

Home > Food & Nutrition > Food Labelling

## Food and Nutrition

### Questions and Answers About the New Regulations to Enhance the Labelling of Food Allergens, Gluten and Added Sulphites

#### General

**Q1.** What are the foods that will need to be declared under the new allergen labelling regulations?

**A1.** Under the new regulations, when protein, modified protein or protein fractions from the following foods are present in prepackaged products, these allergens will need to be declared using plain language.

- a. almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;
- b. peanuts;
- c. sesame seeds;
- d. wheat and triticale;
- e. eggs;
- f. milk;
- g. soybeans;
- h. crustaceans (common name of the crustaceans);
- i. shellfish (common name of the shellfish);
- j. fish (common name of the fish); or
- k. mustard seeds.

Also,

Gluten sources will need to be declared when a food contains gluten protein, modified gluten protein, or gluten protein fractions from barley, oats, rye, triticale or wheat (or a hybridized strain of any of these cereals) [please see [questions & answer # 20](#) for information on beer labelling requirements].

Sulphites will still have to be declared at any level of use when directly added to a food as a food additive or when indirectly added to a food as components of an ingredient that is not exempted from component declaration. In addition, the new regulations will require that sulphites added as components of an ingredient exempted from component declaration will have to be declared when the total amount of sulphites contained within the food is 10 parts per million or more in the finished product.

**Q2.** What is the difference between a food, an ingredient, and a component?

**A2.** The legal definition of "food" is in the *Food and Drugs Act*, and the definitions for "ingredient" and "component" are in the *Food and Drug Regulations*. Essentially, a food is anything that is manufactured, sold or represented for use as food or drink for humans, including any ingredients that may be mixed with food for any purpose. Ingredients are individual foods that are combined to make prepackaged food products. Components can be thought of as ingredients of ingredients.

**Q3.** What is a "prepackaged food" or a "prepackaged product"?

**A3.** In practice, the terms are used interchangeably. According to the *Food and Drug Regulations (FDR)*, "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.

All prepackaged foods must carry a label. There are two exceptions in the FDR and these are:

- One-bite confectionary, such as a candy or a stick of chewing gum, sold individually; and,
- Fresh fruit or vegetables packaged in a wrapper or confining band of less than 1/2 inch (12.7 mm) in width.

These products are not required to carry a label. Therefore, the enhanced labelling for food allergens, gluten sources and added sulphites will not apply to these products.

For more details on prepackaged products required to have a label but exempted from providing an ingredient list, please see [Question 17](#).

**Q4.** How was it determined which foods should be declared under the new regulations?

**A4.** A working group consisting of representatives from Health Canada, the Canadian Food Inspection Agency (CFIA), and practising pediatric allergists, working in consultation with various consumer groups,<sup>1</sup> developed a scientifically-based list of foods known to cause severe adverse reactions in sensitive individuals. This working group published its conclusions in 1999, providing the scientific foundation for the identification of priority allergens in Canada.<sup>2</sup> These priority allergens are mostly consistent with the list of foods and ingredients known to cause hypersensitivity which are required to be declared in the list of ingredients by the Codex Alimentarius General Standard for Labelling of Prepackaged Foods. Moreover, in 2009 Health Canada adopted [criteria](#) for amending the Canadian list of priority food allergens and, in response to feedback received during the public consultation about the new labelling regulations, initiated systematic reviews of the available literature in order to determine the scientific validity of the inclusion of other food allergens on the Canadian list of priority allergens. The list of foods that must be declared under the new regulations is based on the working group's conclusions and these systematic reviews.

[↑ Top of Page](#)

**Q5.** Are Canada's new requirements for labelling food allergens the same as those of other countries?

**A5.** Every effort has been made to harmonize with other countries which have developed similar food labelling laws, i.e.: the European Union, Australia/ New Zealand, and the United States. However, each authority must balance between regulating the priority food allergens that form a significant health risk within their country and adapting the particularities of their own national and federal statutes. For example, both the U.S. and Canada require food allergens to be declared either in the list of ingredients or in a "Contains" statement. Canada requires that the statement be entitled "Contains" to clearly indicate that the information in the statement is in addition to the information in the list of ingredients and that this information has to be exhaustive (i.e. all allergens present as ingredients are declared).

