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## **Health Canada's Response to Comments Received Following Publication of Regulatory Project 1220 – Enhanced Labelling of Food Allergen and Gluten Sources and Added Sulphites in *Canada Gazette*, Part I**

### **Revised Food Labelling Requirements for Added Sulphites**

Bureau of Chemical Safety  
Food Directorate  
Health Products and Food Branch

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Canada 

## Background

The term “sulphites” refers to the group of food additives composed of sulphurous acid and its salts. Sulphites, also known as sulphiting agents, are regulated under the *Food and Drug Regulations* as food additives. Approximately 6% of individuals with asthma have a chemical sensitivity to sulphites. This represents approximately 200,000 Canadians. A range of reactions may be observed following ingestion of sulphites by a sensitive individual. They range from dermatitis and hives to life-threatening anaphylactic and asthmatic reactions.

Sulphites require enhanced labelling since they can also cause anaphylaxis-type reactions in sensitive individuals.

## Current Situation

Canada's *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 B.01.009 (1) and (2) of the Regulations specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients. In addition, some prepackaged products that do not require a list of ingredients may contain food allergens, gluten sources and sulphites, e.g.: certain wines and beer.

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.

## Overview of Declaration of Added Sulphites as Proposed in *Canada Gazette*, Part I:

Declaration of added sulphites on prepackaged food labels, as outlined in Health Canada's CGI proposal, would have required the following:

When sulphites are present in a prepackaged product in a total amount of 10 parts per million or more, the regulatory amendments, as proposed in *Canada Gazette*, Part I,

would have required that sulphites be declared in a statement starting with the words "Allergy and Intolerance Information - Contains:" followed by one of the common names: sulphites, sulfites, sulphiting agents, sulfiting agents. This statement would have been required even when sulphites were declared in the list of ingredients.

In addition, the CGI proposed regulations would have required that if the "Allergy and Intolerance Information - Contains:" statement was used on the label of a prepackaged product it would have to be comprehensive for all food allergen and gluten sources and added sulphites. Thus, the source of each food allergen and the source of any gluten present in the product would have had to be declared in this statement as well as one of the common names for sulphites, if sulphites were present in a total amount of 10 parts per million or more.

### **Comments Received concerning Declaration of Added Sulphites Following the Publication of the Proposed Amendments in *Canada Gazette* Part I**

Overall, more than 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.

Numerous comments were received regarding the prefix for the statement - "Allergy and Intolerance Information – Contains:". Through these comments, both industry and patient groups have expressed an overwhelming preference for use of the prefix "Contains:". After analyzing the comments received, Health Canada recognizes that removing the words "Allergen and Intolerance Information" and using "Contains:" as the prefix for the statement would be more practical for industry and consumers. This would also harmonize with international trade practice.

Certain stakeholders indicated that a mandatory requirement to declare added sulphites in a separate statement would give the impression that sulphites are more of a health concern than priority food allergens. It was also noted that the proposed labelling requirements for sulphites would have a greater impact on certain industry sectors. The mandatory requirement to declare sulphites, present at levels of 10 ppm or more, in a separate statement was also noted as being inconsistent with the current requirements of some of Canada's major trading partners.

### **Health Canada's Revised Approach to Declaration of Added Sulphites**

After further analysis and consideration, Health Canada will keep the portion of the proposed amendments that requires the declaration of added sulphites, if present in a total amount of 10 ppm or more, on the label of a prepackaged product.

However, based on the concerns raised by stakeholders, Health Canada will no longer be requiring added sulphites present at levels of 10 ppm or more to be declared in a separate

"contains" statement. The use of a "contains" statement will therefore be optional for sulphites, as it is for declaration of food allergens and gluten sources.

Whenever added sulphites are present in the total amount of 10 ppm or more, HC will now be requiring that, one of the words "sulphite", "sulfite", "sulfiting agent" or "sulphiting agent" appear, at least once, on the label - either in the "Contains:" statement or in the list of ingredients. The word may appear as part of the name of an ingredient or component shown in the list of ingredients. This requirement would not only fulfill HC's policy objective of using plain and common language, but would be consistent with the approach being proposed for declaring food allergen and gluten sources.

More specifically, HC will permit added sulphites, that are present in the total amount of 10 ppm or more, which are not already required to be shown in the list of ingredients in accordance with the *Food and Drug Regulations*, to be listed either in the list of ingredients or in the "Contains:" statement. However, when a "Contains" statement appears on the label added sulphites present in an amount of 10 ppm or more would also have to appear in this "Contains:" statement.

HC acknowledges that the removal of the mandatory requirement to list added sulphites present in the total amount of 10 ppm or more in a separate statement may limit the choice of foods available to sulphite sensitive individuals. Currently, the *Food and Drug Regulations* requires that sulphites be listed, at any level of use, in the list of ingredients when sulphites are added as an ingredient and **this requirement will not change**. Thus, in some cases, the consumer will not be able to distinguish, through the labelling information, if the level of sulphites is below 10 ppm or not, which could potentially restrict choices for sulphite sensitive individuals. After analyzing the situation, HC has concluded that there will be only a very limited number of products where sulphites are added as ingredients and the resulting amount of sulphites in the prepackaged product is less than 10 ppm. Thus the overall impact on food choice is expected to be small.

As a result of comments received, Health Canada has updated the provisions for enhanced labelling of sulphites, while maintaining the overall objectives of the regulatory amendments to enhance the labelling of food allergen and gluten sources and added sulphites.

### **Additional Information**

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