



Health
Canada

Santé
Canada

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

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

Labelling for Food Allergen and Gluten Sources and Added Sulphites

**Food Allergen Labelling / Domestic Canada Brand Sessions
February 16-17, 2012**



Canada 

Outline

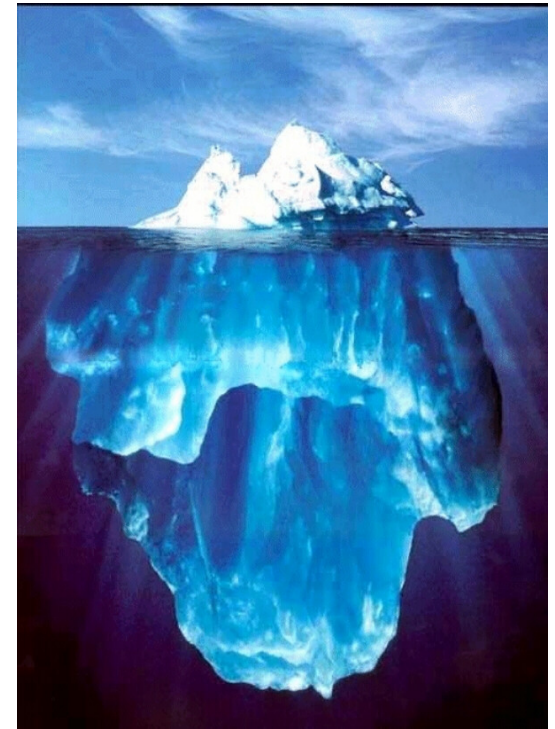
- ❑ The Public Health Issue
- ❑ Labelling of Prepackaged Foods
- ❑ Enhanced Labelling Regulations
- ❑ Food Allergen Precautionary Labelling
- ❑ Gluten-Free Labelling



Food Allergies and Celiac Disease

A High Priority Public Health Issue ? - Prevalence

- ❑ Food allergies and celiac disease affect over 1.6 Million Canadians.
- ❑ Food allergies affect an estimated 5 - 6% of Canadian children and 3 - 4% of adults.
- ❑ Asthma is linked to sulphite sensitivity: about 200,000 asthmatics have a sulphite sensitivity.
- ❑ Celiac disease affects about 340,000 Canadians (1% of the population) and is under-diagnosed.



Public Health Issue: Impact of Food Allergies

- ❑ The health impacts are serious : hospitalization, anaphylaxis and **death**
 - 150 - 200 deaths/year due to food anaphylaxis in North America; estimated 2.6 deaths/year in Ontario)
- ❑ About 12% allergic reactions to foods need treatment in emergency rooms.
- ❑ Celiac disease is associated with multiple complications including osteoporosis and cancer.
- ❑ These conditions impact individuals, families and social circles.

Food allergies and celiac disease are life long and incurable conditions – Avoidance is the only line of defense.



Why were changes to labelling regulations needed ?

- ❑ Labels are the only way for consumers to know the composition of prepackaged foods
- ❑ **1/3 of those who experienced a food allergy incident attributed it to a problem with the label**
- ❑ Allergic consumers and their caregivers need:
 - Reliable/accurate labelling (no doubt should be left for allergens)
 - Clear and consistent labelling (no shopping dictionary should be needed)

While ingredient labelling is mandatory for most prepackaged foods, there are instances where allergenic ingredients are not readily disclosed and remain « hidden » for consumers



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



Gaps in Labelling Regulations

- ❑ Certain ingredients are exempt from component declaration.
 - ❑ E.g. Groups of Ingredients listed in the table following B.01.009, FDR
 - ❑ Examples: butter, margarine, flavours, seasonings

- ❑ Some prepackaged foods do not require a list of ingredients.
 - ❑ E.g. Foods listed in B.01.008 (2), FDR
 - ❑ Examples: wine, vinegars

- ❑ Ingredient names do not always reflect the “source” of the ingredient.
 - ❑ E.g. starch, sodium caseinate, spelt, lecithin



Scope

- ❑ Applicable for all ingredients intentionally added to pre-packaged foods.

