Food and Nutrition

Regulatory Impact Analysis Statement

Project 1220 Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites.

Executive summary

Issue: Scientific evidence has clearly linked certain foods and food ingredients with adverse reactions when consumed by individuals with food allergies, celiac disease or a sulphite sensitivity. For individuals with food allergies or a sulphite sensitivity, these reactions can range from mild to severe and, in some cases, the reaction can progress to anaphylactic shock and death. For individuals with celiac disease, the consumption of foods containing gluten can lead to long term complications. In all cases, avoidance of specific foods or food ingredients is a principle element in the management of the condition. Food allergies, celiac disease and sulphite sensitivity affect approximately 1.75 million Canadians.

The *Food and Drug Regulations* (the Regulations) require that most ingredients and components of prepackaged products be shown in descending order of their proportion in a list of ingredients on the label of the product. Subsection B.01.009 (1) of the Regulations exempts components of certain ingredients and classes of ingredients while subsection B.01.009 (2) exempts ingredients and components of certain preparations and mixtures from the requirement to be shown in the list of ingredients. In addition, some of the common names which are permitted to be used in the list of ingredients do not provide sufficient information to assist consumers with food sensitivities to avoid foods that can trigger adverse reactions. As a result, the ingredient information on the label is not always complete with respect to the needs of these consumers.

Description: The enhanced labelling requirements set out in these regulatory amendments will assist consumers with food allergies, celiac disease or a sulphite sensitivity in avoiding those prepackaged products that may trigger an adverse reaction.

These regulatory amendments will require that the source of a food allergen or gluten be shown on the label of most prepackaged products when the food allergen or gluten is present in the prepackaged product. The food allergen or gluten source will be required to be shown on the product label in consistent and easy to understand terminology. For example, if casein is present in a prepackaged product, the word "milk" will be shown on the product label. The source of the food allergen or gluten will be shown either in the list of ingredients or in a "Contains" statement.

The list of food allergens included in the scope of these regulatory amendments (priority allergens) are based on those identified in 1999 by a committee consisting of representatives of Health Canada, the Canadian Food Inspection Agency (CFIA), and practicing pediatric allergists and updated using the criteria recently developed and adopted by Health Canada.

These amendments will not apply to food allergens or gluten that may be present in the prepackaged product as a result of cross-contamination. The cross-contamination of prepackaged foods with food allergens or gluten are unique issues which are beyond the scope of this regulatory initiative.

Sulphite is a general term that refers to the salts of sulphurous acid. Most sulphites, also known as sulphiting agents, are regulated as food additives. These regulatory amendments will require

those sulphites that are regulated as food additives and added to the prepackaged product be shown on the label of most prepackaged products when present in a total amount of 10 parts per million (p.p.m.) or more. Sulphites will be required to be shown either in the list of ingredients or in a "Contains" statement.

Cost-benefit statement: The enhanced labelling requirements set out in these regulatory amendments are expected to reduce accidental consumption of undeclared food allergens, gluten and added sulphites. A corresponding reduction in adverse reactions is expected to follow. As a result, it is anticipated that there will be: reduced costs to the health care system; reduced costs for individuals with food allergies, celiac disease or a sulphite sensitivity; and improved quality of life for these individuals and their families.

There are costs associated with implementing these regulatory amendments for both industry and government. However, both the quantitative and qualitative cost benefit analyses indicate a net positive impact. Using the data available in the literature, a net positive impact of $ 69.3 M is expected annually over 10 years following the coming into force of these regulatory amendments. In addition, it is anticipated that there will be an increased quality of life for individuals with food allergies, celiac disease or a sulphite sensitivity and their families.

Business and consumer impacts: These regulatory amendments will create additional labelling requirements with which industry must comply. However, most of the products within the scope of the amendments already require that ingredients and components be shown in a list of ingredients. These labelling requirements build on the existing regulatory requirements for ingredient and component labelling.

The enhanced labelling information that will be required to be shown on the label of most prepackaged products as a result of these regulatory amendments, will assist consumers with food allergies, celiac disease or a sulphite sensitivity in making informed choices about the prepackaged products they purchase and consume and to avoid those foods and ingredients that may trigger an adverse reaction.

Domestic and international trade and cooperation: These regulatory amendments are in line with the general approach taken by Canada's key trading partners, namely the United States, the European Union and Australia/New Zealand. These jurisdictions have implemented legislation or regulations which require that certain ingredients and components always be declared on the label as recommended by the Codex Alimentarius Commission[1] (CAC) with slight modifications to reflect the applicable situation and legislation in the respective jurisdiction. These regulatory amendments will address the CAC recommendations. To meet the specific needs identified in Canada, sesame seeds, shellfish and mustard seeds have been added to Canada's list of priority allergens.

Top of Page

Issue

Scientific evidence has clearly linked certain foods and food ingredients with adverse reactions when consumed by individuals with food allergies, celiac disease or a sulphite sensitivity. For the purpose of this document, food allergies, celiac disease and sulphite sensitivity will be referred to collectively as "food sensitivities". A food sensitivity is an adverse reaction to a food that other people can safely eat.

Food allergies, celiac disease and sulphite sensitivity affect approximately 1.75 million Canadians.

Individuals with a food allergy who come into contact with that allergen can have an adverse reaction that may rapidly progress to anaphylactic shock and death. While some individuals may have a single food allergy, it is not unusual for individuals to have multiple food allergies[2]. The management of food allergies requires the avoidance of the specific food allergen or food allergens. Food allergies affect approximately 5 to 6% of young children and 3 to 4% of older children and

adults in westernized countries. This equates to approximately 1.2 million Canadians.[3]

In Canada, the foods most frequently associated with severe allergic reactions (herein referred to as "priority allergens") are: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts, peanuts, sesame seeds, wheat, triticale, eggs, milk, soybeans, crustaceans, fish, shellfish and mustard seeds. The Canadian list of priority allergens includes those food allergens that were identified in 1999 by a committee with representatives of Health Canada, the Canadian Food Inspection Agency (CFIA), and practicing pediatric allergists. This list has been updated using the criteria recently developed and adopted by Health Canada as a result of the comments received following pre-publication of the proposed regulatory amendments in *Canada Gazette*, Part I on July 26, 2008.[4, 5]

Celiac disease is a lifelong medical condition observed in genetically susceptible individuals. Symptoms and complications occur in response to the ingestion of the gluten in wheat and related grains. Exposure to gluten leads to a series of immune mediated adverse reactions and progressive deterioration of the lining of the small intestine. Individuals with celiac disease have an increased risk of developing other diseases, including osteoporosis, lymphoma and type I diabetes mellitus. They are also at increased risk of reproductive problems. In children, celiac disease can be associated with growth failure and delayed puberty. Celiac disease affects approximately 1% of the population or 340,000 Canadians[6, 7].

A life-long gluten-free diet is the only way to avoid the symptoms and the complications of celiac disease. As a result, individuals with celiac disease are advised to avoid the consumption of wheat, rye, barley, oats and triticale and their hybridized strains. However, there is recent evidence to indicate that when oats are grown and processed under conditions to minimize cross-contamination with wheat, rye, barley and triticale they may safely be consumed in limited quantities by most individuals with celiac disease[8]. Although the scientific knowledge concerning the safety of these oats in a gluten-free diet is evolving, individuals with celiac disease, and in particular those who cannot tolerate the specially grown and processed oats, need to be aware when gluten from oats is present in prepackaged products.

Sulphite is a general term that refers to the salts of sulphurous acid. Most sulphites, also known as sulphiting agents, are regulated as food additives.

Sulphite sensitivity is seen mainly among individuals with asthma.[9] About 6% of individuals with asthma have a chemical sensitivity to sulphites or approximately 200,000 Canadians.[10, 11] The most commonly observed reactions are acute asthma and skin reactions such as hives and flushing. In rare cases, these reactions can be severe and can lead to death, usually due to acute asthma. For individuals with a sulphite sensitivity, consumption of a food with a total amount of sulphites lower than 10 parts per million (p.p.m.) is unlikely to lead to possible reactions.[12]

While some food allergies may be outgrown by children (e.g. milk and egg allergies), celiac disease, a sulphite sensitivity and most food allergies are life-long. Management of food sensitivities requires strict avoidance of the food or foods that can trigger a reaction. Label reading is one of the cornerstones of managing a food sensitivity. One of the safest and most efficient ways for those with food sensitivities to avoid a reaction is to read the label for all foods all of the time[13]. Consumers with food sensitivities are advised to read ingredient labels and to avoid products that do not have a list of ingredients.[14]

The *Food and Drug Regulations* (the Regulations) require that most ingredients and components be shown in descending order of their proportion in a list of ingredients on the label of most prepackaged products. This regulatory requirement provides consumers with information regarding the ingredients and components of the prepackaged product and can assist consumers with food sensitivities in making informed decisions about the prepackaged foods that they purchase and consume. However, subsection B.01.009 (1) of the Regulations specifically exempts components of certain ingredients or classes of ingredients, while subsection B.01.009 (2) exempts ingredients and

components of certain preparations and mixtures from the requirement to be shown in the list of ingredients. In addition, some of the common names which are permitted in the list of ingredients do not provide sufficient information to determine if the ingredient or component contains a food allergen, gluten or sulphites. As a result, prepackaged products may contain undeclared food allergens, gluten or added sulphites. Thus, consumers with food sensitivities cannot avoid, with any certainty, foods that may cause an adverse reaction.

Objectives

The objective of this regulatory initiative is to assist consumers with food allergies, celiac disease or a sulphite sensitivity in making informed choices and to avoid those prepackaged foods that may trigger an adverse reaction. The enhanced labelling requirements set out in these regulatory amendments will assist consumers with food allergies, celiac disease or a sulphite sensitivity in making informed choices when purchasing or consuming prepackaged products.

Specifically, for food allergens and gluten, the objective is that information regarding the presence of food allergens and gluten be shown on the product label in simple and consistent terminology. For example, if casein is present in a prepackaged product, the word "milk" will be shown on the product label either in the list of ingredients or in a statement that begins with the word "Contains" (herein referred to as "Contains" statement).

It is not Health Canada's intent that these regulatory amendments will apply to food allergens or gluten that may be present in a prepackaged product as a result of cross-contamination.

