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Regulations Amending the Food and Drug Regulations (1220 — Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites)

Statutory authority

Food and Drugs Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive summary

Issue: Scientific evidence has clearly linked certain food ingredients with adverse reactions when consumed by individuals with a food allergy, celiac disease 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 these individuals, avoidance of the specific food is a key element in the management of their condition.

The current *Food and Drug Regulations* ("the Regulations") require that the ingredients of prepackaged products be declared in descending order of their proportion in a list of ingredients on the label of most prepackaged products. However, subsections B.01.009(1) and (2) of the Regulations specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients. Also, some of the common names which are currently permitted to be used in the list of ingredients do not provide sufficient information to sensitive consumers to enable them to avoid foods that can trigger potential adverse reactions. As a result, the information on the label is not always complete with respect to the needs of these consumers.

Description: The proposed regulatory amendments would enhance the labelling of prepackaged products by requiring the mandatory declaration of the sources of the common food allergens and gluten when present in a prepackaged product. The declaration of a food allergen source or gluten source would be required in consistent and easy to understand terminology. For example, if casein is present in a prepackaged product, the word "milk" would be required to appear on the label of the product either in the list of ingredients or in a statement that begins with the words "Allergy and Intolerance Information – Contains:". In addition, the common names for starches, modified starches, hydrolyzed protein and lecithin would be modified to provide information regarding the source from which these ingredients are derived (e.g. wheat starch).

These proposed amendments would also require the declaration of added sulphites when present in a prepackaged product in a total amount of 10 parts per million (ppm) or more. This declaration would be required in a statement beginning with the words "Allergy and Intolerance Information – Contains:" followed by one of the common names for sulphites.

These proposed regulatory amendments would not apply to a food allergen or gluten that is present in the prepackaged product as a result of cross-contamination.

Cost-benefit statement: There is limited data available in Canada, the United States, Europe

and other countries concerning the incidence and associated costs of adverse reactions due to food allergies, celiac disease and sulphite sensitivity. Thus, it is difficult to quantify the cost and benefits of the proposed Regulations.

There would be costs associated with implementing these proposed Regulations for both industry and government. However, the proposed Regulations would have a positive impact on the health and quality of life of Canadian consumers with a food allergy, celiac disease or a sensitivity to sulphites. It is also anticipated that there would be some cost savings to the health care system and for these individuals that would result from the proposed amendments.

Business and consumer impacts: While this regulatory proposal would increase the labelling requirements with which industry must comply, most of the products within the scope of the proposed Regulations already require the declaration of ingredients and components in a list of ingredients. Thus, for the majority of products impacted by the proposed Regulations, the labelling requirements would build on existing regulatory requirements.

For standardized alcoholic beverages and vinegars, which currently do not require a list of ingredients, the declaration of food allergen and gluten sources and added sulphites, as proposed by these amendments, would be required in a statement on the label of the product.

For consumers with a food allergy, celiac disease or a sensitivity to sulphites, these enhanced labelling requirements would provide essential information on the label of prepackaged products. This information would enable these consumers to make an informed choice about the prepackaged products they purchase and consume and assist them in managing their medical condition.

Domestic and international trade and cooperation: The proposed regulatory amendments are in line with the general approach taken by Canada's trading partners, namely the United States, the European Union and Australia/New Zealand. These countries have implemented legislation or regulations for the declaration on food labels of the substances specified by the Codex Alimentarius Commission with slight modifications to reflect the situation and legislation in their countries. These proposed regulatory amendments would address the Codex recommendations by requiring the declaration of the list of specified substances, with the addition of sesame seeds and shellfish to meet specific Canadian needs.

Issue

Scientific evidence has linked certain food ingredients with severe adverse reactions when consumed by individuals with food sensitivities. A food sensitivity is an adverse reaction to a food that other people can safely eat and includes food allergies, food intolerances, and chemical sensitivities.

