑ Canadian data shows that approximately 7% or 2.5 million Canadians self report at least one food allergy (with convincing history)
- ❑ Celiac disease affects approximately 1% of the Canadian population.
- ❑ Significant societal impacts.



AVOIDANCE

The Key to Preventing Potentially Serious Health Consequences

- ❑ Consumers depend on the information provided on the label to avoid any food allergens, gluten sources and added sulphites in prepackaged foods.



Policy Objectives

- ❑ **Enhanced protection to avoid inadvertent consumption of foods containing the « culprit ingredient »:**
 - Minimize risks of inadvertent consumption of undeclared ingredients in food which can trigger adverse reactions.
- ❑ **Avoid undue restrictions on choice from among safe and nutritious foods:**
 - Maximize choices for consumers with food allergies, intolerances or sensitivities.



Canada Food and Drug Regulations

- ❑ Require that a complete and accurate list of ingredients appears on the label of most pre-packaged foods
- ❑ However, there are exemptions in the regulations. Ingredients exempt from component declaration include:
 - seasonings, spices, flavouring
 - flour, margarine, butter, sweetening agents
- ❑ Although most components do not pose a health risk, food allergens, if not declared in the list of ingredients, can pose a risk to allergic consumers.
 - One of the reasons enhanced labelling regulations were needed
- ❑ Some common ingredient names don't clearly identify their allergen source (ovalbumin, betalactoglobulin)



Primary Objectives

- ❑ To require the mandatory “source” declaration of the priority food allergens and gluten using simple, plain language in English and French
 - Including allergens and gluten present in components of ingredients that would otherwise be exempt from component declaration.
- ❑ To enhance the declaration requirements for sulphites when present in the prepackaged food in a total amount of 10 ppm or more.
- ❑ Scope: Applicable for all ingredients intentionally added to prepackaged foods.



Canada's Allergen Labelling Regulations

“Food Allergen” Defined

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

- Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts
- Peanuts
- Sesame seeds
- Wheat, triticale
- Eggs
- Milk
- Soybeans
- Crustacea (common name)
- Fish (common name)
- Shellfish (common name)
- Mustard seeds



Canada's Allergen Labelling Regulations

Label Declaration

- ❑ Sources of priority food allergens must be declared either:
 - in the list of ingredients, OR
 - in the statement: “Contains”

- ❑ In addition to standard requirements for ingredient declaration



Canada's Allergen Labelling Regulations

- ❑ For products which do not require a list of ingredients but on which manufacturers have chosen to place an ingredient list, the list must be complete and accurate for all ingredients, including food allergens, gluten sources and added sulphites



Canada's Allergen Labelling Regulations

- ❑ When the statement “**Contains** ” is present on a label, this statement must be complete and identify all priority food allergens, gluten sources and added sulphites at 10 ppm and above in the prepackaged product



Example of label information – Cake Mix

Prior to allergen labelling regulations

Ingredients : Sugar, Flour, Ovalbumin, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

Since allergen labelling regulations

Ingredients : Sugar, Flour (Wheat), Ovalbumin (Egg), Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

OR

Ingredients : Sugar, Flour, Ovalbumin, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

Contains : Egg, Wheat



Ovalbumin is a protein found in egg whites



Example of Label Information – Potato Chips

Prior to allergen labelling regulations

Ingredients : Potatoes, sunflower oil, salt, seasonings

Since allergen labelling regulations

Ingredients : Potatoes, sunflower oil, salt, seasonings (mustard)

OR

Ingredients : Potatoes, sunflower oil, salt, seasonings

Contains : mustard

Seasonings are a multi-component ingredient which are exempt from component declaration



Example of Label Information – Wine

Prior to allergen labelling regulations :
No ingredients or Contains statement was required for food allergens, gluten sources or sulphites in wine (standardized alcoholic beverages are exempt from list of ingredients)

Since allergen labelling regulations (if added sulphites present at 10ppm or higher)*

Contains : sulphites

*applies to non-vintage wines and vintage wines with a year date of 2012 and later. Older vintage wines continue to be sold with original labels.



Beer Labelling

- ❑ Standardized beer, ale, porter, stout, and malt liquor are exempt from carrying a list of ingredients
 - By regulation, these must be made with barley or wheat
- ❑ Unstandardized beers have to provide a list of ingredients
- ❑ Beer had been exempted from the enhanced labelling regulations for food allergens and gluten sources, however this was recently revisited.
- ❑ Changes in the beer standard have been made to be more flexible and allow the introduction of new ingredients. Since some of these could be allergens, beer will now have to comply with the enhanced labelling regulations just like any other prepackaged food.



Compliance / Uptake of New Regulations

- ❑ Almost nine years since the regulatory amendments came into force
- ❑ In general, manufacturers are doing a good job with compliance
- ❑ Initially some violations where mustard was not being declared
 - Expected because it was a new addition to the list of priority allergens
- ❑ CFIA continues inspection/ monitoring/ surveillance activities to ensure compliance



- ❑ Allergen-Free Claims
- ❑ Precautionary Allergen Labelling (PAL)



Allergen-Free Claims

- ❑ No specific regulations in Canada for claims such as “peanut-free” or “milk-free” etc.
- ❑ However, any such claims must be truthful and accurate, based on Section 5.1 of the *Food and Drugs Act*
- ❑ Manufacturers must ensure these statements are true and have processes in place to ensure accuracy, control of incoming ingredients, production, cross contamination, etc.
- ❑ Products with allergen-free claims that turn out to be false would be dealt with according to the risk posed to the consumer, but this risk is increased by the presence of the free-from claim.