- ❑ Does not address:
 - Food ingredients resulting from cross contamination;
 - Precautionary labelling (e.g. “may contain”); or,
 - Allergen-free claims



Primary Objectives

- ❑ To require the mandatory “source” declaration of the common 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.
- ❑ Applicable for all ingredients intentionally added to prepackaged foods.



Publication of Schedule 1220

Canada Gazette Part II, Vol. 145, No. 4 - February 16, 2011
Date of Registration - February 4, 2011
Regulations Amending the Food Regulations
Schedule 1220
Enhanced Labelling for Food Allergen
and Gluten Sources and Added Sulphites

- ❑ PDF: <http://canadagazette.gc.ca/rp-pr/p2/2011/2011-02-16/pdf/g2-14504.pdf> (page 248)



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 (name of the species)
- Fish (name of the species)
- Shellfish (name of the species)
- 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



Regulatory Amendments

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 declaration remain valid.



Regulatory Amendments

- ❑ When the statement “**Contains** ” is present on a label this statement must be complete and identify all common 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, **Wheat** starch, **Ovalbumin**, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate

After allergen labelling regulations

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

OR

Ingredients : Sugar, Flour, **Wheat** starch, Ovalbumin, Monocalcium phosphate monohydrate, Sodium bicarbonate, Potassium bitartrate
Contains : Egg, Wheat



Ovalbumin is a protein found in egg whites.



Example 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 (milk)**

OR

Ingredients : Potatoes, sunflower oil, salt, seasonings

Contains : milk



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



Example of Label Change – Salad Dressing

Prior to allergen labelling regulations:

Ingredients: Olive oil, water, vinegar, lemon juice, salt, spices

After allergen labelling regulations:

Ingredients: Olive oil, water, vinegar, lemon juice, salt, spices (mustard)

OR

Ingredients: Olive oil, water, vinegar, lemon juice, salt, spices
Contains : mustard



Spices are a multi-component ingredient which are exempt from component declaration.





Ingredients: flour, water, vegetable oil margarine, sugar, yeast, canola oil shortening, potato starch, garlic, salt, parsley, seasoning, diacetyl acid, esters of mono & diglycerides, whey powder, calcium propionate.

Undeclared Food Allergen and Gluten Sources and Added Sulphites:

Flour (**wheat, barley**)

Vegetable Oil Margarine (**milk and soy**)

Potato Starch (**sulphites, ≥ 10 ppm**)

Seasoning (**sesame**)

Whey Powder (**milk**)





Milk is already identified here

ur (**wheat, barley**), water, vegetable oil margarine (**milk, soy**), sugar, yeast, canola oil shortening, potato starch, garlic, salt, parsley, seasoning (**sesame**), diacetyl acid, esters of mono & diglycerides, whey powder, calcium propionate, **sulphites**.

So, no requirement to declare milk again here

Sulphites can be declared at the end of the list of ingredients, in any order





Ingredients: flour, water, vegetable oil margarine, sugar, yeast, canola oil shortening, potato starch, garlic, salt, parsley, seasoning, diacetyl acid, esters of mono & diglycerides, whey powder, calcium propionate.

Contains wheat, barley, soy, milk, sesame, sulphites



Regulatory Amendments

Voluntary Ingredient Lists

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



Regulatory Amendments

Common Name of Starches, Modified Starches, Hydrolyzed Protein and Lecithin

- ❑ The name of the source of protein be identified in the common name of all **hydrolyzed plant 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**.



Regulatory Amendments

Alcoholic Beverages and Vinegars

- Under the regulatory amendments:
 - Alcoholic beverages and vinegars will not be required to provide a list of ingredients, however they would require a “Contains” statement to identify any food allergens, gluten sources or added sulphites at levels of 10 ppm or above present in the product.



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



Mandatory Declaration of 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 the 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 the 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.



Other considerations

□ Additional Guidance

- Additional guidance will be provided to address situations such as foods or ingredients derived from priority allergens or gluten sources which may not pose a risk to consumers with food allergies or celiac disease.
- This guidance will be developed based on the best available scientific information and take into account whether food allergens or gluten are present at levels of public health concern based on a health risk assessment.