An individual with a food allergy who comes in contact with a food allergen may have a reaction that develops quickly and may rapidly progress from a mild to a severe reaction, including anaphylactic shock and death. The management of a food allergy requires the avoidance of the food allergen. In Canada, the foods most frequently associated with allergic reactions are: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts, peanuts, sesame seeds, wheat, kamut, spelt, triticale, eggs, milk, soybeans, crustacea, fish and shellfish. Current estimates are that food allergies affect as many as 6% of young children and 3% to 4% of adults. (see footnote 1)

Celiac disease is an intolerance to the gluten from wheat, spelt, kamut, oats, barley, rye and triticale. For an individual with celiac disease, exposure to gluten can result in the deterioration, over time, of the cell lining of the small intestine. Untreated celiac disease can result in short stature in children, increase the risk of osteoporosis and lymphoma and other types of malignancies and a number of autoimmune diseases, including insulin dependent diabetes in children. The only treatment for celiac disease is a strict gluten-free diet for life. Celiac disease affects approximately 1% of the population. (see footnote 2)

The term "sulphites" refers to the group of food additives composed of sulphurous acid and its salts. Sulphites, also known as sulphiting agents, are regulated under the Regulations as food additives. A chemical sensitivity to sulphites affects approximately 1% of the general population and approximately 4% of individuals with asthma. (see footnote 3) Although sulphites do not cause a true allergic reaction, individuals with a sulphite sensitivity may experience similar reactions as those individuals with food allergies. Current scientific data indicate that adverse reactions are caused by consumption of foods

containing sulphites in amounts of 10 ppm or more.

The current Regulations require that the ingredients of prepackaged products be declared in descending order of their proportion in a list of ingredients on the label of most prepackaged products. This regulatory requirement provides the consumer with information regarding the ingredients and components of the prepackaged product and can assist the consumer with a food sensitivity to avoid those foods that can trigger an adverse food reaction. However, subsections B.01.009(1) and (2) of the Regulations specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients. In addition, some of the common names, which are currently permitted to be used in the list of ingredients, do not provide sufficient information for the sensitive consumer to determine if the ingredient or component contains substances that can trigger adverse reactions. As a result, prepackaged products may contain undeclared sources of food allergens and gluten, or added sulphites. Thus, consumers with a food sensitivity cannot avoid, with any certainty, the substances that may cause adverse effects to their health.

Objectives

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

Specifically, for food allergens and gluten, the goal is to ensure that information regarding food allergens and gluten present in the prepackaged product is provided on the label in simple and consistent terminology. For example, if casein is present in a prepackaged product, the word “milk” would be required to appear either in the list of ingredients or in a statement that begins with the words “Allergy and Intolerance Information – Contains:”.

It is not the intent of this regulatory proposal to address food allergens or gluten that may be present in the prepackaged product as a result of cross-contamination.

For sulphites, the goal is to provide information to the consumer, in a simple and consistent manner, when the prepackaged product contains 10 ppm or more of added sulphites.

Health Canada is supported by various other federal agencies in developing and implementing programs aimed at enhancing the protection of consumers with food sensitivities. This regulatory proposal is one of the key deliverables of Health Canada’s Food Allergy Incident Prevention Strategy. The overall objectives of this strategy 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.

Description

Overview

The proposed regulatory amendments would require the declaration of the source of a food allergen or gluten on the label of prepackaged products, either in the list of ingredients or in a statement beginning with the words “Allergy and Intolerance Information – Contains:”, when a food allergen or gluten is present in the prepackaged products. The proposed amendments would 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, kamut, spelt, triticale, eggs, milk, soybeans, crustaceans, shellfish, fish or gluten from the grains of the following cereals: barley, oats, rye, triticale, wheat, kamut and spelt. The proposed amendments would also require the declaration of added sulphites, when present in a total amount of 10 ppm or more in the prepackaged product, in a statement beginning with the words “Allergy and Intolerance Information – Contains:” on the label of the product.

