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## **Health Canada Considers Comments for Possible Exemptions from the Enhanced Labelling Requirements for Foods or Ingredients Derived from Food Allergen or Gluten Sources**

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

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# Health Canada's Response to Comments for Consideration of Exemptions from Food Allergen Declaration on Prepackaged Food Labels if Supported by Scientific Evidence.

## Background

Food allergies are sensitivities caused by a reaction of the body's immune system to specific proteins in a food. Current estimates are that food allergies affect as many as 5-6% of young children and 3% to 4% of adults in westernized countries.

Celiac disease or gluten-sensitive enteropathy is an inherited condition triggered by the consumption of cereal grains containing "gluten". This disease affects nearly 1% of the population.

In Canada, 'food allergens requiring enhanced labelling' are those which are most frequently associated with severe food allergies. The Canadian 'priority food allergens' are currently defined as: [peanuts](#); [tree nuts](#) (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts pistachio nuts and walnuts); [sesame seeds](#); [milk](#); [eggs](#); fish; crustaceans; shellfish; [soy](#) and [wheat](#).

The grains considered to be capable of producing negative effects in individuals with celiac disease include the different species of wheat (e.g., durum, spelt, kamut), barley, rye, oats, triticale, wheat and their cross-bred hybrids.

## Current Situation

The current *Food and Drug Regulations* require that the ingredients of prepackaged products be declared in descending order of their proportion in a list of ingredients on the label of most prepackaged products. However, subsections the *Food and Drug Regulations* specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients. Also, some of the common names which are currently permitted to be used in the list of ingredients do not provide sufficient information to sensitive consumers to enable them to avoid foods that can trigger potential adverse reactions. As a result, the information on the label is not always complete with respect to the needs of these consumers.

- On July 26, 2008, Health Canada published proposed amendments to the *Food and Drug Regulations* (1220 – Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites) in *Canada Gazette*, Part I (CGI).

The objective of the proposed regulatory amendments is to enhance the labelling requirements for food allergens, gluten sources and added sulphites present in prepackaged products. The enhanced labelling requirements would enable consumers with a food allergy, celiac disease or a sensitivity to sulphites to make an informed choice when purchasing or consuming prepackaged products and enable them to avoid those substances that may trigger an adverse reaction.

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The proposed regulatory amendments would require that the source of the food allergen or gluten be shown on the label of a prepackage product whenever a food allergen requiring enhanced labelling or gluten is present in the product. The regulatory amendments do not address allergens or gluten present in a prepackaged product as a result of cross-contamination.

Just over 140 comments were received from the general public, patient groups, health professionals, consumer organizations, and governmental agencies following the publication of these proposed regulatory amendments in *Canada Gazette*, Part I.

Some comments requested a method or process for seeking exemptions from the enhanced labelling regulations. Health Canada has considered comments for rare cases where science might support claims that exempting certain foods and ingredients from enhanced labelling requirements would not cause a health risk to the allergic consumer.

Health Canada is committed to developing a process under which exemptions from the enhanced labelling requirements could be provided for food products containing priority allergens or gluten sources if they did not pose a risk to consumers with food allergies or celiac disease. As part of this process, Health Canada would perform a health risk assessment for the food or ingredient being considered for an exemption from the enhanced labelling requirements, ensuring that the highest possible food safety and scientific standards are met for safe consumption of that food by allergic and celiac individuals.

Health Canada intends to seek input from Canadians on a process for exemption of specific foods or ingredients from the enhanced labelling regulations for food allergen and gluten sources. Stakeholders will be invited to make comments once a proposed exemption process is posted on Health Canada's website.

## **Additional Information**

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