



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Canadian Food Inspection Agency



Our vision:

To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:

Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Overview of the new Canadian Food Allergen Labelling Regulations

For FFIGS Educational Workshop

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Objectives

To provide an overview on :

- ❑ Background to the New Amendments to the *Food and Drug Regulations* (FDR) to enhance labelling requirements for food allergens, gluten sources and added sulphites
- ❑ Application of the new regulations with specific foods as examples
- ❑ CFIA's enforcement approach, pre and post implementation of the new regulations

Background

A High Priority Public Health Issue

- ❑ Food allergies affect an estimated 6% of Canadian children and 3-4% of adults.
- ❑ Celiac disease affects approximately 1% of the Canadian population.
- ❑ Allergic reactions to food can result in severe or life-threatening reactions in some people.
- ❑ There is no treatment for food allergies, gluten and sulphite sensitivities. Avoidance of the problematic food is the key management strategy. Labelling information is a critical tool in this strategy.

Why Were New Regulations Needed?

Current Gaps In Labelling Regulations

- ❑ Certain multi-component ingredients are exempt from declaring their components
 - ❑ Examples: butter, margarine, flavours, colours

- ❑ Some prepackaged foods do not require a list of ingredients.
 - ❑ Examples: wine, vinegars

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

(Reference: B.01.009, B.01.008 (2), FDR)

FEDERAL FOOD RESPONSIBILITIES

HEALTH CANADA

- establishes regulations, policies and standards respecting consumer health, food safety & nutritional quality
- assesses effectiveness of CFIA's activities related to food safety

CANADIAN FOOD INSPECTION AGENCY

- sets and enforce non-safety labelling policy & regulations
- enforces food safety and nutritional quality standards
- carries out inspection & enforcement activities for food, animal & plant health inspection programs
- issues recalls



New Regulations

- ❑ The amendments to the *Food and Drug Regulations* (FDR) regarding Enhanced Labelling of Food Allergens, Gluten Sources and Added Sulphites were published in *Canada Gazette Part II* on February 16, 2011.
- ❑ The new Regulations will come into force 18 months after their registration for publication on **August 4, 2012**.

Primary Objectives of the New Regulations

- ❑ To minimize risks associated with inadvertent consumption of undeclared food allergens, gluten sources and added sulphites in food; and maximizing choice of safe and nutritious foods for consumers with dietary restrictions by:
 - ❑ Requiring mandatory “**source**” declaration of the common food allergens and gluten using simple, plain language in English and French, and
 - ❑ Enhancing the declaration of sulphites when present in the prepackaged food in a total amount of 10 parts per million (ppm) or more.

Scope: Applicable for all ingredients intentionally added to prepackaged foods. Issues of cross-contamination are not addressed by the new regulations.



“Food Allergen” Definition

- ❑ Any protein from any of the following foods or any modified protein, including any protein fraction (e.g. hydrolyzed protein), that is derived from the following foods:
 - ❑ Almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts
 - ❑ Peanuts
 - ❑ Sesame seeds
 - ❑ Wheat or triticale
 - ❑ Eggs
 - ❑ Milk
 - ❑ Soybeans
 - ❑ Fish, crustaceans and shellfish
 - ❑ Mustard seeds



[B.01.010.1(1), FDR]

NEW

“Gluten” Definition

- a) 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)
- b) Any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals listed above or from the grain of a hybridized strain of any of the cereals listed above.



[B.01.010.1(1), FDR]

GLUTEN FREE DEFINITION

B.24.018. No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the **food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale** or any part thereof



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), FDR.

“Sulphites” Definition

“**Sulphites**” means one or more of the **food additives** listed in column I of item 21 of the table to paragraph B.01.010(3)(b), FDR:

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



[B.01.010.2, FDR]

NOTE: This does not include naturally occurring sulphites

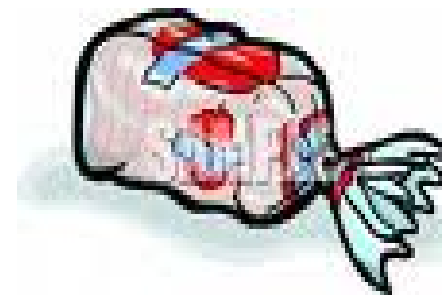
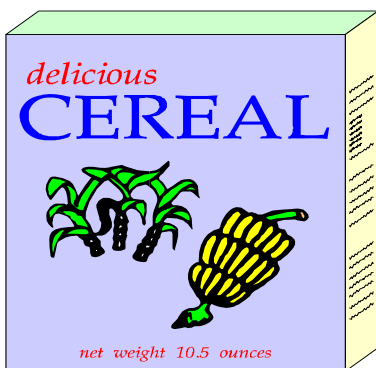
What Foods are Applicable Under the New Regulations?