These proposed amendments would not apply to a food allergen or gluten present in a prepackaged product as a result of cross-contamination and hence, the resulting voluntary use of the “may contain” statement by manufacturers.

Declaration of food allergen and gluten sources

For the purposes of the proposed regulations, “food allergen” and “gluten” would be defined as proposed in new subsection B.01.010.1(1).

The proposed regulatory amendments would require that the source of each food allergen and the source of each gluten present in the product be declared on the label, unless the food allergen or gluten is present as a result of cross-contamination [see proposed subsections B.01.010.1(2) and (3)]. Pursuant to the proposed subsection B.01.010.1(2), the source of the food allergen or gluten could be declared either in the list of ingredients or in a statement that begins with the words “Allergy and Intolerance Information – Contains:”. Proposed subsections B.01.010.1(5) and (6) set out the specific names by which the source of a food allergen or the source of gluten would be declared.

Details concerning where the source of a food allergen or source of gluten would have to be declared in the list of ingredients, in relation to the other ingredients and components, is provided in proposed subsection B.01.010.1(7). Proposed subsection B.01.010.1(9) provides additional details for labelling including the option to declare the source of the food allergen or gluten only once in the list of ingredients. Proposed subsection B.01.010.1(10) would ensure that the current provision in paragraph B.01.010(3)(*b*) of the Regulations, regarding the use of common names set out in column II of the table to that paragraph, would continue to apply when an ingredient or a component listed in column I of the table to paragraph B.01.010(3)(*b*) contains a food allergen or gluten.

Proposed section B.01.010.3 provides details concerning the statement beginning with the words “Allergy and Intolerance Information – Contains:”. For example, this statement must follow the list of ingredients, if an ingredient list is provided, and it must be comprehensive. Thus, the source of each food allergen and the source of each gluten present in the prepackaged product would have to be declared in the statement as well as one of the common names for sulphites, if added sulphites are present in a total amount of 10 ppm or more in the prepackaged product.

As indicated in the proposed amendments to items 8, 20, 21 and 22 of the table to paragraph B.01.010(3)(*b*), the common names of hydrolyzed protein, starch, modified starch and lecithin would be modified as follows:

- the name of the source of protein be identified in the common name of all hydrolyzed proteins;
- the name of the plant be identified in the common name of all forms of starch or modified starch; and
- the name of the source of lecithin be identified in the common name of lecithin.

Declaration of added sulphites

For the purposes of the proposed regulations, the term “sulphites” would refer specifically to the group of food additives composed of sulphurous acid and its salts that are currently regulated under the Regulations [see proposed subsection B.01.010.2(1)].

Proposed subsection B.01.010.2(2) would require that sulphites be declared in a statement starting with the words “Allergy and Intolerance Information – Contains:” when added sulphites are present in a prepackaged product in a total amount of 10 ppm or more. Sulphites would be declared in this statement using one of the following common names: sulfites, sulfiting agents, sulphites or sulphiting agents [see proposed subsection B.01.010.2(4)].

Standardized alcoholic beverages and vinegars

Standardized alcoholic beverages and vinegars, referred to in paragraphs B.01.008(2)(*f*) and (*g*) of the Regulations, do not require a list of ingredients. For these products, the source of each food allergen and the source of each gluten present in the product, as well as added sulphites when present in the product in a total amount of 10 ppm or more, would have to be declared on the label in a statement beginning with the words “Allergy and Intolerance Information – Contains:”.