For sulphites, the objective is to require that added sulphites be shown on the label when they are present in the prepackaged product in a total amount of 10 p.p.m. or more. To facilitate label reading, one of the terms "sulphite", "sulfite", "sulphiting agent" or "sulfiting agent" will be required to appear on the label of the prepackaged product, either in the list of ingredients or in a "Contains" statement.

These regulatory amendments are one of the key elements of Health Canada's program area related to food sensitivities. The overall objectives of this program area are:

- to minimize risks associated with inadvertent consumption of undeclared food allergens, gluten sources and added sulphites in food; and
- to maximize choice of safe and nutritious foods for consumers with dietary restrictions.

Top of Page

Description

Overview:

These regulatory amendments will require that the source of a food allergen or gluten be shown on the label of most prepackaged products, either in the list of ingredients or in a "Contains" statement. These amendments will apply to food allergens derived from any of the following foods: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts; peanuts; sesame seeds; wheat and triticale; eggs; milk; soybeans; crustaceans; shellfish; fish; mustard seeds and to gluten from the grains of the following cereals: barley; oats; rye; triticale; and wheat.

These amendments do not apply to food allergens or gluten that may be present in a prepackaged product as a result of cross-contamination.

Most sulphites, also known as sulphiting agents, are regulated as food additives. However, some forms of sulphites, namely sulphur dioxide, can be formed during certain manufacturing processes such as fermentation. These amendments will apply to sulphites that are food additives and that are added to the prepackaged product. For the purposes of this document, these sulphites will be referred to as "added sulphites". These amendments will not apply to sulphites that are formed during the fermentation process.

Sulphites added as ingredients or components will continue to be shown in the list of ingredients when required pursuant to sections B.01.008 or B.01.009 of the Regulations. When added sulphites are not required to be shown in the list of ingredients pursuant to sections B.01.008 or B.01.009 of the Regulations and they are present in the prepackaged product in a total amount of 10 p.p.m. or more, they will be required to be shown on the label, either in the list of ingredients or in a "Contains" statement. However, if a "Contains" statement is provided on the label and added sulphites are present in a total amount of 10 p.p.m. or more, they will also be required to be shown in the statement whether or not they are already shown in the list of ingredients.

These regulatory amendments will apply to most prepackaged products. Paragraphs B.01.008 (2) (*a*) to (*g*) of the Regulations exempt certain prepackaged products from carrying a list of ingredients. While the exemption from carrying a list of ingredients has been maintained, the labelling requirements of these regulatory amendments will apply if a list of ingredients is voluntarily provided for the products listed in B.01.008 (2) (*a*) to (*e*). These regulatory amendments will apply to Bourbon whisky and most alcoholic products subject to a standard in Division 2 of the Regulations whether or not a list of ingredients is provided. However, for prepackaged beer, ale, stout, porter or malt liquor for which a standard is prescribed in section B.02.130 or B.02.131, the labelling requirements of these regulatory requirements will apply only if a list of ingredients is voluntarily provided. For the products listed in B.01.008 (2)(*g*) (vinegars subject to a standard in Division 19), the labelling requirements specified in these regulatory amendments will apply whether or not a list of ingredients is provided.

The prepackaged products identified in subparagraphs B.01.003 (1) (*a*) (i) and (ii) (prepackaged confections, commonly known as one bite confections, that are sold individually and prepackaged products consisting of fresh fruits or fresh vegetables that are packaged in a wrapper or confining band of less than ½ inch in width) are exempt from carrying a label. Thus, these regulatory amendment will not apply to prepackaged products that are exempt from carrying a label pursuant to subparagraphs B.01.003 (1) (*a*) (i) and (ii).

Food Allergen and Gluten Sources - Labelling Requirements:

Subsection B.01.010.1 (1) will set out the definition of "food allergen" and "gluten". Subsections B.01.010.1 (2) and (3) will set out the requirement to show the source of each food allergen and the source(s) of gluten present in the product on the product label, either in the list of ingredients or in a "Contains" statement unless the food allergen or gluten is present as a result of cross-contamination.

Subsections B.01.010.1 (6) and (7) will set out the specific names by which the source of a food allergen or the source of gluten must be shown. Subsections B.01.010.1 (8) and B.01.010.1 (10) will set out where the source of a food allergen or gluten is to be shown in the list of ingredients. Subsection B.01.010.1 (9) will set out that the source of the food allergen or gluten must be shown in a "Contains" statement when the specific conditions identified in the subsection occur.

Paragraph B.01.010 (3) (*b*) of the Regulations provides that, in certain circumstances, all of the ingredients or components present in the foods set out in the Table to this paragraph may be shown collectively in the list of ingredients by the common name set out in that Table. Subsection B.01.010.1 (11) will provide that, for greater certainty, nothing in subsection B.01.010.1 (8) affects how an ingredient or component may be shown in the list of ingredients under paragraph B.01.010 (3) (*b*).

Item 8, of the table to paragraph B.01.010 (3) (*a*) has been amended to require that the name of the plant be identified in the common name of all hydrolyzed plant proteins. Previously, this requirement applied only to hydrolyzed proteins produced by the enzymatic process. Alternative spellings of "hydrolyzed" and "hydrolysed" will also be permitted in the English common names.

Items 20 to 24 have been added to the table to paragraph B.01.010 (3)(*a*) to specify that:

- the name of the plant 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;
- the name of the crustacean be identified as the common name for a crustacean;
- the name of the shellfish be identified as the common name of a shellfish.

Added Sulphites – Labelling Requirements:

Subsection B.01.010.2 (1) will set out the definition of the term "sulphites" for the purposes of these regulatory amendments. Subsection B.01.010.2 (2) provides the reader with greater certainty regarding the scope of the regulatory definition of "sulphites".

Subsections B.01.010.2 (3), B.01.010.2 (6) and B.01.010.2 (7) will provide that added sulphites, which are not required to be shown in the list of ingredients pursuant to sections B.01.008 and B.01.009 of the Regulations, must be shown on the label of the prepackaged product, either in the list of ingredients or a "Contains" statement when added sulphites are present in a prepackaged product in a total amount of 10 p.p.m. or more. These provisions provide the details of how and where these sulphites must be shown on the product label.

Subsections B.01.010.2 (8) and B.01.010.2 (10) will provide an additional requirement to show one of the common names "sulfites", "sulfiting agents", "sulphites" and "sulphiting agents" on the label when "sodium dithionite", "sulphurous acid" or "sulphur dioxide" is the ingredient name used in the list of ingredients and the total amount of added sulphites in the prepackaged product is 10 p.p.m. or more.

Subsection B.01.010.2 (9) will provide that sulphites, required to be shown in the list of ingredients pursuant to sections B.01.008 and B.01.009 of the Regulations, may also be shown in a "Contains" statement when the total amount of sulphites present in the prepackaged product is 10 p.p.m. or more.

Top of Page

"Contains" Statement - Requirements:

Section B.01.010.3 will provide requirements for the "Contains" statement. This includes the requirement that the statement appear immediately after the list of ingredients when a list is provided. It is also specifies that a food allergen or gluten source is not required to be shown more than once in the statement. This section also requires that when a "Contains" statement is used, it must be complete for all food allergens and gluten present in the prepackaged product as well as for added sulphites when they are present in a total amount of 10 p.p.m. or more in a prepackaged product.

Standardized Alcoholic Beverages and Vinegars - Labelling Requirements:

Bourbon whisky, standardized alcoholic beverages and vinegars, referred to in paragraphs B.01.008 (2)(*f*) and (*g*) of the Regulations are exempt from carrying a list of ingredients but they do require a label. These products remain exempt from carrying a list of ingredients. In accordance with subsections B.01.010.1 (2) and B.01.010.2 (3) of the regulatory amendments, food allergens, gluten or added sulphites in a total amount of 10 p.p.m. or more must be shown on the label of these products in a "Contains" statement or in a list of ingredients. Subsection B.01.010.1 (5) and B.01.010.2 (5) specifically exempt prepackaged beer, ale, stout, porter and malt liquor for which a standard is prescribed in section B.02.130 or B.02.131 from the labelling requirements specified in these regulatory amendments unless a list of ingredients is voluntarily provided.

Exemptions:

As set out in subsections B.01.010.1 (4) and B.01.010.2 (4), the labelling requirements of these regulatory amendments will not apply to food allergens, gluten or added sulphites present in the following prepackaged products unless the product label includes a list of ingredients;

i. products packaged from bulk on retail premises, except prepackaged products that are a mixture of nuts,

ii. individual portions of food that are served by a restaurant or other commercial enterprise with meals or snacks or individual servings of food prepared by a commissary and sold by automatic vending machines or mobile canteens,

iii. meats, meat by-products, poultry, poultry meat, or poultry meat by-products that are barbequed, roasted or broiled on the retail premises.

As noted above, subsections B.01.010.1 (5) and B.01.010.2 (5) specifically exempt beer, ale, stout, porter and malt liquor for which a standard is prescribed in section B.02.130 or B.02.131 from the labelling requirements specified in these regulatory amendments unless a list of ingredients is voluntarily provided.

Other Amendments:

Several provisions of the Regulations will be modified or repealed.

In the English version of the Regulations, the spelling of "hydrolysed" in item 30 of the table to subsection B.01.009 (1) and paragraph B.01.009 (3) (*c*) will be changed to "hydrolyzed". This will be consistent with the spelling of "hydrolyzed" in other provisions of the Regulations. In the French version of the Regulations, the term « protéines végétales hydrolysées » will be written in singular in paragraph B.01.009(3)*c*) for consistency with other provisions in the Regulations.

Subsection B.01.009 (5) of the Regulations will be repealed. Subsection B.01.009 (5) was originally added to the Regulations to provide information to food allergic consumers about the presence of a food allergen from the use of lysozyme as a food additive. This requirement would be redundant since these regulatory amendments will require that egg be shown as a food allergen source if any protein, modified protein or any protein fraction of egg is present in the prepackaged product.

Item 21 of the Table to paragraph B.01.010 (3)(*b*) of the English version of the Regulations is modified to allow for the alternate spelling of the term "sulfites" and "sulfiting agent" as the common name of an ingredient or component.

