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Regulatory Amendments

Labelling of Food Allergen and Gluten Sources and Added Sulphites

Technical Briefing

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Canada 

Food Allergies and Celiac Disease

A High Priority Public Health Issue

- ❑ Food allergies affect an estimated 5-6% of Canadian children and 3-4% of adults.
- ❑ Celiac disease affects approximately 1% of the Canadian population.
- ❑ Significant societal impacts.



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.



Current Labelling Regulations

Current 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



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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.
- ❑ Scope: Applicable for all ingredients intentionally added to prepackaged foods.



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“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



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“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



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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 (eg: products containing pure sources of oats, barley or wheat, which are free from contamination of gluten protein)
- ❑ A benefit to celiac patients, since it could lead to further expand the availability of healthy food choices for this group



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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



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Declaration of allergens, gluten sources and sulphites on standardized beer

- ❑ Health Canada has heard from stakeholders with respect to the inclusion of beer labelling in these regulations.
- ❑ bulk of the comments received have been addressed; however, there remain some outstanding concerns
- ❑ department is moving forward with a phased approach
- ❑ any additional amendments dealing with enhanced labelling of beer will be dealt with once further consultations and discussions can be held
- ❑ if a list of ingredients is voluntarily provided on standardized beer, that list will have to be complete (i.e., include all allergens, gluten sources and sulphites) at the end.



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- ❑ 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



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Common names of starches, modified starches, hydrolyzed protein and lecithin would now be modified 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.**



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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



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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.



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- When the statement “**Contains:** ” is present on a label (either by choice, or because it was triggered by the presence of food allergens, gluten sources or sulphites at 10 ppm or above) 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



Guidance for Industry

www.healthcanada.gc.ca/foodallergies

❑ Health Canada continues to urge food manufacturers and importers to declare common food allergens, added sulphites and gluten sources on food labels without exception, either in:

- The **ingredient list**;

OR

- The statement:

“Contains: ”



Guidance for Industry

www.inspection.gc.ca/english/fssa/labeti/allerg/allergee.shtml

- ❑ Should Health Canada identify a significant health risk with respect to the undeclared presence of common food allergens, added sulphites or gluten sources in prepackaged foods, the Canadian Food Inspection Agency will take appropriate enforcement action, which may include recall of the product



Other considerations

o 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



Next Steps

Coming into Force

- ❑ New regulatory amendments to come into force on **August 04, 2012**
- ❑ 18 months after date of registration