Exemptions

The proposed requirements outlined above would not apply to

(*a*) fining agents derived from eggs, fish or milk that are used in the manufacture of Bourbon whisky or alcoholic beverages that are subject to a compositional standard in Division 2, whether the Bourbon whisky or alcoholic beverage is a prepackaged product or added to a prepackaged product;

(*b*) wax coating compounds and their components that are used on prepackaged fresh fruits or vegetables; and

(*c*) the following prepackaged products unless a list of ingredients has been provided for the product:

(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, and

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

Other amendments

Several provisions of the Regulations would also be modified or repealed. Subsections B.01.009(4) and (5) of the Regulations would be repealed as they would be considered redundant given the new requirements being proposed. Item 21 of the table to paragraph B.01.010(3)(*b*) of the English version of the Regulations would be modified to allow for alternate spelling of the term “sulphites” which would enable manufacturers to use the American spelling of the term. To ensure consistency with paragraph B.01.010(3)(*a*), item 20, which specifies the common name for starch, section B.13.011 would 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*) and B.01.009(3)(*c*) would be modified for consistency with other elements of this proposal.

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; and

(2) sulphites.

1. Food allergens and gluten

Since the protein is the portion of the food to which an individual with a food allergy or celiac disease will react, the options proposed for food allergens were also considered suitable for gluten.

Option 1

To maintain the status quo of the current regulatory requirements and provide limited government intervention so food manufacturers and importers would declare components of ingredients, preparations and mixtures specified in subsections B.01.009(1) and (2) of the Regulations that are known to cause adverse effects in sensitive individuals.

In the past, Health Canada and the CFIA encouraged industry to declare food allergens on a voluntary basis that would otherwise be exempt from label declaration under the current Regulations. However, from the consumer’s perspective, there were concerns about the reliability of the information provided using such an approach since the consumer could not know if the manufacturer listed all the food allergens.

More recently, the CFIA and Health Canada reissued guidance to address risks associated with undeclared allergens. See www.inspection.gc.ca/english/fssa/invenq/inform/20070323e.shtml.

Option 2

To propose regulatory amendments to remove the exemption for the declaration of components of ingredients, preparations and mixtures specified in subsections B.01.009(1) and (2) of the Regulations if the components are foods known to be a food allergen or gluten that can cause adverse effects in sensitive individuals, including all derivatives of these foods.

This option would capture too many products within its scope as it would require the declaration of ingredients and components that may not contain the causative protein. As a result, this option could reduce the number of suitable food choices available to consumers with food allergies and celiac disease.

These individuals, on the basis of such labelling, would avoid foods presenting no risk to their health since the protein portion causing the adverse reaction may not necessarily be present in the food.

Option 3

To propose regulatory amendments to require the declaration of the source of a food allergen or the source of gluten. In this case, “food allergen” would be defined as any protein from any of the foods specifically listed in the proposed 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 proposed definition or the grain of a hybridized strain created from at least one of these cereals. The definition for gluten 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. The proposed amendments would not apply to a food allergen or gluten that is present in the prepackaged product as a result of cross-contamination.

This is the selected option. See the section entitled “Rationale” for the discussion and details of this option.

2. Sulphites

Five options were considered to address labelling requirements when sulphites are added to prepackaged products. It is not the intent of the proposed requirements to identify the presence of naturally occurring sulphites or the presence of sulphurous compounds as a result of the application of agricultural chemicals.

Option 1

To maintain the status quo of the current regulatory requirements and provide limited government intervention so food manufacturers and importers would declare added sulphites in components of ingredients, preparations and mixtures specified in subsections B.01.009(1) and (2) of the Regulations, when the amount of sulphites equals or exceeds 10 ppm in the final food.

In the past, Health Canada and the CFIA encouraged industry to declare added sulphites on a voluntary basis that would otherwise be exempt from label declaration under the current Regulations. However, from the consumer’s perspective, there were concerns about the reliability of the information provided using such an approach since the consumer could not know if the manufacturer listed all sources of added sulphites.

More recently, the CFIA and Health Canada reissued guidance to address risks associated with undeclared sulphites. See www.inspection.gc.ca/english/fssa/invenq/inform/20070323e.shtml.