To ensure consistency with paragraph B.01.010(3)(*a*), item 20, which specifies the common name for starch, section B.13.011 will be amended by placing the term "corn starch" in boldface type, thus making this term the common name of the food.

Paragraphs B.01.008 (5)(*a*), D.01.007 (1) (*a*) and D.02.005 (1) (*a*) are modified to specify the order in which the ingredient name, food allergen or gluten source and components are to be shown in the list of ingredients.

Section B.24.018, which sets out the criteria for foods making a "gluten-free" claim, has been modified to align with the definition of "gluten" in subsection B.01.010.1 (1).

Top of Page

Regulatory and non-regulatory options considered

The discussion on regulatory and non-regulatory options has been organized in the following manner:

1. food allergens and gluten;
2. sulphites.

1. Food Allergens and Gluten:

A food allergy is an immune response to the protein in specific foods.[15] Individuals with either a food allergy or celiac disease react to the protein portion of the food. Consequently, the options considered for food allergens were also considered suitable for gluten.

It is not Health Canada's intent that these regulatory amendments would apply to a food allergen or gluten that is present in the prepackaged product as a result of cross-contamination. The cross-contamination of prepackaged foods with priority allergens and gluten are unique issues which are beyond the scope of this regulatory initiative.

Three options for the labelling of food allergens and gluten were considered.

Option 1:

To maintain the status quo of the Regulations and to provide limited government intervention to encourage food manufacturers and importers to declare components and ingredients that are known to trigger a reaction in food allergic individuals or provoke symptoms of celiac disease. These ingredients or components are exempt from the requirement to be shown in the list of ingredients pursuant to subsections B.01.009 (1) and (2) of the Regulation.

Under the status quo, Health Canada and the CFIA have encouraged industry to declare, on a voluntary basis, food allergens that are ingredients and components of prepackaged products but which are exempt from label declaration under the Regulations. However, from the consumer's perspective, there have been concerns about the reliability and completeness of the information provided on the product label with this approach since the consumer had no assurance that all the food allergens would be declared. In addition, industry did not have clear guidance on how to declare these ingredients in such situations.

Option 2:

To propose regulatory amendments that would remove the exemptions provided in subsections B.01.009 (1) and B.01.009 (2) of the Regulations when the ingredients or components are foods identified as food allergens or gluten. The definition of food allergen or gluten would include all derivatives of those foods identified as food allergens or gluten.

This option would require declaring ingredients and components that do not contain the protein or protein derivatives. As a result, this option could unnecessarily reduce the number of suitable food choices available to consumers with food allergies and celiac disease. This over-labelling requirement would also be a burden to industry. Furthermore, since this option focuses on ingredients and components, it would not capture allergen or gluten protein present as a result of the formulation of a component of a component.

Option 3:

To propose regulatory amendments that would require that the source of a food allergen or gluten be shown on the product label. In this case, "food allergen" would be defined to include any protein from any of the foods specifically listed in the definition, or any modified protein, including any protein fraction, that is derived from any of these foods. "Gluten" would be defined as any gluten protein from the grain of any of the cereals listed in the definition or the grain of a hybridized strain created from at least one of these cereals. The definition would also include any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of these cereals or the grain of a hybridized strain mentioned above. This option is science based and would capture any food allergens or gluten present in the product, including those present as a result being added as a component of any component of the prepackaged product. This option would specifically exclude food allergens or gluten present in the prepackaged product as a result of cross-contamination.

This was the option selected for the development of the proposed amendments published in *Canada Gazette*, Part I in July 2008. See section entitled "Rationale" for further discussion and details regarding this option.

2. Sulphites:

Five options were considered for labelling requirements when sulphites are added to prepackaged

products. It is not Health Canada's intent that these regulatory amendments would apply to the presence of naturally occurring sulphur containing compounds or, sulphurous compounds as a result of the application of agricultural chemicals. In addition, following the pre-publication of the proposed amendments, Health Canada further clarified that the regulatory amendments are not intended to apply to sulphites that are produced during the fermentation of wine and beer.

Option 1:

To maintain the status quo of the Regulations and to provide limited government intervention to encourage food manufacturers and importers to declare sulphites whenever they are ingredients or components and the amount of added sulphites equals or exceeds 10 parts per million in the prepackaged product. Sulphites are components in many ingredients, preparations and mixtures exempt from the requirement to be declared in the list of ingredients pursuant to subsections B.01.009 (1) and (2) of the Regulations.

Under the status quo, Health Canada and the CFIA have encouraged industry to declare, on a voluntary basis, added sulphites present in a total amount of 10 p.p.m. or more that are exempt from being shown on the label under the Regulations.& However, from the consumer's perspective, there have been concerns about the reliability and completeness of the information on the product label using such an approach since the consumer could not know if the manufacturer voluntarily listed all added sulphites.

Option 2:

To amend the Regulations to require that sulphites be shown in the list of ingredients whenever they are added, in any amount, as an ingredient or component of an ingredient. This would include components of ingredients or classes of ingredients listed under subsections B.01.009 (1) and ingredients and components of preparation or mixtures listed under B.01.009 (2) of the Regulations. This declaration would be required regardless of the amount of added sulphites present in the prepackaged product.

This option is not supported by a health rationale and the scientific information which indicates that exposure to a food with sulphites below 10 p.p.m. is unlikely to lead to an adverse reaction.

Top of Page

Option 3:

To amend the Regulations to require that sulphites, added as ingredients or components, be shown in the list of ingredients only when the total amount of added sulphites in the prepackaged product is 10 p.p.m. or more. This regulatory requirement would apply to sulphites added to the prepackaged product as an ingredient or a component required to be shown in the list of ingredients pursuant to sections B.01.008 and B.01.009 as well as sulphites added as ingredient or components of ingredients, class of ingredients, preparation or mixture listed under subsections B.01.009 (1) and B.01.009 (2) respectively of the Regulations.

This option would result in an inconsistent labelling approach between sulphites and other food additives. Currently, food additives, with the exception of those present in an ingredient, component or mixture listed in subsections B.01.009 (1) or (2), must be shown in the list of ingredients whenever they are added as an ingredient or a component, regardless of their amount. The labelling requirement for food additives enables consumers to determine when food additives have been added to a prepackaged product that they purchase.

Option 4:

To propose a regulatory amendment to remove the exemption for showing sulphites in the list of ingredients when sulphites are added as a component of an ingredient or class of ingredients listed under B.01.009 (1) or as a ingredient or component of a preparation or mixture listed under subsection B.01.009 (2) of the Regulation. These sulphites would be required to be shown on the label when they are added in a total amount of 10 p.p.m. or more.

In 2004, Health Canada provided information to the general public and to industry regarding the enhanced labelling of sulphites, via a webposting, indicating that this option was feasible. However, it was later noted that this option would establish two distinct rules for showing sulphites in the list of ingredients. Section B.01.008 of the Regulations would require that sulphites, added as ingredients or components, be shown regardless of the amount added to the prepackaged product. However, sulphites added as a component of an ingredient or class of ingredients listed in B.01.009 (1) or ingredient or component of a preparation or mixture listed in B.01.009 (2) would only be shown when the total amount of added sulphites in the prepackaged product is 10 p.p.m. or more. This was not considered to be a viable option because of this inconsistency and because it could lead to consumer confusion regarding the presence and the level of sulphites in the prepackaged product.

Option 5:

To maintain the regulatory requirements for showing sulphites in the list of ingredients pursuant to section B.01.008 and B.01.009 of the Regulations and to propose an amendment to require that sulphites be shown in a separate statement on the label when added sulphites are present in a prepackaged product in a total amount of 10 p.p.m. or more.

This option was selected under the proposed amendments which were pre-published in July 2008 in *Canada Gazette*, Part I. Under this option, the separate statement for showing added sulphites would begin with the words "Allergy and Intolerance Information - Contains".

Based on comments received following the pre-publication of the proposed amendments in *Canada Gazette*, Part I, modifications have been made to this option.

The requirement to show added sulphites on the label of a prepackaged product, when they are present in a total amount of 10 p.p.m. or more, has been retained. However, the statement "Allergy and Intolerance Information - Contains:" has been changed to "Contains". In addition, when sulphites are shown in the list of ingredients pursuant to sections B.01.008 or B.01.009 of the Regulations and added sulphites are present in a total amount of 10 p.p.m. or more, they will not be required, as previously proposed, to be shown in the "Contains" statement - unless a "Contains" statement appears on the label. In the case of added sulphites that are present in the prepackaged product in the total amount of 10 p.p.m. or more and not required to be shown in the list of ingredients pursuant to sections B.01.008 or B.01.009 of the Regulations, these regulatory amendments will require that they be shown on the label of the product, either in the list of ingredients or in the "Contains" statement.

There will be an additional labelling requirement to show one of the terms "sulphite", "sulphiting agents", "sulfite" or "sulfiting agent" on the label when added sulphites are present in a total amount of 10 p.p.m. or more. Thus, when "sodium diothionite", "sulphurous acid" and "sulphur dioxide" are used as the ingredient name in the list of ingredients, this additional requirement will apply.

Top of Page

Benefits and costs

Benefits:

As described in detail below, the key benefits that are expected to result from these regulatory amendments include:

- a reduction in accidental ingestion of foods to which individuals with food sensitivities react, accompanied by a corresponding reduction in adverse reactions;
- reduced costs to the health care system;
- reduced costs for individuals with food sensitivities and their families;
- improved quality of life for individuals with food sensitivities and their families.

A Reduction in Accidental Ingestion of Foods to which Individuals with Food Sensitivities React, Accompanied by a Corresponding Reduction in Adverse Reactions:

Food allergies affect approximately 1.2 million Canadians (5 to 6% of young children; 3 to 4% of older children and adults)[16], [17], [18]. Celiac disease affects about 1% of the population or approximately 340,000 Canadians[19] A chemical sensitivity to sulphites affects approximately 200,000 Canadians, the majority of whom also have asthma.[20], [21] Taken together these conditions affect the health of approximately 1.75 million Canadians.