Precautionary Labelling: Definition

Allergen precautionary labelling

- ❑ Labelling that warns about priority allergens that may be in products, even though they are not in the list of ingredients

Food allergen precautionary labelling statement

- ❑ A declaration on the label of a prepackaged food that identifies the priority food allergens that are not among the listed ingredients, but may have been inadvertently to a product during the manufacturing process.

Examples: “may contain...”; “may contain traces of...”; “not suitable for consumption by persons with an allergy to...”

“made in a facility that also processes...”, “made on equipment that also processes...”



Precautionary Labelling: Why and when?

In Canada, allergen precautionary labelling was identified as a judicious risk management measure...

- ❑ To address instances of « unavoidable » cross-contamination with priority food allergens during food processing
- ❑ To alert allergic consumers of the « unsuitability of the product » for their condition and of **a possible risk**
- ❑ Precautionary statement differs from a « contains » statement, however risk may be identical
 - ❑ No specific limit on amount that can be present



Consumer Perception

Allergen precautionary labelling...

- ❑ Was welcomed by allergic consumers when initially introduced
- ❑ Since then, has become devalued partly because of consumer perception of over-use and inconsistent application by the food industry



Consumer Perception

Reasons that some allergic consumers and/or their caregivers ignore precautionary labels include:

- ❑ Proliferation of allergen precautionary labelling statements
- ❑ No reactions to products that had not been previously labelled with allergen precautionary labelling statement
- ❑ Presumption that allergen precautionary labelling is for legal rather than health concerns



Examples



Examples

What does it mean ?

Risk? No risk ?

INGREDIENTS: Seasoned Beef (beef, water, salt, sodium phosphate, dextrose, spice), BBQ Sauce (water, tomato paste, sugar, dextrose, vinegar, maltodextrin, salt, autolyzed yeast extract, spices, citric acid, colour, sodium benzoate, potassium sorbate, flavour, corn syrup solids, silicon dioxide, sulphites (less than 3 ppm)).

INGRÉDIENTS : Boeuf assaisonné (boeuf, eau, sel, phosphate de sodium, dextrose, épice), sauce au BBQ (eau, pâte de tomates, sucre, dextrose, vinaigre, maltodextrine, sel, extrait de levure autolysée, épices, acide citrique, couleur, benzoate de sodium, sorbate de potassium, saveur, matières sèches du sirop de maïs, dioxyde de silicium, sulfites (moins de 3 ppm)).

ALLERGENS: Manufactured in a facility with the following allergens present: wheat, soya milk, sulfites.

ALLERGENES : Fabrique dans une usine où les allergènes suivants sont présents : blé, soya lait, sulfites.



Examples

Rotisserie Chicken™ Poulet rôti B.B.Q.

Reheating Instructions: Microwave: Remove lid. Leave chicken in
Heat on HIGH for 5 to 7 minutes, rotating dish 1/4 turn occasion
Oven: Preheat oven to 350°F (190°C). Remove chicken from pack;
Heat 15 to 20 minutes.

Mode de cuisson: Au micro-ondes: Enlever le couvercle. Laisser
maximale (MAX.) de 5 à 7 minutes, en tournant occasionnelleme
Au four conventionnel: préchauffer le four à 350°F (190°C). Retirer
profond allant au four avec 1/4" d'eau. Cuire à découvert de 15 à

Ingredients/Ingrédients: Chicken, salt/poulet et sel.

Net weight after cooking/Poids net après cuisson: 1.1 kg

THIS PRODUCT MAY HAVE COME INTO CONTACT WITH EGGS,
NUTS, SESAME SEEDS, SULPHITES, SEAFOOD.

Ingredient list much shorter than allergen precautionary statement



Precautionary Allergen Labelling (PAL)

- ❑ There is consensus among the various stakeholders that further guidance is needed regarding the use of allergen precautionary labelling, and some additional policy work is required
- ❑ Precautionary labelling should only be used when, despite all reasonable measures, the inadvertent presence of allergens in food is unavoidable.
- ❑ It must not be used when an allergen or allergen-containing ingredient is deliberately added to a food.



Precautionary Allergen Labelling (PAL)

- ❑ The use of a precautionary statement where there is no real risk of an allergen being present in the food is contrary to the Department's goal of enabling a variety of safe and nutritious food choices for the allergic consumer.
- ❑ To address the potential risks associated with misuse or misinterpretation of food allergen statements, Health Canada has recommended a single food allergen precautionary statement.

"may contain [X]"

where X is the name by which the allergen is commonly known.



Next Steps

- ❑ There is a lot of interest in the area of PAL
- ❑ CODEX committee on food labelling has agreed to work on this area, including looking at the area of thresholds for food allergens
 - Canada is involved in this work

- ❑ We will continue to work with food allergy associations and other stakeholders to try to improve guidance and consistency in the use of PAL



Web Links

Information page on food allergen labelling

<http://hc-sc.gc.ca/fn-an/label-etiquet/allergen/index-eng.php>

Information on Precautionary Labelling

http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette-eng.php



Thank you!

Merci!