Option 2

To maintain the current regulatory requirement for the declaration of sulphites in the list of ingredients when sulphites are added as an ingredient or component. However, a regulatory amendment would be made to require the declaration of sulphites, in the list of ingredients, when they are added as a component of an ingredient, preparation or mixture listed under subsections B.01.009(1) and (2) of the Regulations. This declaration would be required regardless of the amount of added sulphites present in the prepackaged product.

This option was rejected. This option would not account for current scientific evidence which indicates that the likelihood of adverse effects in sensitive individuals occurs when sulphites are present at 10 ppm or more in the food product. Thus, this option would not meet one of the objectives of the Government’s broader initiative relating to food sensitivities, which is to maximize the choice of safe foods for those with dietary restrictions.

Option 3

To propose regulatory amendments to require the declaration of sulphites, in the list of ingredients, only when the total amount of added sulphites in the finished product is 10 ppm or more. This regulatory requirement would apply to sulphites added to the product as an ingredient, a component of an ingredient and to components of an ingredient, preparation or mixture listed under subsections B.01.009(1) and B.01.009(2) of the Regulations.

This option was rejected because it 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 declared in the list of ingredients whenever they are added as an ingredient or a component regardless of their level. The current labelling requirement for food additives enables consumers to determine when food additives have been added to a prepackaged product that they wish to purchase.

Option 4

To maintain the current regulatory requirement for the declaration of sulphites in the list of ingredients when sulphites are added as an ingredient or a component. A regulatory amendment would be made to remove the exemption from the declaration of sulphites, in the list of ingredients, when they are added as a component of an ingredient, preparation or mixture listed under subsections B.01.009(1) and (2) of the Regulations and resulting in a total amount of 10 ppm or more of sulphites in the prepackaged product.

In 2004, Health Canada provided information to the general public and to industry regarding the enhancement of labelling of sulphites, via a Web posting, indicating that this option was feasible. However, it was later noted that this option would establish two distinct rules for the declaration of sulphites in the list of ingredients. Sulphites that are added as ingredients or components would be declared regardless of the level present in the prepackaged product, while sulphites added as a component of an ingredient that is exempt from declaring its components under subsections B.01.009(1) and (2) would only be declared when the total amount of added sulphites in the prepackaged product is 10 ppm or more. This option was rejected 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 current regulatory requirements for declaring sulphites in the list of ingredients and amend the Regulations to require the declaration of sulphites in a separate statement on the label when added sulphites are present in a prepackaged product in a total amount of 10 ppm or more.

This is the selected option. See section entitled “Rationale” for the discussion and details of this option.

Benefits and costs

Benefits

The key benefits that would result from the proposed regulatory amendments are

- improved management of adverse reactions by enabling informed choice by consumers;
- reduced costs to health care systems and individuals;
- improved quality of life of individuals with food allergies, celiac disease and sulphites sensitivity; and
- protection of Canadian consumers.

Management of adverse reactions: Enabling informed choice by consumers

Food allergies affect approximately 6% of young children and 3% to 4% of adults. Celiac disease and a sensitivity to sulphites are each estimated to affect 1% of the population. Thus, these three conditions impact approximately 6% of the Canadian population or roughly 2 million Canadians.

The management of a food allergy, celiac disease and sulphite sensitivity requires the avoidance of foods containing the food allergen, gluten sources or sulphites. For consumers with a food allergy, consuming a product containing the food allergen can be fatal. These proposed regulatory amendments would enhance the information on labels, thus enabling consumers with a food allergy, celiac disease or a sulphite sensitivity to be better informed of the contents of prepackaged foods and be able to avoid substances with the potential to give rise to adverse reactions.