Recent Canadian evidence suggests that consumer use of labelling information does not always result in food allergic individuals successfully avoiding food allergens present in prepackaged products. Sheth et al.[22] conducted a survey of Canadian families with food allergic members. About half of the respondents reported having experienced at least one accidental exposure to a food allergen in a prepackaged product. Approximately 13% of respondents attributed the accidental exposure to the food allergen not being identified in plain language on the label. Another 16% reported that the food allergen was a "hidden ingredient" that was not shown on the product label.

Individuals with celiac disease experience similar problems with food labels. In 2006, Zarkadas et al.[23] reported that 85% of respondents to a survey of members of the Canadian Celiac Association had problems determining, from the label information, whether a prepackaged product contained gluten.

With regard to sulphites, extremely sensitive individuals are counselled to read food labels carefully[24].

The enhanced labelling information on prepackaged products that will result from the regulatory amendments is expected to be used not only by food sensitive consumers and their immediate families, but also by extended family members, friends and others who interact with food sensitive individuals on a regular basis. By assisting all consumers in identifying foods that are likely to trigger a reaction in a food sensitive individual, it is expected that the labelling requirements set out in these regulatory amendments will contribute to decreased rates of accidental ingestion of foods that can trigger adverse reactions. It is also expected that these labelling requirements will indirectly assist some organizations and institutions in implementing their own food allergy management policies. For example, many school boards have anaphylaxis management policies[25], [26].

Reduced Costs to the Health Care System:

Food Allergies

An allergic reaction to food is a common cause of anaphylaxis, accounting for one-third to one-half of the anaphylaxis cases treated in hospital emergency rooms[27], [28]. While anaphylaxis has a rapid onset and can result in death, most affected individuals recover completely[29]. It has been estimated that there are 150 to 200 deaths from food-induced anaphylaxis in the United States each year[30]. Comprehensive data are not available for Canada, but it was reported that 32 of 63 confirmed anaphylaxis deaths that occurred in Ontario between 1986 and 2000 were food-related[31].

There are a number of ways in which a food allergen can be accidently ingested. These include, but are not limited to: the label of a prepackaged product can be incomplete or use complex language; a food allergen can be present as a result of cross-contamination; or consumer error can occur. No information could be located in the published literature that linked deaths from food induced anaphylaxis with the circumstances under which the food allergen that triggered the adverse reaction had been ingested. Consequently, a reduction in potential deaths was not

included in the estimation of anticipated cost savings associated with the regulatory amendments. This has resulted in a potential under-estimation of cost savings from these regulatory amendments. The magnitude of the potential under-estimation is not known.

In terms of non-fatal allergic reactions, Sheth et al[32] reported that 29% of survey respondents attributed an accidental ingestion of a food allergen to the allergen not being identified in plain language on the label (13%) or to the allergen being a "hidden ingredient" (16%). Assuming that these respondents reported accidental ingestion that had occurred during the three years prior to the survey, it can be estimated that, in a given year, approximately 10% of respondents (29/3) accidentally ingested an allergen because of problems with the completeness or clarity of the ingredient information provided on the label of prepackaged products.

To estimate the reduction among Canadians in the annual number of adverse reactions to food allergens requiring medical care that can be expected to follow implementation of these regulatory amendments, two assumptions were made:

- 10% of adverse reactions to food allergens treated in hospital emergency rooms, in hospital in-patient settings and in physicians' offices are attributable to accidental ingestion of a food allergen present in a prepackaged product[33]. Specifically, included in the scope of this assumption are those accidental ingestions that occurred either because the food allergen was not identified in plain language on the product label or because it was a "hidden ingredient" that was not shown on the label;

- a 50% reduction in the number of accidental ingestions of food allergens[34, 35] attributable to the conditions described in the previous bullet is anticipated following implementation of these regulatory amendments because of the enhanced labelling requirements.

To estimate the savings in health care costs associated with the reduction in adverse reactions to food allergens expected to follow these regulatory amendments, published data on the annual number of physician visits, emergency room visits and hospitalizations for treatment of food allergies in the United States[36, 37] were extrapolated to the Canadian population. Canadian remuneration rates[38] for physician care, emergency room care and hospitalization were then applied. Estimated saving in health care costs are presented as Benefit 1, under Quantified Impacts, in the Cost-benefit statement. A saving of $0.4M is estimated for 2012-3, rising to an estimated $0. 7M for 2013-14.

Top of Page

Celiac disease

An improved ability to identify gluten in prepackaged products is expected to improve an individual's ability to follow a gluten-free diet. In turn, this can be expected to result in a reduction of both the short-term problems associated with celiac disease and the probability of long-term complications. Cost savings can be expected to follow from a reduced need for medical care. Because these cost savings have not been estimated quantitatively, their impact is included in the Qualitative Impacts section of the cost-benefit summary statement.

Sulphite Sensitivity

An improved ability to identify added sulphites present in prepackaged products in a total amount of 10 p.p.m. or more is expected to reduce the frequency with which acute asthmatic reactions are triggered among susceptible individuals. A corresponding reduction in costs associated with visits to hospital emergency rooms, hospitalizations and physician visits would be expected. Because these cost savings have not been estimated quantitatively, their impact is included in the Qualitative Impacts section of the cost-benefit summary statement.

Reduced Costs for Individuals with Food Sensitivities and their Families:

Fox et al (2009)[39] reported that households with food sensitive members had annual costs for items such as special foods and equipment, travelling to medical appointments, absentee time from paid work and time spent seeking information about the food they purchase or consume that averaged 3651 euro (approximately $4894 Canadian) higher than costs for households without food sensitive members. Assuming that the approximately 1.75 million Canadians with food sensitivities live in approximately 1.2 million households (1.5 food-sensitive members per household) and using the value of $4894 Canadian (converted) from the report by Fox et al. (2009), the additional costs for Canadian households with food sensitive members can be estimated to approach $5.7B annually.

Cost savings associated with these regulatory amendments have been estimated for two categories of additional costs for households with food sensitive members. These are:

- cost savings associated with fewer days absent from work for adults, and for parents of children, who required medical care for an adverse reaction to a food allergen;[40, 41]
- cost saving associated with time saved by households with food sensitive members in identifying and verifying information about the foods that they purchase and consume.

Cost Savings Associated with Fewer Days Absent from Work

Cost savings associated with fewer days absent from paid employment were estimated quantitatively for food allergies only, using the information discussed above and from reports by Flabbee et al. (2008)[42] and Rivas[43]. Flabbee (2008) et al. reported three work/classroom days were lost per patient treated for severe food-induced anaphylaxis. Rivas reported that when adults took time off work because of their allergy (of any type) the median length of leave taken was three days. Three days was also the median length of leave taken by parents of allergic children when the children were off school for their allergy.

It was assumed that treatment in an emergency room or an in-hospital setting for an adverse reaction to a food allergen resulted in three days of leave from paid employment by an adult experiencing the reaction or by one parent of a child experiencing the reaction. As well, it was assumed that when an individual had an adverse reaction to a food allergen that required treatment in a physician's office, this was associated with one day of leave from paid employment. Further it was assumed that adults received the average hourly wage for Canadians[44] and worked an average of eight hours/day.

Estimated saving from fewer days absent from work for adults with food allergies and parents of children with food allergies are presented as Benefit 2, under Quantified Impacts, in the Cost-benefit statement. A saving of $0.7M is estimated for 2012-3, rising to an estimated $1.2M/year in 2013-14.

An improved ability to identify gluten present in prepackaged products is also expected to reduce days absent from work subsequent to short-term problems as well as long-term complications associated with celiac disease. Because these cost savings have not been estimated quantitatively, their impact is included in the Qualitative Impacts section of the cost-benefit summary statement.

An improved ability to identify added sulphites present in a total amount of 10 p.p.m. or more in prepackaged foods is expected to reduce days absent from work subsequent to acute asthmatic reactions requiring medical care. Because these cost savings have not been estimated quantitatively, their impact is included in the Qualitative Impacts section of the cost-benefit summary statement.

Top of Page

Cost Saving Associated with Reduced Time Needed Identifying and Verifying Information about Prepackaged Products

Adults with food sensitivities and parents of children with food sensitivities need to know exactly what is in each and every food they purchase or consume. For this reason, they are advised not to purchase foods that do not have a list of ingredients. They are also advised that, because ingredients of prepackaged products can change, they need to read the product label every time they make a purchase. To further enhance safety, often they are advised to verify the label of a prepackaged product at least three times; when they purchase it, when they unpack and store it, and when they consume or serve it. This advice applies to all prepackaged products, including those that have been consumed repeatedly, and without problem by the food sensitive individual in the past[45], [46], [47]. As well, whenever they feel that the information provided on the label is incomplete or unclear, consumers are advised to call the manufacturer or importer to obtain additional information.

Activities such as those described above can be time consuming. For example, Cureton and Fasabo (2009)[48] reported that shopping for a gluten-free diet takes between 10 and 20 hours longer per month than is needed by the average family. The additional time was used for activities such as contacting food manufacturers, reading product labels and searching the Internet to identify foods that do not contain gluten.

These regulatory amendments will require that food allergens and gluten present in a prepackaged product, but not as a result of cross-contamination, be identified on the label using clear, simple language. For example, if mustard is a component of a spice mixture, it will be required to be shown on the label of the prepackaged product. As well, if casein is used as an ingredient or component, the food allergen source "milk" will also be required to be shown on the label of the prepackaged product. In addition, added sulphites present in a total amount of 10 p.p.m. or more will be required to be shown on the label of the prepackaged product.

This enhanced labelling information can be expected to reduce the additional time families with food sensitive members need to identify and verify what is in the prepackaged products they purchase or consume. Because the information in simple and consistent language will be readily available on the label of prepackaged products in simple and consistent language, label reading will be simplified. Households with food sensitive members will no longer need to interpret the many technical terms that can be used to describe a food allergen such as milk. As well the need to contact product manufacturers and importers to obtain additional information about what is in a product is expected to be reduced.

It is estimated that the enhanced labelling requirements set out in these regulatory amendments could result in a time saving of about 10 minutes per week[49] (40-50 minutes/month) for each household with a food sensitive member. This corresponds to 5 to 10% of the 10-20 additional hours per month reported by Cureton and Fasano for households shopping for a gluten-free diet and to about 4% of the additional costs reported by Fox et al (2009)[50] for households with food sensitive members. With an estimated 1.2 million Canadian households with food sensitive members, the average hourly wage for Canadians and an assumed eight hour work day, an associated saving of $106.5.M is estimated for 2012-3 and $197.1M for 2013-14.