**Q6.** Once the new regulations are in place, how much time do manufacturers and importers have before their food products must comply with the new labelling requirements?

**A6.** Manufacturers and importers will have 18 months to adopt the new labelling changes once the regulations are registered. That means that the new regulations will come into force on **August 04, 2012**.

It is important to understand that until this 18 month transition period ends on **August 04, 2012**, the absence of a declaration in plain language of allergens, gluten sources and sulphites (particularly for mustard and gluten sources) will not necessarily mean that these substances are not part of the product ingredients. Only after **August 04, 2012** will all labelling be expected to comply with the new regulations. During the transition period, the same level of vigilance as before should be applied to label reading.

Until the new regulations come into force, more information on what to look for on food labels to safely identify the presence of allergens, gluten sources and sulphites can be found in Health Canada's pamphlet ["Common Food Allergies: A Consumer's Guide to Managing the Risks"](#).

**Q7.** Since manufacturers and importers have 18 months to change their food labels, how will consumers who are food allergic, or gluten intolerant or sulphite-sensitive be protected in the meantime?

**A7.** Right now both Health Canada and the Canadian Food Inspection Agency (CFIA) are strongly urging manufacturers and importers to follow [Health Canada's directions](#) for the labelling of prepackaged foods containing priority allergens, gluten sources and added sulphites. Individuals who need to avoid certain foods should carefully read food product labels. Should Health Canada identify a significant health risk regarding undeclared food allergens, gluten sources, or added sulphites in a prepackaged food, the CFIA may take enforcement action as needed to protect the health of Canadians.

**Q8.** Why has Health Canada updated section B.24.018 of the Food and Drug Regulations?

**A8.** Section B.24.018 of the *Food and Drug Regulations* (FDR) has been updated to better reflect the [current internationally adopted scientific description](#) of '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.

**Q9.** Will updating section B.24.018 of the *Food and Drug Regulations* have an impact on food labelling requirements?

**A9.** Yes, with this updated terminology, companies that manufacture products made with barley, oats, rye, triticale or wheat but do not contain gluten protein will have the option of labelling them as gluten-free in Canada (eg: products containing pure maltodextrin derived from wheat will now be able to label themselves as gluten free). It is felt that this change will be of benefit to celiac patients, since it could further expand the availability of healthy food choices for this group.

**Q10.** Is there a website for the Canadian Food Inspection Agency where I can find more information about food allergen labelling in Canada?

**A10.** Yes. Please visit the [CFIA's Food Allergens website](#).

**Q11.** When the new regulations come into force on **August 04, 2012**, what should I look for on a food label to find out if the food product has a food allergen, gluten source, or sulphites added to it?

**A11.** You should always read the list of ingredients first. Under the new regulations manufacturers will have the option of declaring an added food allergen or gluten source either in the list of ingredients or in a statement immediately after the list of ingredients called "Contains". If you don't see the allergen or gluten source in the list of ingredients, look for the "Contains" statement [please see [questions & answer # 20](#) for information on beer labelling requirements]. As always, you should also look for and respect any allergen precautionary statement present on the label.

**Q12.** Can foods not on the Canadian priority allergen list be declared in the "Contains" statement?

**A12.** There is no prohibition in including other foods considered allergens in other countries in the "Contains" statement.

**Q13.** Under the new regulations, will all components of an ingredient exempt from component declaration have to be declared?

**A13.** The component exemption provided by section B.01.009, *Food and Drug Regulations* still applies. The new regulations will only require the declaration of the allergen, gluten source or added sulphite at 10ppm or more. This information may be declared in brackets immediately after the ingredient name in the list of ingredients or in a "Contains" statement [please see [questions & answer # 20](#) for information on beer labelling requirements].

**Q14.** What about hydrolysed plant protein, starch, and lecithin? Will the new regulations require that the sources of these ingredients be identified?

**A14.** Yes, the new regulations will require that the specific sources of all hydrolysed plant proteins, starches and modified starches, and lecithins be identified by their common names in the list of ingredients or in a "Contains" statement. Animal-based hydrolysed proteins are currently declared by their common names. These plant or animal sources may or may not be food allergens themselves, but this will allow allergic individuals to make informed choices when purchasing foods containing these.