The enhanced labelling of food allergens on prepackaged products would be a tool that could assist parents, students and school staff in implementing strategies to reduce the risk of exposure to anaphylactic causative agents in classrooms, such as those required in Ontario under the stipulations of *Sabrina’s Law, 2005*. (see footnote 4)

For individuals with celiac disease, improved labelling would enhance their ability to avoid inadvertent or accidental ingestion of gluten and would facilitate label reading. A study of the membership of the Canadian Celiac Association noted that newly diagnosed patients with celiac disease must learn where

hidden sources of gluten might be present in foods and must become expert label readers to be able to manage their disease. Eighty-five percent of respondents in this survey reported having problems determining whether foods are gluten-free. (see footnote 5) The proposed regulatory amendments would facilitate label reading by requiring the use of simple, easy to understand terminology and would require the declaration of each source of gluten that is present in the product.

Reduced costs to health care system and individuals

Anaphylaxis is a serious allergic reaction that can be life threatening. Food is the most common cause of anaphylaxis. It is estimated that 1% to 2% of Canadians live with the risk of anaphylactic reaction. (see footnote 6) In the United States, food allergy remains a leading cause of anaphylaxis treated in emergency rooms, and it is estimated that there are 150 deaths from food-related anaphylaxis per year. (see footnote 7) Comprehensive data is not available in Canada. However, a single study examined deaths related to anaphylaxis in Ontario over the period of 1986 to 2000. In this study, 63 confirmed deaths due to anaphylaxis were identified with 32 related to adverse reactions to foods (2.3 deaths per year). (see footnote 8)

These proposed regulatory amendments would reduce some costs for health care systems, individuals and employers. Savings to the health care systems would result from a reduction in the number of emergency room visits due to adverse reactions. As noted previously, food allergy is a leading cause of anaphylaxis treated in emergency rooms in the United States. While there are no similar statistics available in Canada, it is expected that the proposed Regulations would contribute to reducing the number of food allergy incidents and hence associated emergency room visits.

There is limited Canadian data upon which to base estimates of the costs of allergies. However, such costs were recently estimated in Australia. They are seen as relevant in the Canadian context because both Australia and Canada have publicly funded health care systems with similar per capita expenditures, as well as a similar percentage of gross domestic product spent on health care.

The cost of allergies in the Australian study was estimated to be approximately $7,200 per person, per year, in Australian dollars. These cost estimates were for all types of allergies, including asthma and non-asthma allergies such as food, drug, latex, sting and bite allergies, contact dermatitis and anaphylaxis. Burden of disease (disability, premature death) accounted for 73% of costs, reduced productivity for 19% of costs and health system costs for 4%. The largest share of allergy costs (86%) was borne by individuals with allergy due to the large burden of disease costs. Nine percent of costs were borne by the Australian federal government due to its share of health system and productivity costs. (see footnote 9)

While costs specific to food allergies were not located in our search of the published literature, we note than in a 2007 article in *Allergy*, the EuroPrevall group indicated that a prototype questionnaire to address the economic cost of food allergies was being validated and would be used later in the project. (see footnote 10) Until such data become available, the Australian data provide a first estimate of the overall costs of allergies in a country with a health care system similar to the Canadian system.

Improved quality of life

Allergies can be associated with reduced productivity and lower quality of life. (see footnote 11) The proposed enhancements to the labelling requirements for prepackaged products would become a tool to assist individuals with food allergies to avoid foods that may cause reactions and associate impacts on health and quality of life.

These proposed regulatory amendments would also improve the quality of life for celiac sufferers. In a survey of the membership of the Canadian Celiac Association, it was found that one of the four key elements to improve the quality of life of those with celiac disease would be improved food labelling. (see footnote 12) Similar results were found in a survey of Canadian families with children with celiac disease. According to this survey, better labelling of gluten-containing ingredients was selected by 63% of the respondents when asked to select two items that would improve the quality of life. (see footnote 13)

Protection of Canadian consumers: Recalling foods containing undeclared food allergens