- ❑ What foods are required to declare to food allergen and gluten sources and added sulphites?
- ❑ Most **prepackaged** foods

Prepackaged Product means:

Any food that is contained in a package in the manner in which it is ordinarily sold to or used or purchased by a person.

B.01.001, FDR



New Labelling Requirements for Alcoholic Beverages and Vinegars



NEW

- ❑ Standardized alcoholic beverages and vinegars continue to be exempt from declaring a list of ingredients, however they will be required to declare a “Contains” statement to identify any food allergens, gluten sources or added sulphites at levels of 10 ppm or above present in the product.

NOTE: HC’s labelling position for standardized wines with vintage date of 2011 or earlier posted at HC website:

<http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/vintage-wine-vin-millesimes-eng.php>



NEW

New Labelling Requirements for Produce Wax Coatings

- ❑ Although produce wax components are exempt from declaration in list of ingredients, any food allergens, gluten sources or added sulphites present in wax coating compounds of **prepackaged** fresh fruits or vegetables, will need to be declared.
- ❑ Wax coatings on produce can be made with milk, soy or other food allergens and/or may contain gluten sources.



Note: This will affect fresh fruit and vegetable ingredients used in pre-packaged foods with a list of ingredients declared

Additional Regulatory Amendments

NEW

- ❑ Common names of all starches, modified starches, hydrolyzed plant proteins and lecithins must now be modified as follows:
 - ❑ The name of the source of protein be identified in the common name of all **hydrolyzed plant proteins**.
 - ❑ E.g. “hydrolyzed **soy** protein”
 - ❑ The name of the plant source must be identified in the common name of all forms of **starches or modified starches**.
 - ❑ E.g. “**wheat** starch”, “**corn** starch”
 - ❑ The name of the source of lecithin must be identified in the common name of **lecithin**.
 - ❑ E.g. “**soy** lecithin”

What Foods Are Exempt?

1. Prepackaged Foods that are exempt from all labelling requirements

- ❑ One bite confections



- ❑ Fresh Fruits and Vegetables packed with a confining band of less than ½ inch in width



- ❑ Fresh Fruit and Vegetables in a wrapper.



What Foods Are Exempt?

2. Foods Listed in B.01.008(2)(a) to (e), FDR:

- a) prepackaged products packaged from bulk on retail premises, except prepackaged products that are a mixture of nuts;
- b) prepackaged individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks;
- c) prepackaged individual servings of food that are prepared by a commissary and sold by automatic vending machines or mobile canteens;
- d) prepackaged meat and meat by-products that are barbecued, roasted or broiled on the retail premises;
- e) prepackaged poultry, poultry meat or poultry meat by-products that are barbecued, roasted or broiled on the retail premises.

What Foods Are Exempt?

3. Standardized Beers, Ales, Stouts, Porters and Malt Liquors, described in sections B.02.130 and B.02.131, FDR



- ❑ Currently, these products are exempt, but the following should be considered:
 - ❑ If a list of ingredients is voluntarily provided on standardized beer, that list will have to be complete for all food allergen and gluten sources and added sulphites (10 ppm or more).
 - ❑ Unstandardized beers, such as flavoured beers, require a list of ingredients and are **not exempt** from the new regulations.
 - ❑ When beer products are added as ingredients to other pre-packaged food with a list of ingredients declaration, the ingredient list must be complete for all food allergen and gluten sources and added sulphites (10 ppm or more).

How must allergen and gluten sources and sulphites be labelled?



Regulatory Amendments

Label Declaration

When Added sulphites are present in ingredients or components that are exempt from declaration in the list of ingredients, sulphites must be declared if they are present at levels of 10 ppm or higher in the final food.

Sulphites must be declared either:

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

Note: All current requirements for ingredient declaration remain valid. For sulphites, this means if added directly as food additives or are components of an ingredient, not exempt from component declaration, they must be declared regardless of the level.

Current Requirements



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.
 - ❑ E.g. Dried Apricot Ingredients: apricots, **sulphites**.
(Sulphites are added as an ingredient).

- ❑ For ingredients that are **not exempt** from component declaration, if sulphites are a **component** of one of these ingredients, they must be declared when present **at any level** in the finished product.
 - ❑ E.g. Cookie Ingredients: Rolled oats, wheat flour, . . . , dried apricot (apricots, **sulphites**), baking soda.

