Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Labelling Of Food Allergens and Gluten in Canada

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A High Priority Public Health Issue

- Food allergies affect an estimated 5-6% of Canadian children and 3-4% of adults.
- Canadian data shows that approximately 7% or 2.5 million Canadians self report at least one food allergy
- Celiac disease affects approximately 1% of the Canadian population.
- Significant societal impacts.

Policy Objectives

- **Enhanced protection to avoid inadvertant consumption of foods containing the « culprit ingredient »:**
  - Minimize risks associated with inadvertent consumption of undeclared allergens in food;
- **Avoid undue restrictions on choice for a safe and nutritious food supply:**
  - Maximize Choices for food allergic consumers

Roles and Responsibilities for Allergens

Health Canada

- Development and administration of health and safety policies and standards
  - -conducts risk assessments
  - -establishes regulations and guidelines

Risk Assessment

Method Development and Evaluation

Canadian Food Inspection Agency

- Responsible for all federal food inspection service
  - -risk management strategies
  - -enforces established regulations and guidelines

Investigation/ Testing

Risk Management/ Risk Mitigation

Food Allergies and Celiac Disease

AVOIDANCE

The Key to Preventing Potentially Serious Health Consequences

- Consumers depend on the information provided on the label to avoid the food allergen, gluten sources and added sulphites in a prepackaged food.

Previous Labelling Regulations

Previous Requirements

- The *Food and Drug Regulations* require that a complete and accurate list of ingredients appear on the label of most prepackaged foods
- In most cases, the list of ingredients must include the components of ingredients

  (i.e. ingredients of ingredients).

Gaps

- Certain ingredients are exempt from component declaration.
- Some prepackaged foods do not require a list of ingredients
- Ingredient names do not always reflect the “source” of the ingredient

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 are currently exempt from component declaration.
- To enhance the declaration of 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.

Regulatory Amendments

"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

Regulatory Amendments

“Gluten” Defined

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 :

- Wheat
- Oats
- Barley
- Rye
- Triticale

Label Declaration

- Sources of common food allergens and gluten must be declared either:
  - **in the list of ingredients,** OR
  - **in the statement: "Contains"**
- Added sulphites when present at levels of 10 ppm or higher must be declared either:
  - **in the list of ingredients,** OR
  - **in the statement: "Contains"**
- All current requirements for ingredient continue

Regulatory Amendments

- For products which do not require a list of ingredients but which choose to add an ingredient list, the list must be complete and accurate for food allergens, gluten sources and sulphites

Regulatory Amendments

Common names of starches, modified starches, hydrolyzed protein and lecithin are now as follows :

- The name of the source of protein be identified in the common name of all **hydrolyzed proteins**
- The name of the plant source be identified in the common name of all forms of **starch or modified starch**
- The name of the source of lecithin be identified in the common name of **lecithin.**

Sulphites

- **All previous requirements for declaration maintained:**
  - sulphites will continue to be declared in the ingredient list when intentionally added as a food additive ingredient at any level in finished product
  - for ingredients that are not exempted from component declaration, if sulphites are a component of one of these ingredients, they will have to be declared at any level in finished product

Regulatory Amendments

(sulphites…)

- **In addition to these requirements for declaration in the list of ingredients**
  - When added sulphites are present at levels of 10 parts per million or more in the finished product as a component of an exempted ingredient they must be identified either in the list of ingredients or using the statement **“Contains sulphites”**
  - When added sulphites are present at levels lower than 10 parts per million in an ingredient that is exempt from component declaration they are not required to be declared.

Regulatory Amendments

- 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 changes – Cake Mix

Prior to allergen labelling regulations

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

After 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

Ex. of Label Change – Potato Chips

Prior to allergen labelling regulations

Ingredients : Potatoes, sunflower oil, salt, seasonings

After 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 Change – Wine

Prior to allergen labelling regulations :
No ingredients or Contains statement required for food allergens, gluten sources or sulphites in wine

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

Contains : sulphites

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

Beer Labelling

- Standardized beer, ale, porter, stout, porter and malt liquor are exempt from providing a list of ingredients
  - By regulation these must be made with barley or wheat
- Standardized beer is specifically exempted from the new regulations and will not have to list ingredients or provide a contains statement
- Unstandardized beers already have to provide a list of ingredients and will continue to do so
- If a standardized beer chooses to provide a list of ingredients it must be accurate and identify all food allergen and gluten sources and added sulphites