As part of its compliance and enforcement role, the CFIA issues an allergy alert to the media when a product recall is initiated as a result of a health risk assessment conducted by Health Canada. A product recall is initiated when there is a reasonable probability that the consumption or exposure to a food could lead to adverse health consequences which are serious or life-threatening. In 2006, the CFIA issued 59

allergy alerts. In the two previous years, the numbers of allergy alerts issued by CFIA were 36 and 54 respectively. (see footnote 14)

An analysis of the CFIA's recall data from 1997 to 2001 indicates that about 58% of the allergen-related food recalls conducted by the CFIA were considered to be Class I recalls. A Class I recall occurs when there is a reasonable probability that consumption or exposure to the product could cause serious health consequences or death. Over this four-year period, it was noted that the percentage of Class I recalls attributed to food allergens was higher than any of the other types of recalls (microbiological, extraneous and chemical). (see footnote 15)

The proposed regulatory amendments would assist industry by clearly specifying the labelling requirements with which it must comply. The proposed amendments would also provide the CFIA with a clear regulatory framework upon which to request a product recall when undeclared food allergens, gluten sources or added sulphites are detected in a prepackaged product. While the number of recalls is expected to increase initially following the implementation of these regulations, it is anticipated that the eventual result would be a decrease in recalls due to the availability of better guidance for industry through the amended regulations and the expected adherence to this guidance by food processors and importers. A decrease in the number of allergy alerts may also contribute to building consumer confidence in the labelling of prepackaged food products available for sale in Canada.

Costs

Costs to Government

Estimated costs for the CFIA to implement these proposed amendments are $3M annually. These funds would be required to train inspectors and program staff; update inspection manuals, including the *2003 Guide to Food Labelling and Advertising* and chapter 7 of the *Meat Hygiene Manual of Procedures*; develop educational and training tools for use by food manufacturers and importers; implement new food allergen detection methodologies; and establish enforcement activities. The CFIA also anticipates an initial increase in the number of enforcement actions, including recalls, once the regulations are in place.

Costs to Health Canada to ensure effective start-up and on-going delivery of this facet of the Food Directorate's food allergen program are projected to be $1M annually. Implementation activities would include responses to food manufacturers/ importers, health associations, the CFIA and consumers with regard to the interpretation of the amended Regulations. Ongoing activities would include health risk assessments and advice to the CFIA. It is also expected that Health Canada would experience an increased number of requests from industry to issue letters of opinion related to the need to identify food allergen sources in foods and ingredients; specifically, in cases where processing conditions can influence the presence and characteristics of protein fractions derived from allergens (in refined oils, sugars derived from cereals, etc.). A process would need to be developed matching those of other jurisdictions for use with Canada's major trading partners (i.e. petitioning process available in the United States and European Union). Furthermore, there would be a need to pursue research and methodology development for the establishment and refinement of food allergen protein detection and quantification and to work with the CFIA to develop related operational policy. These activities would require technical, communication and training expertise.

Cost to industry

In order to obtain data from the food industry on the potential impacts of the proposed regulatory amendments, a Business Impact Test (BIT) was conducted by Consulting and Audit Canada in 2002.

Based on concerns identified during the BIT, the scope of the products required to adhere to the proposed amendments was reduced. As a result, the following products would only have to provide the information required by the proposed amendments if a list of ingredients is voluntarily provided on their label:

- Prepackaged products packaged from bulk on retail premises, except prepackaged products that are a mixture of nuts;
- 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; and
- Meats, meat by-products, poultry, poultry meat, or poultry meat by-products that are barbequed, roasted or broiled on the retail premises.

These modifications to the scope of the project would reduce the impact on industry with minimal effect on the benefits to consumers. As the above-noted products are not required to have a list of ingredients, the inclusion of these products in the scope of this project would have constituted a significant burden on the industries involved. It is unlikely that a consumer with a food sensitivity would purchase or consume a prepackaged product without a list of ingredients. However, in order to protect sensitive consumers, if a list of ingredients is voluntarily provided for these products, the labelling requirements of these proposed amendments would apply.