(Apricots are not exempt from component declaration).

NEW

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 a “**Contains**” statement.

[Sulphites are present in the apricot jam with pectin (<5% of cookie); the jam is exempt from component declaration].

Examples:

1. Cookie Ingredients: Rolled oats, wheat flour, . . . , apricot jam with pectin (**sulphites**), baking soda.
2. Cookie Ingredients: Rolled oats, wheat flour, . . . , apricot jam with pectin, baking soda.

Contains oats, wheat, **sulphites**

NEW

Regulatory Amendments



Sulphites

In addition to these requirements for declaration in the list of ingredients:

- 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.

[Sulphites are present in the apricot jam with pectin (<5%); the jam is exempt from component declaration].

Examples

1. Cookie Ingredients: Rolled oats, wheat flour, . . . , apricot jam with pectin, baking soda.
2. Cookie Ingredients: Rolled oats, wheat flour, . . . , apricot jam with pectin, baking soda.
Contains oats, wheat

Regulatory Amendments

Label Declaration

Added food allergens and gluten must be declared **by their prescribed source names**

in the list of ingredients, OR

in the statement: “Contains”



Source Names [B.01.010.1 & B.01.010.2, FDR]

Food Allergen, Gluten or Sulphite Source	Prescribed Source Names
almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts	almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts (may be expressed singular or plural)
peanuts	peanuts (may be expressed singular or plural)
sesame seeds	sesame, sesame seed, sesame seeds
eggs	eggs (may be expressed singular or plural)
milk	milk

Source Names [B.01.010.1 & B.01.010.2, FDR]

Food Allergen, Gluten or Sulphite Source	Prescribed Source Names
soybeans	soy, soya, soybean or soybeans
wheat	wheat
triticale	triticale
barley	barley
rye	rye
oats	oats
mustard seeds	mustard, mustard seed or mustard seeds

Source Names [B.01.010.1 & B.01.010.2, FDR]

Food Allergen, Gluten or Sulphite Source	Prescribed Source Names
fish, crustaceans, shellfish	<p>the common name of the fish, crustacean or shellfish.</p> <p>E.g.: salmon, lobster or oyster.</p>
<p>Potassium bi<u>sulphite</u>, potassium metabi<u>sulphite</u>, sodium bi<u>sulphite</u>, sodium dithionite, sodium metabi<u>sulphite</u>, sodium <u>sulphite</u>, sulphur dioxide and/or sulphurous acid</p>	<p>“sulfiting agents” or “sulphiting agents”, “sulfites” or “sulphites” or</p> <p>As one or more of the ingredient common names in the left column where “sulfite” or “sulphite” is part of the common name.</p>

Source Names

Group names or other names that are not prescribed source names are **not acceptable**, on their own, as a source declaration for food allergen or gluten sources in the list of ingredients or in the “Contains” statement:

- ❑ **“Nuts”** or **“Tree Nuts”** cannot be used as a source declaration for one or more of the tree nuts listed in the food allergen definition [B.01.010.1(1), FDR].
 - ❑ Must declare specific source name ie walnuts, pecans

- ❑ **“Fish”**, **“Crustacean”**, **“Shellfish”**, **“Seafood”** or **“Mollusc”** cannot be used as a source declaration for a fish, crustacean or shellfish.
 - ❑ Must declare common name ie salmon, crab, anchovy

- ❑ **“Gluten”** cannot be used to identify one or more of the gluten sources.
 - ❑ Must declare specific source name ie rye, barley, oats, wheat

Source Declaration in List of Ingredients

How will this look on the label?

- ❑ In parentheses immediately after the ingredient:

E.g. Ingredients: flour (**wheat**), butter (**milk**), liquid albumin (**egg**), apricot jam with pectin, vegetable oil (**soy**), sugar, flavour, **sulphites***

- ❑ *New provision: sulphites may be shown at the end of the list of ingredients in any order.
- ❑ Added food allergen and gluten sources must be declared when **present at any level**, applicable to **all ingredient generations**.
- ❑ Bolding is not required, but not prohibited, by the new regulations, it is only done here to highlight the focus of the examples.

Source Declaration in List of Ingredients

How will this look on the label?

- ❑ In parentheses immediately after the component:

E.g. Ingredients: pastry pieces (flour (**wheat**), butter (**milk**), liquid albumin (**egg**), vegetable oil (**soy**)), apricot jam with pectin, sugar, flavour, sulphites.

- ❑ Food allergen and gluten sources must be declared when **present at any level**, applicable to all ingredient generations.

NOTE: If highly refined soy oil with no detectable soy protein is added, it may be declared as vegetable oil.