It is possible that after these regulatory amendments have been implemented, consumers will come to consider the enhanced label information on prepackaged products as the status quo. To account for this, the estimated initial time savings of 10 minutes per week per affected household was reduced to 5 minutes per week per affected household for 2015-16 and thereafter.

Improved Quality of Life for Individuals with Food Sensitivities and their Families:

Food sensitivity can be associated with a lower quality of life. Individuals with food sensitivities and their families need to be continuously alert so that accidental ingestion of foods to which they react is minimized. Efforts to minimize the risk of accidental ingestion of foods that can trigger an adverse reaction can unduly restrict consumption of other foods[51]. Such efforts can also negatively impact the socialization of individuals with food sensitivities, particularly children and their parents[52].

The enhanced labelling information resulting from these regulatory amendments is expected to assist individuals with food sensitivities and their immediate families in avoiding foods that can trigger adverse reactions. As well, this information can be expected to assist extended family members, friends and others identify prepackaged products that can be safely consumed by those with food sensitivities.

It is anticipated that these regulatory amendments will contribute to a reduction in uncertainty and fear among food sensitive individuals and their families regarding accidental ingestion of the food allergens, gluten or added sulphites they are trying to avoid. As well, there may be fewer foods that are unduly restricted. Furthermore, opportunity for socialization may be increased. Each of these changes can be expected to contribute to an improved quality of life for individuals with food sensitivities and their families.

Top of Page

Costs:

Costs to Government:

Estimated costs for the CFIA to implement these amendments are $3 M annually. These funds are required to: increase inspection capacity; train inspectors and program staff; update inspection manuals; update educational material for consumers; develop educational and training tools for use by food manufacturers and importers; validate and implement new food allergen detection methodologies; and establish and conduct risk based monitoring and compliance activities. The CFIA also anticipates an initial increase in the number of compliance and enforcement actions once the regulations are in place.

Costs to Health Canada for the start-up and on-going delivery of this component of the Food Directorate's program activities are projected to be $1 M annually. These activities include: responses to questions from food manufacturers/importers, health associations, the CFIA and consumers with regard to the interpretation and scope of the Regulations; provision of health risk assessments and related advice to the CFIA regarding compliance and enforcement issues; and research and methodology development for the establishment and refinement of food allergen protein detection and quantification. In addition, Health Canada will work with the CFIA to develop related operational policy and educational materials for consumers.

Cost to Industry:

In order to obtain data from the food industry on the potential impacts of the regulatory amendments, a Business Impact Test (BIT) was conducted by Consulting and Audit Canada in 2002. Based on the BIT, the one time costs of these regulatory amendments was estimated to be $101.8 million over a two (2) year phase-in period with ongoing costs of $12.95 million/year.

Health Canada notes that the authors of the BIT indicated that based on comments received, some respondents may have included the costs of controlling cross-contamination in their estimates. Controlling cross-contamination is not included in the scope of these regulations. Consequently, these estimates may over-state the true cost of the regulatory amendments. Furthermore, during the development of these regulatory amendments, certain aspects initially considered to be within the scope of the BIT were subsequently excluded. It is anticipated that the exclusions will further reduce the costs estimated in the BIT.

Cost benefit statement[53], [54], [55], [56]

A. Quantified Impacts ($ millions 2011)		2011-12	2012-13	2013-14	2014-15	2020-21	Total (PV)[57]	Average Annual (PV)
Benefit-1 Reduced health care costs associated with allergic	Provinces and territories	----	0.4	0.7	0.6	0.4	4.5	0.4

reactions to food								
Benefit-2. Reduced costs for families, due to few days absent from work following allergic reactions requiring medical care	Canadians	----	0.7	1.2	1.0	0.7	8.2	0.8
Benefit-3: Reduced cost for families, because they will need less time to identify and verify information about allergens, gluten and added sulphites present in prepackaged foods	Canadians	----	106.5	197.1	84.5[58]	57.5	908.1	90.8
Total (PV) Benefits per year (B1+B2+B3)		----	107.5	199.0	86.1	58.6	920.7	92.1
Cost-1: Costs for Health Canada	Health Canada	1.1	1.0	0.9	0.8	0.5	7.6	0.8
Cost-2: Costs to enhance CFIA's allergen monitoring and compliance activities	Manufacturers and Importers	3.2	2.9	2.7	2.3	1.6	22.9	2.3
Cost-3: Initial and on-going costs to industry	Food Producers	60.0	55.6	13.1	11.2	7.6	196.8	19.7
Total (PV) Costs per year (C1+C2+C3)		64.2	59.5	16.7	14.3	9.7	227.4	22.7
(PV) Benefits- Costs: (B1+B2 + B3)- (C1+C2+C3)		-64.2	48.0	182.3	71.8	48.9	693.4	69.3

Top of Page

B. Qualitative Impacts

There are a number of other benefits that can be expected to follow implementation of these regulatory amendments. Examples are provided below. While these additional benefits have not been quantified, their monetized value is expected to be substantial, potentially more than the costs quantified above.

Benefit-1: Fewer adverse reactions that require medical care.	Provincial and Territorial Governments	Reduced costs are expected to be associated with: • reduced costs for medical treatment of acute asthmatic reactions triggered by sulphite ingestion; • reduced costs for medical treatment of short-term symptoms or long-term complications of celiac disease; • costs for schools, daycare providers and others implementing strategies for the management of food sensitivities may also be reduced.
Benefit-2: Reduced costs for affected families	Canadians	Reduced costs are expected to be associated with: • reduced need for medication to treat reactions; • reduced number of sick days following reactions that did not require medical care; • reduced travel for medical care; • improved quality of life for adults and children with food sensitivities and for parents of children with food sensitivities.

Summary:

The enhanced labelling requirements set out in these regulatory amendments are expected to reduce the accidental consumption of food allergens, gluten or added sulphites present in prepackaged products by food sensitive consumers. This will result in a corresponding reduction in adverse reactions. Consequently, reduced costs to the health care system, as well as reduced costs and improved quality of life are expected for individuals with food sensitivities and their families.

It was not possible to quantify all of the expected benefits of the regulatory amendments. Quantified benefits include: reduced health care costs for provinces and territories associated with food allergic reactions; reduced costs for families due to fewer days absent from work following a food allergic reaction; and reduced time for identifying and verifying information about prepackaged foods that can trigger an adverse reaction by all families with food sensitive members. Qualitative benefits are more numerous and include: improved quality of life for adults and children with food sensitivities, and for parents of children with food sensitivities; reduced costs for the medical treatment of acute asthmatic reactions triggered by sulphite ingestion and reduced costs for the treatment of the short term symptoms and the long-term complications of celiac disease.

Rationale

Enhanced labelling of prepackaged products was considered the most effective means to assist consumers with food allergies, celiac disease or a sulphite sensitivity in making informed choices and to avoid those prepackaged foods that may trigger an adverse reaction. Since the Regulations set out requirements for the labelling of ingredients and components of most prepackaged products, amending the Regulations to enhance the labelling of prepackaged products was considered an appropriate option.

A regulatory approach is consistent with the approach taken by Canada's major trading partners. The United States, the European Union and Australia/New Zealand have implemented legislation or regulations for the mandatory declaration of food allergens and added sulphites. The European Union and Australia / New Zealand also require the mandatory labelling of cereals containing gluten.

The amendments to the Regulations are consistent with the recommendations set out by the Codex Alimentarius Commission in its standard, *General Standard for the Labelling of Prepackaged Foods*, Codex Stan 1-1985 (amended 2010). The Codex Alimentarius Commission was created in 1963 by Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers, ensuring fair practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Section 4.2.1.4 of the Codex *General Standard for the Labelling of Prepackaged Foods*, specifies:

The following foods and ingredients are known to cause hypersensitivity and shall always be declared:

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

Top of Page

The following table outlines the key elements of the approaches taken by the United States, the European Union, Australia/ New Zealand and Canada in implementing the Codex recommendations.

Element	United States	European Union	Australia / New Zealand	Canada
1. Policy Instrument(s)	*Food Allergen Labeling and Consumer*	*Directive 2000/13/EC* Updated with	*Australia New Zealand Food Standards Code,*	Amendments to Division 1 of the *Food and Drug Regulations*

	Protection Act of 2004 (FALCPA) *Code of Federal Regulations*, Title 21 - *Food and Drugs*, Part 130-*Food Standards: General Sec. 130.9. Sulphites in Standardized foods*.	*Directive 2007/68/EC*	Standard 1.2.3, December 2002	(Pre-published in *Canada Gazette,* Part I on July 26th, 2008 with some modifications as outlined in this document)
2. Consistency with the Codex list of foods and ingredients that require mandatory declaration	Codex list **minus** cereals containing gluten are included in FALCPA. Sulphites are covered by *Code of Federal Regulations*, Title 21.	Codex list **plus** celery & products thereof, mustard and products thereof, sesame seeds and products thereof, lupin and products thereof, molluscs and products thereof.	Codex list **plus** sesame seeds.	Codex list **plus** shellfish (meaning mollusc in Canada); sesame seeds and mustard seeds.
3. Exemptions to the list of foods and ingredients that require mandatory declaration	Highly refined oil.	Multiple (see Note 1).	Gluten in standardized beer and spirits; isinglass from swim bladders in beer and wine.	None listed in regulations. Note: the Canadian regulations apply only to the part of the ingredient or component that is responsible for the adverse reaction (e.g. the protein fraction).
4. Scope of products to which mandatory labelling requirements apply	FALCPA - prepackaged products excluding standardized alcoholic beverages. Sulphites - prepackaged products including standardized alcoholic beverage.	Includes foods that carry a label. Also applies to standardized alcoholic beverages with some exemptions as outlined in Note 1 below	Includes foods that carry a label and do not carry a label. Also applies to standardized alcoholic beverages with some exemptions (see row above)	Prepackaged products that carry a label and a list of ingredients plus vinegars subject to a standard in Division 19 and most alcoholic beverages subject to a standard in Division 2 of the Regulations. Note: Prepackaged beer, ale, stout, porter and malt liquor, subject to a standard prescribed in section B.02.130 or B.02.131, are exempt unless a list of ingredients is voluntarily provided.
5. Trigger for the mandatory declaration of foods or ingredients identified in element 2	Food is or contains an ingredient that is a major food allergen.	When used as a food ingredient and still present in the product.	When present as: an ingredient; an ingredient of a component ingredient; a food additive or component of a food additive; a processing aid or a component of a processing aid.	For food allergens and gluten - when protein, modified protein, including any protein fraction (of the foods listed in element 2) is present, but not as a result of cross-contamination. Sulphites - when the total amount of added sulphites is 10 p.p.m. or more.
6. Format of	FALCPA:	Indicate on the	Declare in the list of	Declaration can be done in the