 [Top of Page](#)

**Q15.** Will allergens such as casein (a milk protein) be required to be declared when used as a component in wax coatings on fresh fruits and vegetables?

**A15.** The new regulations will require the declaration of allergenic and gluten components of wax coatings of prepackaged fresh fruit and vegetable products on any part of the label in a "Contains" statement or a list of ingredients. The label must not be placed on the bottom of the package. Also, whole fresh fruit or vegetables packaged in a wrapper or confining band of less than 1/2 inch (12.7 mm) in width do not require any labelling.

**Q16.** Coconut is a "tree nut". Will all tree nuts, including coconut, need to be declared on food labels?

**A16.** No, only the tree nuts identified in the new regulations will have to be declared. However, coconut will have to be declared in the same manner as any other ingredient that is not a food allergen.

**Q17.** Will some food products be exempt from the requirement to declare food allergens, gluten sources or added sulphites?

**A17.** The new regulations will cover all prepackaged foods that have a list of ingredients and most prepackaged foods that are not required to have a list of ingredients when protein or protein fraction from allergens, gluten sources or sulphites are present (see also the sections on standardized foods, mustard, gluten and celiac disease, and sulphites).

Some foods that are not required to have a list of ingredients will however continue to be exempt from ingredient declaration [please see [questions & answer # 20](#) for information on beer labelling requirements]. They are:

- 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;

If a manufacturer chooses to provide a list of ingredients for any of these foods, then the allergen labelling requirements as defined by the regulations will apply.

Health Canada is committed to developing a process under which exemptions from the enhanced labelling regulations 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, on a case-by-case basis, a health risk assessment for the food or ingredient considered for an exemption ensuring that the highest possible food safety and scientific standards are met for safe consumption of that food by people with food allergies and individuals diagnosed with celiac disease.

**Q18.** I have noticed statements such as "May contain milk ingredients" or "Manufactured in a facility that also processes nuts" on many food product labels. Does this kind of labelling have something to do with the new regulations?

**A18.** No, these are examples of "allergen precautionary labelling", used to notify consumers that a food allergen may be unintentionally present in a food. The new regulations cover food allergens, gluten sources and sulphites that have been deliberately added to foods as part of their manufacturing process.

For more information on [precautionary labelling](#), please visit Health Canada's website.

## Standardized Foods

**Q19.** What is a "standardized food"?

**A19.** The *Food and Drug Regulations* contain composition descriptions of certain foods that specify, for example, what is allowed in those foods as ingredients. These descriptions are standards of identity and composition that have to be met for a food to be legally called by the name in the standard. The foods are referred to as "standardized foods". Examples of **Standardized Foods** include bread, milk, cheese, orange juice, sausage, jam, wine, [beer](#) and salt. Foods that do not have a standard of identity are referred to as "unstandardized foods". Snack foods like potato chips, various bakery items such as rolls, donuts and cakes, yogurt, and pizza are examples of unstandardized foods.

**Q20.** Will these new labelling requirements be extended to beer labels also?

**A20.** Health Canada has heard from numerous stakeholders, including various industry groups, patient associations and the general public with respect to the inclusion of beer labelling in these regulations. While the bulk of the comments received have been addressed, there remain some outstanding concerns about the best way to handle the labelling of allergens, sulphites and gluten sources when it comes to [standardized](#) beer. Rather than delay the publication of the regulations any further, the department is moving forward with a phased approach. The bulk of the regulations are being published now, while any additional amendments dealing with enhanced labelling of beer will be dealt with once further consultations and discussions can be held.

While the current amendments do not require [standardized](#) beer to be labelled with a list of ingredients, it is important to note that if a list of ingredients is voluntarily provided on beer, that this list will have to be complete in accordance with the new food allergen labelling regulations [please see [question & answer #17](#) for information on exemptions].

**Q21.** Will the new regulations require food allergens to be declared for beer, wine, and other standardized alcoholic beverages that do not need a list of ingredients?

**A21.** Although standardized alcoholic beverages such as beer and wine are not required to have a list of ingredients, if wine or other standardized alcoholic beverages, ([except standardized beer](#)) contain a food allergen, gluten source or added sulphites (at 10 ppm or more) then the food allergen, gluten source or sulphites will need to be declared on any part of the label using either a list of ingredients or in a "Contains" statement. The label must not be placed on the bottom of the package.