Coming into Force

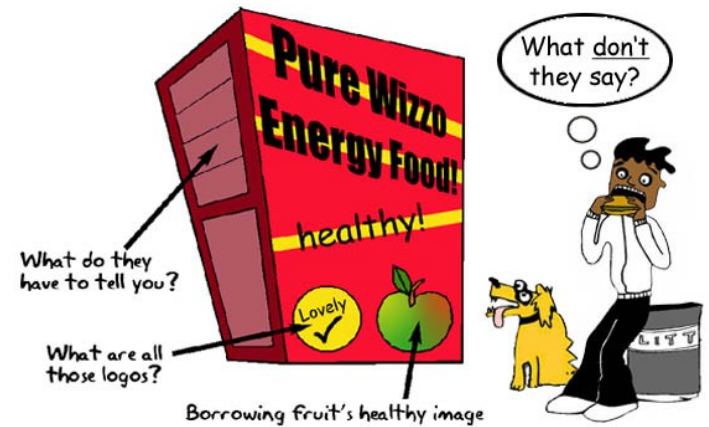
❑ New regulatory amendments come into force on:

August 04, 2012

❑ 18 months after date of registration.



Food Allergen Precautionary Labelling



Update on Food Allergen Precautionary Labelling

- ❑ Public consultations:
 - Face to face meetings in 7 cities across Canada in late 2009.
 - Online consultation in February 2010.

- ❑ Report on consultations published August 2011.

- ❑ Health Canada acknowledges that additional policy work is required.

- ❑ Likely that Health Canada will be recommending a single statement
“May contain:”



□ Objectives

- Reinstating the use of allergen precautionary labelling as a meaningful and effective risk management tool in order to:
 - **minimize risks** associated with inadvertent consumption of undeclared priority allergens in food; and,
 - **maximize available choice** of safe and nutritious foods for consumers with food allergies and celiac disease.



Precautionary Labelling: Truthful /Helpful ?

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



Precautionary Labelling: Truthful /Helpful ?

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 Labelling: What's in the Product?

- ❑ Health Canada survey on chocolate and granola bars (2007):
 - The most common precautionary statement found was « *May contain traces of...* »
 - Levels of food allergens found varied very widely, from non-detected to 6500 ppm (or 0.65%) in a chocolate product which consistently used « may contain **traces** »:
 - The word « traces » can be misleading.
 - Corroborate the fact that allergic consumers **must avoid** products with precautionary statements.



2007 Health Canada Communication

In 2007, Health Canada posted information on its website indicating that:

“Health Canada continues to consider the use of allergen precautionary labelling to be a useful tool for reducing adverse reactions to priority food allergens **when used appropriately.**”



2007 Health Canada Communication

- ❑ Recommended conditions of use of allergen precautionary labelling:
 - Precautionary labelling should be used only when the presence of allergens in food is inadvertent and unavoidable, despite all reasonable measures.
 - Precautionary labelling must not be used when an allergen is deliberately added to a food. When deliberately added, the ingredient should appear on the list of ingredients.
 - Precautionary labelling should not be used where there is no actual risk of an allergen being present.



Recommended Precautionary Statements

- ❑ In addition, Health Canada recommended that manufacturers and importers use one of the following two precautionary statements on food labels:
 - "may contain [allergen X]" (*now the preferred choice*)
 - or**
 - "not suitable for consumption by persons with an allergy to [allergen X]"



Allergen-Free & Gluten-Free Labelling



Allergen-Free or Free-From Claims

- Currently there are no specific regulations governing allergen-free claims, though any claim must be in compliance with section 5.1 of the Food and Drugs Act:

« 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, quality, composition, merit or safety. »



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:
 - B.24.018. “It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains any gluten protein or modified gluten protein, including any gluten protein fraction, referred to in the definition “gluten” in subsection B.01.010.1(1).”
- ❑ 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.



Guidance Document on Gluten-Free Regulation

- ❑ Health Canada is developing a guidance document related to the gluten-free regulations that will outline:
 - 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.
 - Guidance will be published on the Health Canada website and will support CFIA inspection/enforcement activities.



Questions or Comments

Thank you!

Please send any questions or comments to:

Bill Slater
Food Policy Liaison Officer
Health Canada
Bill.slater@hc-sc.gc.ca
Tel: 780-495-3682
Fax: 780-495-2624