Declaration	Declaration can be done in the list of ingredients or in a "Contains" statement.	label. For foods that do not carry a label, the information must be displayed with the food or provided to the purchaser upon request.	ingredients on label of food product.	list of ingredients or in a "Contains" statement. When "Contains" statement appears on the label, it must be complete for all food allergens and gluten present in the prepackaged product as well as for added sulphites when they are present in a total amount of 10 p.p.m. or more in the prepackaged product.
7. Mechanism to update the list of food and ingredients that require mandatory declaration	Two processes available as part of FALCPA; a petition process (see Note 2) and a notification process (see Note 3).	*Directive 2003/89/EC* provides for a systematic re-examination of the list of Annex IIIa.	Written applications can be made to FSANZ for consideration of an exemption. If successful then the table 4 (list of exemptions) of Standard 1.2.3 is amended.	Modifications to the list would require a regulatory amendment to the *Food and Drug Regulations*. (see note 4)

Notes to Table:

Note 1: These exemptions include: gluten in wheat based glucose syrups including dextrose; gluten in wheat based maltodextrins; gluten in glucose syrups based on barley; cereals used for making distillates or ethyl alcohol of agriculture origin for spirits and other alcoholic beverages; fish gelatine used as carrier for vitamin or carotenoid preparations; fish gelatine or isinglass used as fining agents in beer and wine; fully refined soybean oils and fat; natural mixed tocopherols, natural D-alpha tocopherols, natural D-alpha tocopherols acetate, natural D-alpha tocopherol succinate from soybean sources; vegetable oils derived from phytosterols and phytosterol esters from soybean sources; plant stanol ester produced from vegetable oil sterols from soybean sources; whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; lactitol; nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

Note 2: FALCPA has established a process by which any person may file a petition that provides scientific evidence (including the analytical method used to produce the evidence) that demonstrates that an ingredient, as derived by the method specified in the petition, does not cause an allergenic response that poses a risk to human health.

Note3: FALCPA has also established a process under 21 U.S.C. 343(w)(7) by which any person may file a notification containing scientific evidence demonstrating that an ingredient "does not contain allergenic protein." The scientific evidence must include the analytical method used and the ingredient must be derived by the specified method. Absent an objection, the food ingredient is exempt from FALCPA's labeling requirements for major food allergens.

Note 4: Criteria for addition of new food allergens to the list was developed and published on the Health Canada website. The document entitled, *The Canadian Criteria for the Establishment of New Priority Food Allergens*, is also available through Publications, Health Canada.

Top of Page

For the purposes of these regulatory amendments, Health Canada has included all the foods and ingredients identified in section 4.2.1.4 of the Codex *General Standard for the Labelling of Prepackaged Foods* in the scope of the regulatory amendments. Health Canada has also added mustard seeds, sesame seeds and shellfish to the definition of food allergen. These foods have been added to the Canadian definition of food allergen to meet the needs of the Canadian population.

For the purposes of these regulatory amendments, Health Canada has chosen to define the terms "food allergen" and "gluten" specifically as the protein, modified protein and protein fractions of the foods listed in the respective definitions. These definitions are based on the fact that it is the protein portion of the food allergen or the gluten that triggers the reaction in people with food allergies or celiac disease. Defining "food allergen" and "gluten" in terms of the protein, modified protein and protein fractions is driven by the health rationale associated with this regulatory initiative and will result in the application of the mandatory labelling requirements only when

prepackaged products contain the protein or protein portion of the ingredient or component.

Health Canada has excluded food allergens and gluten that may be present in a prepackaged product as a result of cross-contamination from these labelling requirements. The presence of food allergens and the presence of gluten in food products, as a result of cross-contamination, are unique issues and are beyond the scope of this regulatory initiative.

Health Canada has published the criteria it has adopted for the determination of the scientific validity of including new foods in the regulatory definition of food allergen. These criteria are being used by Health Canada to identify priority allergens in Canada and the resulting review will form the scientific justification for considering any subsequent regulatory amendments to the definition of food allergen.

These regulatory amendments do not include exemptions for specific ingredients. Health Canada will continue to monitor scientific evidence as it evolves nationally and internationally with particular emphasis on data specific to the Canadian context. As new scientific evidence becomes available, Health Canada will consider if further regulatory amendments may be necessary.

In developing these regulatory amendments, two options were considered with regard to where the source of the food allergen or gluten will be shown on the label of most prepackaged products. Both options were found appropriate to meet the information needs of the consumers with a food allergy or celiac disease. In order to provide manufacturers and importers some flexibility in the labelling of their products, both options for showing the source of food allergens or gluten were developed and incorporated into the regulatory amendments.

The two locations for showing the source of the food allergen or gluten are:

- in the list of ingredients, as part of the common name of the ingredient or component or in parenthesis, immediately following the common name of the ingredient or component in which it is present; or
- in a "Contains" statement which would immediately follow the list of ingredients when a list of ingredients is provided.

Initially, the above-noted options were not considered feasible for showing added sulphites in a total amount of 10 p.p.m. or more on the label of the prepackaged product. However, based on comments received following the pre-publication of the amendment in *Canada Gazette*, Part I, the mandatory requirement to always show added sulphites present in a total amount of 10 p.p.m. or more in a separate statement entitled "Allergy and Intolerance Information - Contains:" has been removed. Added sulphites present in a total amount of 10 p.p.m. or more will be required to be shown on the label, either in the list of ingredient or in a "Contains" statement.

Health Canada acknowledges that the removal of the mandatory requirement to show added sulphites that are present in the total amount of 10 p.p.m. or more in a separate statement may limit the choice of foods available to sulphite sensitive individuals. Section B.01.008 of the Regulations requires that when a prepackaged product consists of more than one ingredient, a list of ingredients, including subject to section B.01.009, components, be provided. This requirement would include sulphites added, in any amount, as ingredients or components. Thus, consumers will not be able to determine from the information provided in the list of ingredients, if the level of sulphites in the prepackaged product is below 10 p.p.m.. However, Health Canada has determined that there will be very few prepackaged products in which added sulphites are present as ingredients or components in an amount less than 10 p.p.m.. Thus, while the regulatory amendments may limit the food choices for those with a sulphite sensitivity, the impact is expected to be very small.

In summary, the implementation of these regulatory amendments will enhance the information provided on the labels of prepackaged products. This information will assist consumers with food allergies, celiac disease or a sulphite sensitivity in making informed choices about the foods that they purchase and consume. These regulatory amendments are consistent with the approach

taken by Canada's major trading partners in implementing the Codex recommendations for the mandatory declaration of foods and ingredients that may trigger an adverse reaction in individuals with a food sensitivity.

Top of Page

Consultation

Prior to the development of the *Canada Gazette*, Part I proposal, the following consultations were conducted:

- Prepublication in *Canada Gazette*, Part I on October 15, 1994 of a regulatory proposal for the mandatory declaration of sulphites on the label of all foods when present at a level of 10 p.p.m. or more;
- Consultation with industry, industry associations, patient groups, health professionals and consumer groups by Health Canada and Agriculture and Agri-Food Canada in March 1996;
- Commissioning of a Business Impact Test (BIT) in 2002 to seek input from industry on potential costs of implementing regulations for the labelling of allergens; and
- Issuance of a letter to various stakeholders and publication on Health Canada website regarding the final policy recommendations in February 2004.

Some of the key issues raised by stakeholders in these earlier consultations included: the definition of the food allergen; and the use of the terms "derivative" and "tree nut". In addition, the inclusion of sesame seeds and gluten source in the scope of the proposal was questioned. Other issues raised by stakeholders included the following: alternatives to labelling; test methods and application of the proposed regulations to imported products; application of the regulations to foods sold in bulk; and the effect of the regulations on the labelling of alcoholic beverages. These comments were addressed during the development of the *Canada Gazette*, Part I proposal pre-published on July 26th, 2008.

Following the pre-publication of the proposed amendments, Health Canada received just over 140 comments from stakeholders including consumers, health professionals, patient groups, industry associations, industries and other governments. Overall, the comments received indicate support for the regulatory amendments. Health Canada also received suggestions regarding how specific aspects of the regulatory amendments could be improved.

To address the comments received, Health Canada held a number of targeted meetings with stakeholders. In addition, the following documents were posted on Health Canada's website to keep stakeholders informed of the changes being made to the regulatory amendments:

- *Health Canada Reviews and Answers Comments Received on Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites* (June 2010);
- *Health Canada's Modifications to Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites (June 2010);*
- *Health Canada's Revised Food Labelling Requirements for Added Sulphites* (June 2010);
- *Health Canada Considers Comments for Possible Exemptions from the Enhanced Labelling Requirements for Foods or Ingredients Derived from Food Allergen or Gluten Sources* (June 2010);
- *Garlic & Onion: Insufficient Evidence to Include on the List of Priority Food Allergens in Canada - A Systematic Review* (August 2009);
- *Health Canada's Proposal to Update the Canadian List of Food Allergens Requiring Enhanced Labelling* (August 2009);
- *Mustard: A Priority Food Allergen in Canada - A Systematic Review* - HC Pub: 100325 (August 2009) ;
- *Proposed Exemptions from Food Allergen Declaration for Fining Agents and Wax Coatings* (August 2009);

- *The Canadian Criteria For The Establishment of New Priority Food Allergens* - HC Pub: 100326 (August 2009)); and
- *Health Canada Reviews Comments Received on Regulatory Project 1220 - Enhanced Labelling for Food Allergens and Gluten Sources and Added Sulphites* (May 2009).