[↑ Top of Page](#)

**Q22.** Will this also apply to standardized alcoholic beverages such as beer and wine served in bars and restaurants?

**A22.** Under the new regulations, priority allergen, gluten sources and sulphites will have to be declared if present in prepackaged standardized alcoholic beverages, [except standardized beer](#). Prepackaged products sold or distributed to consumers (including cans, bottles or other containers of these beverages from multi-packs sold/served individually) will be required to declare the presence of any priority allergen, gluten sources or sulphites (when 10 ppm or more). There will be cases where these products are served unpackaged (thus unlabelled) to the consumers (e.g. glass of wine) but the shipping containers from the manufacturers intended for the food service end will have to be duly labelled.

**Q23.** Will fining agents used in alcoholic beverages have to be declared?

**A23.** The new regulations do not systematically mandate the declaration of fining agents. Fining agents derived from allergens (e.g. milk, egg and fish) will have to be declared only if their use results in protein from the allergen being present in the final product. In such cases, the allergen source would be required to be declared on the label in the "Contains" statement. Further guidance specific to this question will be developed. [Standardized beer](#) products are exempt from these requirements.

**Q24.** I have never noticed any ingredients list on vinegar. How will I know if vinegar contains a food allergen?

**A24.** Under the new regulations standardized vinegar products will be required to declare food allergens, gluten sources and added sulphites on any part of the label using either a list of ingredients or in a "Contains" statement. The label must not be placed on the bottom of the package.

### Mustard - An Addition to the Priority Allergens in Canada

**Q25.** I'm allergic to mustard, how will the new regulations better help me to identify safe food choices?

**A25.** Currently, the Food and Drug Regulations requires that food manufacturers provide a complete and accurate list of ingredients on the label of most prepackaged food but until the new amendments become effective on **August 04, 2012** certain components of ingredients are exempted from declaration. For example, when spices or seasonings are used as ingredients in other food, their components are not required to be included in the list of ingredients. As a result, a prepackaged food product labelled with a list of ingredients may be unsafe for individuals with mustard allergy if some of those ingredients (such as spices or seasonings) are from mustard seeds and not declared on the label.

The new regulations require that, whenever protein or protein-containing derivatives from any of the mustard varieties as specified in the regulatory definition of "mustard" are present in a prepackaged food, the word mustard will be required to appear, either in the list of ingredients or in a separate "Contains" statement. The mustard species included in the regulatory definition are: *Sinapis alba*, *Brassica hirta Moench*, *Brassica juncea (L) Cossom*, and *Brassica nigra*.

It is important to understand that even though you may start to see mustard showing up more often on product labels, before the end of the 18 month transition period i.e.: on **August 04, 2012**, the absence of a declaration of mustard will not necessarily mean that the product does not have mustard as part of a spice or seasoning blend. Only after **August 04, 2012** will all labelling be expected to comply with the new regulations.

For more details on the inclusion of mustard in Canada's priority allergens please consult Health Canada's document entitled "[Mustard: A Priority Food Allergen in Canada - A Systematic Review](#)".

### Celiac Disease and Gluten

**Q26.** I have Celiac Disease, how will the new regulations better help me to identify safe food choices?

**A26.** The only treatment for celiac disease is a strict avoidance of cereal grains containing "gluten". These grains include: barley, oats, rye, triticale and wheat (e.g., durum, spelt, kamut). Health Canada still considers regular commercial oats as a source of gluten due mainly to the high potential of cross-contamination with other grain cereals containing gluten. Regular commercial oats are often grown, harvested, transported, stored, milled or packaged in close proximity with these cereal grains and cross-contamination may occur at any point of the production chain. Also oats have protein structures similar to that of gluten (but are present in lesser quantities) to which some people with celiac disease are intolerant

Therefore, the new regulations require that for food containing gluten sources (including oats) these sources must always be declared in the list of ingredients, or in a contains statement. This will make it easier for people with Celiac Disease to avoid those sources of gluten.