Source Declaration in List of Ingredients

Food allergen & gluten sources and added sulphites can alternatively be declared . . .

- ❑ **As part of the common name* of the ingredient or component, of which it is or is present in, in the list of ingredients:**

E.g. Ingredients: **wheat** flour, **milk** ingredients, liquid **egg**-white, **soybean** oil, apricot jam with pectin, sugar, sodium **bisulphite**, flavour.

*Common names must still meet existing requirements of the *Food and Drug Regulations* and any other applicable legislation.



Source Declaration – List of Ingredients

- ❑ Food allergen and gluten sources and added sulphites are only required to be declared once in the list of ingredients unless their declaration is required by name requirement.

Even though **MILK** is already declared here

E.g. Ingredients: Sugar, Skim **Milk** Powder, **Whey Powder**, Cocoa, Evaporated **Milk**, Salt.

It is still required to be declared here because of common name requirements.

MILK source but acceptable common name and milk is already declared, so source name is not necessary here.

Source Declaration in “Contains” Statement

Food allergen & gluten sources and added sulphites can alternatively be declared . . .

❑ In a “Contains” statement.

- ❑ When the statement “**Contains**” is present on a label, it must be complete and identify all food allergens, gluten sources and added sulphites (10 ppm or more) in the prepackaged product.
 - ❑ The regulations **do not specify the order** of the food allergen and gluten sources and added sulphites.
 - ❑ The statement must appear immediately after the list of ingredients for the product, if any, without any intervening printed, written or graphical material.
 - ❑ E.g. The list of ingredients in the other official language or any other language is considered intervening printed material.
 - ❑ Food Allergy and Intolerance Information-contains, Food Allergy-contains headings



Source Declaration in “Contains” Statement

Food allergen & gluten sources and added sulphites can alternatively be declared . . .

- ❑ In a “Contains” statement.

E.g. Ingredients: flour, butter, liquid albumin, vegetable oil, apricot jam with pectin, sugar, flavour. **Contains wheat, milk, egg, soy, sulphites.**

Cross Contamination

The labelling requirements for allergen and gluten sources and sulphites prescribed under sections B.01.010.1, B.01.010.2 and B.01.010.3 **do not apply** when their presence in the food products are a result of cross contamination.

Unavoidable presence due to cross contamination may be addressed by precautionary statements such as “**may contain x**”

B.01.010.1(3),FDR



Compliance and Enforcement

Pre and Post Implementation of the New Regulations



Effective Date- August 4, 2012



On August 4, 2012, applicable pre-packaged products that are ready for sale must comply with the new labelling requirements

"sell" as including offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration.

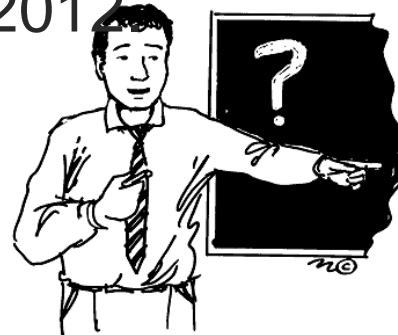
Interim Guidance & Enforcement Approach

- ❑ Until the new regulations come into force on **August 4, 2012**, the CFIA will continue its current compliance and enforcement activities under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*.

- ❑ During this period, CFIA urges industry to declare all food allergen and gluten sources and added sulphites (10 ppm or more) on food labels, either in:
 - ❑ the **list of ingredients**; or
 - ❑ in a **“Contains”** statement.

Interim Guidance & Enforcement Approach

- ❑ If Health Canada identifies a health risk related to the presence of undeclared food allergen and gluten sources or added sulphites in prepackaged foods, the CFIA will take appropriate enforcement action, which may include recall of the product.
- ❑ During the coming into force period, the HC and the CFIA will educate industry on the new requirements in order to promote compliance with the new Regulations by August 4, 2012.



For More Information

Guidance Documents

- ❑ Q & A Documents – Health Canada and CFIA
- ❑ Allergen Web Pages – Health Canada and CFIA

www.inspection.gc.ca

www.hc-sc.gc.ca

Food Allergen Contacts

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Summary

- ❑ New regulations come into force on **August 4, 2012**.

- ❑ Food allergen and gluten sources and added sulphites (10 ppm or more) must be declared either:
 - ❑ In the list of ingredients, OR
 - ❑ In the statement: “Contains”

- ❑ Until the new regulations come into force, the CFIA will continue its current compliance and enforcement activities under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* and work to educate industry to promote compliance with the new Regulations by August 4, 2012.

Questions