The following are the key issues raised following pre-publication of the proposed amendments in *Canada Gazette*, Part I.

Definition of Food Allergen - Mustard Seeds, Onion and Garlic:

Health Canada received several requests to add mustard seeds, onions and garlic to the list of foods included in the regulatory definition of food allergen. In addition, a comment was made regarding the necessity to regularly review the list of foods included in the definition.

Health Canada acknowledges the necessity of such reviews and is committed to this aspect of its policy and regulatory program. Health Canada has published the criteria it has adopted for the determination of the scientific validity of including new foods in the regulatory definition of food allergen. These criteria are used by Health Canada to identify priority allergens in Canada and the resulting review will form the scientific justification for considering any subsequent regulatory amendment to the definition of food allergen.

Health Canada also undertook a systematic review of the scientific literature on mustard seed, onion and garlic against these criteria. As a result, Health Canada has added mustard seeds as one of the foods listed in the definition of "food allergen". Garlic and onion did not meet the criteria for inclusion and have not been added to the regulatory definition of food allergen.

To inform stakeholders of its decision, Health Canada posted the following document on its website in August of 2009:

- *The Canadian Criteria For The Establishment of New Priority Food Allergens*
- *Mustard: A Priority Food Allergen in Canada - A Systematic Review*
- *Garlic & Onions: Insufficient Evidence to Include on the List of Priority Food Allergens in Canada - A Systematic Review*

Comments received from consumers and patient groups following the posting of these documents were positive. However, Health Canada heard that certain industry sectors would incur costs due to the addition of mustard seed in the definition of food allergen. To help offset the costs, the affected industry sectors requested a twenty-four month transition period. In balancing the needs of the food sensitive individuals and the industry concerns stated above, eighteen months will be the timeframe for these regulatory amendments to come into force. As a result of other changes to the proposal, there is no suitable trigger that can be used for compliance purposes during a transition period. Thus, these regulatory amendments will have a delayed coming into force period of 18 months.

Top of Page

Definition of Food Allergen and Gluten - Inclusion of the Terms Kamut and Spelt:

Some stakeholders recommended that all varieties of wheat, including spelt and kamut, be shown on the label by the term "wheat".

In response to this comment, spelt and kamut have been removed as distinct terms in the definition of "food allergen" and "gluten" and as the prescribed name for the food allergen source and gluten source as proposed in the July 2008 pre-publication of the draft amendments. For the purposes of subsection B.01.010.1 (1), Health Canada will interpret the term "wheat" to include all cereal plants from the species *Triticum*. This interpretation includes kamut and spelt.

Definition of Gluten - Inclusion of Oats:

The inclusion of oats in the definition of gluten raised questions from stakeholders regarding the

distinction between regular oats and oats that have been grown and processed in such a manner as to minimize cross-contamination with other sources of gluten such as wheat, rye and barley. There is recent scientific evidence that many people with celiac disease can tolerate limited amounts of the latter type of oats. Some stakeholders recommended that Health Canada make a distinction between these two types of oats in these regulatory amendments as well as re-examine the criteria for permitting gluten-free claims in section B.24.018 of the Regulations.

Health Canada notes that these comments raise two distinct but related issues. The first issue is the inclusion of oats in the definition of gluten for the purposes of these regulatory amendments. The second issue is the criteria for making a gluten-free claim pursuant to section B.24.018 of the Regulations.

For both issues, it is important to recognize that there are several gluten proteins found in wheat, barley, rye, oats and their hybridized strains such as triticale. It is the alcohol soluble fractions of these proteins, known as prolamins, which are of the most concern to individuals with celiac disease. The prolamins found in wheat, barley and rye contain a high amount of the amino acid proline which makes them resistant to complete digestive breakdown. It is these undigested gluten fragments that are considered to elicit the adverse reaction in individuals with celiac disease.

In comparison to wheat, rye and barley, the prolamin in oats, known as avenin, contains a substantially lower content of the amino acid proline. In addition, prolamins constitute only 5-15% of the total protein content in oats, whereas in wheat, barley and rye they constitute 40-50% of the total protein.

In 2007, Health Canada conducted a systematic review of the scientific literature and concluded that the majority of individuals with celiac disease can tolerate limited amounts of oats that have been grown and processed to minimize cross-contamination with other sources of gluten. This conclusion concurs with the Canadian Celiac Association 2007 position statement on oats.

In response to the first issue noted above, Health Canada reviewed the objectives of these regulatory amendments. Health Canada concluded that individuals with celiac disease, in particular the minority of those who cannot tolerate the specially grown and processed oats, would benefit from the inclusion of oats in the definition of gluten, for the purposes of these regulatory amendments. These regulatory amendments and the inclusion of oats in the definition of gluten align with the Codex recommendations regarding ingredients and components that should always be shown on the product label as specified in the Codex Alimentarius *General Standard for the Labelling of Prepackaged Food.*

In response to the second issue, Health Canada has initiated a separate review of the criteria in the Regulations for making a "gluten-free" claim.

In the interim, changes have been made to section B.24.018 to align it with the definition of "gluten" as set out in subsection B.01.010.1 (1).

Hydrolyzed Protein - Showing the Source of the Hydrolyzed Protein as Part of the Common Name:

In the proposed amendments, prepublished in July 2008, the format for the common name of both plant and animal hydrolyzed proteins was prescribed. A concern was raised regarding the changes to the common names of animal based hydrolyzed protein.

Hydrolyzed plant proteins are widely used as ingredients in prepackaged products and are made from a variety of plant sources including, wheat, soybeans and corn. These products may contain residual protein and consumers with food allergies and celiac disease are advised to avoid consuming prepackaged products containing hydrolyzed protein when the ingredient name does not specify the plant source.

As indicated in the *Canada Gazette*, Part I proposal of July 2008, Health Canada proposed to include a requirement to identify the protein source in the common name of hydrolyzed proteins. This requirement applied to all hydrolyzed proteins, not just plant based hydrolyzed proteins.

However, there were concerns raised regarding the change to the common names of hydrolyzed proteins from animal sources. The requirement to include the source of the hydrolyzed protein, as part of the common name of the ingredient, would have changed a number of the common names currently in use for hydrolyzed animal proteins. After further analysis of the issue, Health Canada anticipates that the regulatory amendments will have a positive impact even if the requirement to include the protein source as part of the common names of hydrolyzed proteins from animal sources is not incorporated into these regulatory amendments. It is noted that these regulatory amendments will require that any protein from eggs, milk, fish, crustaceans or shellfish present in the product would be required to be shown, either in the list of ingredients or in a "Contains" statement.

Health Canada will follow the initial 1999 recommendation from the committee of scientific and medical experts from Health Canada, the CFIA and medical committee. This committee recommended that the plant source be identified in the common name of all hydrolyzed plant proteins. Thus, these regulatory amendments will require the plant source to be shown as part of the common name of all hydrolyzed plant proteins.

Labelling of Sulphites - Sulphites Formed During the Production of Beer and Wine:

Stakeholders requested clarification as to whether sulphites that are formed during the production of beer and wine would be included in the scope of these regulatory amendments.

These regulatory amendments will require enhanced labelling of added sulphites when present in the prepackaged product in a total amount of 10 p.p.m. or more. This includes sulphites used as food additives and present in the prepackaged product as result of being added.

Some products, specifically beer and wine may contain sulphites that are not added but are formed during the fermentation process. However, the number of products is limited and sulphite sensitive consumers can be alerted to this issue with targeted educational material.

Health Canada has concluded that sulphites formed during the production of beer and wine will not be included in the scope of these regulatory amendments. This decision is consistent with the initial policy intent of this initiative.

Following extensive consultation with stakeholders after the pre-publication of the proposed amendments in *Canada Gazette*, Part I, changes were made to the proposal with regard to prepackaged beer, ale, stout, porter and malt liquor that are subject to a standard prescribed in section B.02.130 or B.02.131. These products will be exempt from the labelling requirements set out in these regulatory amendments unless a list of ingredients has been voluntarily provided.

Top of Page

Sulphites - Requirement to Show Added Sulphites Present in a Total Amount of 10 p.p.m. or more in a Separate Statement:

Some industry associations expressed concern with the requirement to exclusively use the "Allergy and Intolerance Information - Contains:" statement to show sulphites that are present in a total amount of 10 p.p.m. or more. Some stakeholders suggested that sulphites be shown in the list of ingredients followed by a simple statement that provides additional information about the amount of sulphites present and that the "Allergy and Intolerance Information - Contains:" statement be optional.

After considering the issue, Health Canada has determined that these regulatory amendments will require that added sulphites present in a total amount of 10 p.p.m. or more be shown on the label of the product. However, there will no longer be a mandatory requirement to show these sulphites in a separate statement. Instead, when added sulphites are present in the prepackaged product in a total amount of 10 p.p.m. or more and are shown in the list of ingredients pursuant to B.01.008 or B.01.009 of the Regulations, they would not be required, as previously proposed, to be shown in the "Contains" statement. However, if a "Contains" statement appears on the label, these sulphites will also be required to be shown in the statement. In the case of added sulphites that are present

in the prepackaged product in the total amount of 10 p.p.m. or more and not required to be shown in the list of ingredients pursuant to section B.01.008 or B.01.009 of the Regulations, these regulatory amendments will require that sulphites be shown on the label of the product, either in the list of ingredients or in the "Contains" statement.

Health Canada acknowledges that the removal of the mandatory labelling requirement to show added sulphites that are present in the total amount of 10 p.p.m. or more in a separate statement may limit the choice of foods available to sulphite sensitive individuals. Section B.01.008 of the Regulations requires that when a prepackaged product consists of more than one ingredient, a list of ingredient, including subject to section B.01.009, components, be provided. This requirement would include sulphites added, in any amount, as ingredients or components. Thus, when a prepackaged product carries only a list of ingredients (no "Contains" statement), the consumer will not be able to determine if the amount of sulphites in the product is below 10 p.p.m.. Health Canada has determined that there will be very few prepackaged products in which added sulphites are present as ingredients or components in an amount less than 10 p.p.m. While the regulatory amendments may limit the food choices for those with a sulphite sensitivity, the impact is expected to be small.