Regarding the status of pure oats, based on recent scientific evidence, Health Canada has also concluded that the majority of people with celiac disease can tolerate moderate amounts of **pure uncontaminated oats**. Pure oats, produced from dedicated fields and equipment, have been available on the market for a few years now and can represent a very beneficial addition to the diet of celiac disease sufferers who tolerate oats because of its palatability and nutritional value. For those who are consuming pure oats in their diet, a clinical follow-up is advisable to confirm their tolerance. In addition, Health Canada is currently reviewing the regulations pertaining to the labelling of gluten-free products and consulted with Canadians during the summer 2010 on the possibility of allowing the use of pure oats for these products. Until the regulations are amended, pure uncontaminated oats can not be represented as a gluten free product.

For more details on this [consultation](#), please visit Health Canada's website.

The details of Health Canada [position on the introduction of oats](#) to the diet of individuals diagnosed with celiac disease is also available on Health Canada's web site.

**Q27.** Can I declare all the gluten sources as "gluten" in the "Contains" statement?

**A27.** The new regulations requires the gluten sources to be declared by the grain name, such as barley, oats, rye, triticale or wheat.

**Q28.** More specifically, if gluten or wheat-based ingredients are present in a prepackaged food, how do they have to be declared?

**A28.**

1. Gluten-based ingredients (i.e. containing gluten protein from barley, oats, rye, triticale or wheat) will be required to appear in the list of ingredients or in the "Contains" statement by using the common name of the gluten source.
2. Triticale (a cross-bred hybrid from wheat and rye) will be required to be declared as triticale in the list of ingredients or in the "Contains" statement.
3. Any of the *triticum* species of wheat (i.e. wheat, spelt, durum, kamut, etc.) Will be required to be declared using the word "wheat" in the ingredient list or in the "Contains" statement either as the ingredient or in brackets, beside the ingredient (e.g.: "wheat" or "kamut (wheat)").

## Sulphites

**Q29.** Don't the current *Food and Drug Regulations* already require that sulphites be labelled in the list of ingredients?

**A29.** Yes, and there will be no changes to the requirements of sulphites declaration when used as food additives. The current regulations require that sulphites, like any other food additive, be declared in the list of ingredients of food labels when they are added directly to a prepackaged food. However, the regulations currently exempt certain ingredients from component declaration.

If sulphites are a component of one of these ingredients they do not have to be declared. Under the new regulations, when present in the finished food at a level of 10 parts per million or more, added sulphites must be declared either on the label in the ingredient list or using the statement "Contains". Documented reactions to sulphites occurred at levels of 10 parts per million or above. For ingredients that are not exempted from component declaration, if sulphites are a component of one of these ingredients they will continue to have to be declared (at any level).

**Q30.** If sulphites are added to a prepackaged food, how must they be declared?

**A30.**

1. If any amount of sulphites are added as a food additive ingredient, this must be declared in the list of ingredients as outlined in the current regulation. This is the case for any addition of any food additive.
2. Added sulphites which are components of exempted ingredients present in the final food at a concentration less than 10 ppm do not require declaration.
3. Added sulphites which are components of exempted ingredients present in the final food at a concentration of 10 ppm or greater will have to be listed either in the list of ingredients or in a "Contains" statement.
4. The new regulations will require that one of the words "sulphite", "sulfite", "sulfiting agent", or "sulphiting agent" appear at least once on the label, either in the list of ingredients or in a "Contains" statement. The word may appear as part of the name of an ingredient or component shown in the list of ingredients. However, if a "Contains" statement is used on a label, added sulphites present in an amount of 10 ppm or more would also have to appear in this "Contains" statement.
5. Sulphites generated by transformation processes are exempt from declaration.

## Other Products

**Q31.** Are the new allergen labelling regulations applicable to other products such as drugs or natural health products?

**A31.** The new allergen labelling regulations apply specifically to Part B of the *Food and Drug Regulations* which target only the labelling of prepackaged food sold in Canada. [Other labelling regulations](#) apply to drugs and natural health products.

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<sup>1</sup> The Canadian Society of Allergy and Clinical Immunology, the Allergy/Asthma Information Association, the Canadian Celiac Association and other experts in food allergies and sensitivities in Canada and the United States.

<sup>2</sup> Zarkadas, M., Scott, F.W., Salminen, J., Ham Pong, A. (1999). Common Allergenic Foods and Their Labelling in Canada - A Review. *Can. J. All. & Clin. Immunol.*, 4(3): 118-141.

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Date Modified: 2008-07-22