Compliance / Uptake of New Regs

- Over a year since the new regulatory amendments came into force
- In general manufacturers are doing a good job with compliance
- Number of violations where mustard was not being declared
  - Expected because it was a new addition
- CFIA continues inspection/ monitoring/ surveillance activities to ensure compliance

Other Related Labelling Files

- Gluten-Free Regulations
- Precautionary Labelling
- Adventitious Presence

Gluten Free Regulatory Amendments

Update to Section B.24.018 of FDR

- Updated terminology for gluten will now describe gluten as ‘any gluten protein, including any gluten protein fraction, referred to in Canada’s definition of gluten’, which can be found in subsection B.01.010.1(1) of the FDR
- Better reflects the current internationally adopted scientific description of ‘gluten’ (ie: CODEX)
- Will allow companies that manufacture products that do not contain gluten protein to have the option of labelling them as gluten-free in Canada, even if sourced from gluten containing grains
- A benefit to celiac patients, since it could lead to further expand the availability of healthy food choices for this group

Guidance Document on Gluten-Free Regulation

- Health Canada has developed a guidance document related to the gluten-free regulations which outlines:
  - The purpose of regulation B.24.018
  - Health Canada's position on the 20 ppm level as a cut-off level for gluten-free foods
  - The guidance is published on the Health Canada website and supports CFIA inspection/enforcement activities

Guidance Document on Gluten-Free Regulation

Based on the available scientific evidence, Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of B.24.018 when a gluten-free claim is made.

Guidance Document on Gluten-Free Regulation

- This is a non-regulatory option that supports the use of 20ppm of gluten as the threshold level for foods labelled gluten-free.

- This level is recognized internationally in the Codex Alimentarius Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Stan 118-1979).

http://www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/gluten-position-eng.php

Oats and Gluten-Free in Canada

- Oats are included in the list of gluten sources in Canada, under B.01.010.1 (B.24.018 references this list)
- Currently products made with pure oats cannot make a gluten-free claim in Canada
- In 2007 Health Canada published a position paper on the safety of oats for consumers with Celiac disease
  - Concluded that most but not all consumers with Celiac disease can tolerate limited quantities of pure oats that are uncontaminated with wheat, rye and barley
- Canada is currently exploring options that could allow the use of gluten free claims on foods made with pure oats

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 added to a product during the manufacturing process.

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

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

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

Gourmet Granola Cereal - Céréales Granola Gourmet
100% NATURAL & NUTRITIOUS
100% NATURELLE & NOURISSANTE
60g
Rolled oats, honey, wheat bran, cranberries & blueberries, soya flour, almonds, oat bran,
sunflower oil, coconut, flax. Ing: Flocons d'avoine, miel, son de blé, canneberges & bleuets, farine
de soya, amandes, son d'avoine, huile de tournesol, noix de coco, lin.
05JN14
chol, 10g sugar, 9g protein
May contain traces of nuts/peanuts - Peut contenir des traces de noix/arachides.
Grandma Emily's Granola, Mtl, Qc, Ca 877-943-3861 grandmaemily.com

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.

ALLERGÈNES : Fabriqué 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 i
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 packa
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). Reti
profond allant au four avec 1/4" d'eau. Cuire à découvert de 15 à

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

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

Ingredient list much shorter than allergen precautionary statement

Precautionary Labelling

- Public Consultations were held in Late 2009/early 2010
- Summary report was published on the HC website
- 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 Labelling

- 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 mis-use or misinterpretation of food allergen statements, Health Canada is recommending a single food allergen precautionary statement.

  "may contain [X]"

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

Adventitious Presence

- Canadian grain standards allow some presence of other grains due to the way they are grown, harvested transported and/or processed
- In some cases these other grains could be allergens or gluten sources
  - Ex. Soy, wheat, rye, barley, mustard
- Recently some food products have been investigated for adventitious presence of allergens in other grains
- HC is investigating whether there is a need for more precautionary labelling of grain products and working with the food industry to develop guidance

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

Information on Gluten-Free claims

http://www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/gluten-position-eng.php

Thank you!

Merci!