"Allergy and Intolerance Information - Contains:" Statement:

The majority of the stakeholders, including consumers, patient groups and industry associations commented that the statement "Allergy and Intolerance Information - Contains:" was too long. Many stakeholders indicated a preference for a shorter statement starting with the word "Contains" statement as currently used in the United States and the European Union. In addition, some industries and industry associations, both domestic and international indicated their concerns that the proposed wording of the statement could pose a trade barrier for labelling of certain prepackaged products and, in particular, alcoholic beverages.

To address these concerns, the prefix for the statement has been shortened to "Contains".

Exemption for Beer, Ale, Stout, Porter and Malt Liquor - For Which a Standard is Prescribed in Section B.02.130 or B.02.131:

Extensive consultations took place with stakeholders regarding the labelling of these beverages and specific challenges were identified. As a result of these consultations, prepackaged beer, ale, stout, porter and malt liquor that are subject to a standard prescribed in section B.02.130 or B.02.131 will be exempt from the labelling requirements set out in these regulatory amendments unless a list of ingredients has been voluntarily provided.

Messaging regarding potential exposure to food allergens, gluten and sulphites from consumption of these products will be included in educational materials accompanying the amendments. Further review will be undertaken with regard to enhanced labelling requirements for these products.

Exemption for Fining Agents:

Some patient groups, health professionals and consumers raised concerns about the safety of some fining agents for consumers with food allergies and questioned the rationale for exempting such substances from the proposed amendments.

Health Canada has re-examined this issue and these regulatory amendments will not include an exemption for fining agents derived from eggs, fish or milk used in the production of Bourbon whisky or standardized alcoholic beverages. Health Canada has concluded that not exempting those fining agents will better assist individuals with food allergies in making informed choices when purchasing Bourbon whisky and most standardized alcoholic beverages as well as prepackaged products to which Bourbon whisky and standardized alcoholic beverages are added. It should be noted that prepackaged beer, ale, stout, porter and malt liquor for which a standard is prescribed in section B.02.130 or B.02.131 will be exempt from the labelling requirements set out in these regulatory amendments unless a list of ingredients has been voluntarily provided.

In July 2009, Health Canada notified stakeholders of its decision to remove the proposed

exemptions for fining agents in Bourbon whisky and standardized alcoholic beverages.

Exemption for Wax Coating Compounds and Their Components:

Patient groups, health professionals and consumers raised concerns about the safety of wax coatings, some of which may be derived from or contain food allergens or gluten. Questions were raised about the rationale for exempting such substances from the proposed amendments pre-published in *Canada Gazette*, Part I in July 2008.

Health Canada has re-examined this issue and these regulatory amendments will not include an exemption for wax coating compounds and their components used on prepackaged fresh fruits and vegetables. Health Canada has concluded that not exempting wax coating compounds and their components will better assist individuals with food allergies and celiac disease in making informed choices with regard to the consumption of prepackaged fresh fruits and vegetables.

If a food allergen or gluten is present as a result of the use of a wax coating compound or its components in a prepackaged fresh fruit or vegetable that carries a label, the food allergen or gluten source must be shown on the label of the product either in the list of ingredients or in the "Contains" statement. Similarly, sulphites added to a wax coating compound and it components and present in the total amount of 10 p.p.m. or more would be required to be shown on the label of a prepackaged fresh fruit or vegetable. These requirements would not apply to prepackaged fresh fruits or vegetables that are packaged in a wrapper or confining band of less than ½ inch in width since these products are exempt from carrying a label pursuant to subparagraph B.01.003 (1) (*a*) (ii)

In August 2009, Health Canada notified stakeholders of its decision to remove the proposed exemptions for wax coating compounds and their components.

Top of Page

Ingredient Specific Exemptions - Highly Refined Oils:

Some stakeholders indicated that highly refined oils do not contain sufficient amounts of protein to trigger an adverse reaction. It was suggested that highly refined oils be given an exemption similar to the exemption initially proposed for fining agents and wax coatings. On a similar note, some stakeholders requested that Health Canada develop a mechanism, similar to those developed by other jurisdictions, which would provide for certain ingredients to be exempted from the enhanced labelling requirements when it has been determined that the ingredient does not pose a risk to food allergic consumers or individuals with celiac disease.

These regulatory amendments do not include exemptions for specific ingredients. Health Canada will continue to monitor scientific evidence as it evolves nationally and internationally with particular emphasis on data specific to the Canadian context. As new scientific evidence becomes available, Health Canada will consider if further regulatory amendments may be necessary.

Threshold Levels for Food Allergens and Action Levels for Enforcement Purposes:

Some stakeholders expressed concern that continued progress in analytical method development, and the resulting increase in the sensitivity of the methods, may result in lower levels of allergens being detected. A concern was expressed that this would impact when a food allergen is required to be shown in accordance with these regulatory amendments.

These regulatory amendments will require that the food allergen source be shown on the label when the food allergen is present in the prepackaged product. There are no threshold levels specified in the regulatory amendments. However, these regulatory amendments specifically exclude food allergens present in the prepackaged product as a result of cross contamination.

For compliance and enforcement purposes, the determination of presence may be based on the knowledge of ingredients and components used in the manufacture of the prepackaged product as well as knowledge of the allergen control programs implemented by the manufacturer and ingredient

suppliers. Analytical methods may also be used in determining compliance with these regulatory amendments.

Health Canada recognizes that the absence of threshold levels for food allergens is a challenge for regulatory agencies, industry and consumers with food sensitivities. Health Canada will continue to monitor the ongoing research in the field of food allergen thresholds.

Test Methods and Methodology for Food Allergens:

The lack of available commercial allergen test kits was identified as a concern by certain industries.

Health Canada will strive to continuously update its current guidance on availability and suitability of food allergen analytical techniques, in its web-enabled compendium of food allergen methodologies. This information is updated on a regular basis and available on Health Canada's website.

"May Contain" - Precautionary Labelling Statement:

Health Canada heard concerns about the over-use of precautionary labelling and the need for clearer and stricter guidelines for the use of "may contain" statements. In addition, industry requested that Health Canada align the implementation period of these regulatory amendments with other initiatives it may be undertaking involving changes to the product label.

These regulatory amendments do not include food allergens present in the product as a result of cross-contamination and the resulting voluntary use of precautionary labelling statements such as "may contain". The current policy on precautionary labelling is being reviewed by Health Canada and a public consultation on this file has recently concluded.

Size, Font and Colour of Text for Showing a Food Allergen or Gluten Source or Added Sulphites:

Stakeholders continue to ask if Health Canada will specify the size, font and colour of text for showing food allergens, gluten sources and added sulphites on product labels.

Under the Regulations, the labelling must meet the requirements set out in section A.01.016 which stipulates that all information required by the Regulations to appear on the label of a food must be clearly and prominently displayed on the label and readily discernible to the purchaser or consumer under customary conditions of purchase and use.

Health Canada notes these concerns but acknowledges that they are linked to a broader issue regarding the legibility of the list of ingredients.

Need for Education - Food Industry and Consumers:

Stakeholders noted the need for Health Canada to inform and educate consumers and industry regarding these regulatory amendments.

Health Canada and the CFIA will work with patient and consumer groups and food industry associations to further educate Canadians and the food industry regarding the enhanced labelling requirements for prepackaged products as set out in these regulatory amendments.

Delayed Coming into Force Period:

Certain stakeholders indicated that a two year transition period would help reduce the cost for label changes on prepackaged products. Some stakeholders requested that Health Canada consider extending the transition period beyond two years for products with a long shelf life, such as, canned food or alcoholic beverages, when developing the regulatory amendments.

A transition period was initially proposed for these regulatory amendments. However, with the change of the prefix for the statement from "Food Allergy and Intolerance Information - Contains:" to "Contains", there is no longer a unique trigger that the CFIA or consumers can use to determine

if a prepackaged product has been labelled in compliance with these regulatory amendments during a transition period. Currently the "Contains" statement is in use in Canada and other jurisdictions. Thus, products using a "Contains" statement may not necessarily be in compliance with the requirements specified in these regulatory amendments. As a result, these regulatory amendments will have a delayed coming into force period. With a delayed coming into force period, all prepackaged products offered for sale must be in compliance with these regulatory amendments 18 months after the date on which they are registered.

Considering the impact on industry as well as the need to move forward as soon as possible with enhanced protection for food sensitive consumers, these regulatory amendments will come into force 18 months after the date on which they are registered.

Top of Page

Implementation, enforcement and service standards

In recognition of the time required by industry to change their product labels, these regulations will come into force 18 months after the date on which the Regulations are registered.

The CFIA is responsible for the enforcement of the Food and Drugs Act and Regulations as they relate to food. Compliance will be monitored as part of the ongoing domestic and import inspection programs conducted by the CFIA. Appropriate compliance action will be taken based on risk. Health Canada will provide guidance to the CFIA on health risk assessments and implementation of these regulatory amendments. Health Canada will also work towards common assessment practices with Canada's major trading partners. As part of its role to develop interpretative guidance for labelling regulations, the CFIA will develop tools for industry to assist in the implementation of the new regulations (e.g. food labelling guide, training sessions).

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[1] The Codex Alimentarius Commission was created in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

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[49] For example, time for tasks such as contacting food manufacturers, reading product labels and searching the Internet to identify foods that does not contain gluten.

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[53] Because of the 18 month delayed coming into force period, benefits (B1,B2, B3) are only expected for the second half of 2012-13.

[54] Discount rate of 8%

[55] The cost and benefit estimates have been converted into 2011 numbers using the data from Table 6 Core Consumer Price Index (CPI) (Bank of Canada definition), not seasonally adjusted, historical data. Statistics Canada.

[56] Estimates for reduced costs for medical care were adjusted from 2006 to 2011. Estimates for reduced costs to families (B2 and B3) were adjusted from 2010 to 2011. Cost estimates for Health Canada and the Canadian Food Inspection Agency were adjusted from 2008 to 2011. Costs to industry were adjusted from 2002 to 2011.

[57] PV = Present Value

[58] It is anticipated that once these regulatory amendments have been implemented, consumers will come to consider the enhanced label information on the prepackaged products as the status quo. To account for this, the estimated time saving of 10 minutes per week per affected household for 2012-3 through 2014-5 was decreased to 5 minutes per week per affected household for 2015-16 and thereafter.

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