In addition to the above-noted changes, there was a further reduction of the range of products impacted by refining the definitions of “food allergen” and “gluten” as presented in option 3 in the section “regulatory and non-regulatory options considered.” Previously, as proposed in the BIT, all derivatives of the specified foods would have been required to be labelled. This modification would not only reduce the impact on industry, but it would also benefit consumers with a food allergy or celiac disease by limiting the requirement for declaration to the causative protein. This would prevent any further limiting of food choices for these consumers.

Based on the BIT done in 2002, the one-time costs of the proposed Regulations were estimated to be $101.8 million over a twoyear transition period, with ongoing costs of $12.95 million per year. However, some respondents may have included the costs of controlling cross-contamination in their estimates. In some instances, the only way to eliminate cross-contamination is to use dedicated processing lines or facilities, which would increase costs estimates dramatically. When the one-time and ongoing costs obtained in the BIT were distributed by industry sector, costs for facilities and equipment appeared to comprise most of the one-time cost for several industry sectors. Controlling cross-contamination has never been included in the scope of this regulatory proposal. Hence, Health Canada believes that some of the data submitted in response to the BIT may overestimate the actual cost of the initiative.

Furthermore, as indicated previously, subsequent regulatory development has excluded components initially considered in the scope of the BIT. It is anticipated that the exclusions will further reduce the cost estimated in the BIT.

Summary

Although there would be costs associated with the implementation of these regulatory amendments both for industry and government, the proposed Regulations would have a positive impact on the health and quality of life of Canadian consumers with food allergies, celiac disease and sulphite sensitivity. Savings to the health care system and for individuals with food allergies, celiac disease and sulphite sensitivity are also anticipated. These amendments would also provide benefit to caregivers, schools and others in implementing strategies for the management of food allergies, celiac disease and sulphite sensitivity.

Rationale

Amendments to the Regulations were considered the most effective means of enhancing the labelling of prepackaged products to ensure the declaration of food allergen and gluten sources and added sulphites when present in prepackaged products. The enhanced labelling would enable those Canadians with a food allergy, celiac disease or a sulphite sensitivity to avoid adverse reactions by making informed decisions regarding the prepackaged products they consume. The selected options are also in line with Health Canada’s Food Allergy Incident Prevention Strategy which aims to minimize risks associated with inadvertent consumption of undeclared food allergens, gluten sources and added sulphites in foods and to maximize the choice of safe and nutritious foods for those with dietary restrictions.

The selected option for food allergens and gluten is to proceed with regulatory amendments to require the declaration of the source of any food allergen or gluten on the label of the prepackaged product when the food allergen or gluten is present in the prepackaged product. The proposed regulatory amendments would not apply to a food allergen or gluten that is present in the prepackaged products as a result of cross-contamination, since cross-contamination is outside the scope and intent of this regulatory proposal. The presence of food allergens and gluten sources as a result of cross-contamination is being examined as a separate initiative.

In the proposed amendments, “food allergen” would be defined as any protein from any of the following foods or any modified protein, including any protein fraction, that is derived from any of the following foods: almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts; peanuts; sesame seeds; wheat, kamut, spelt or triticale; eggs; milk; soybeans; crustaceans; shellfish or fish. “Gluten” would be defined as any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals: barley, oats,

rye, triticale, wheat, kamut or spelt. The definition for gluten would also include any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals or the grain of a hybridized strain mentioned above. This option would provide the most accurate and appropriate information for individuals with food allergies or celiac disease and takes into account the scientific evidence which indicates that the protein is the portion of the food which will trigger the adverse reaction in an individual with a food allergy or celiac disease. (see footnote 16)

Two options were considered with regard to where the declaration of the source of the food allergen or gluten would appear on the label of a prepackaged product, and both were found appropriate to meet the information needs of the consumers with a food allergy or celiac disease.

The two options for declaring the source of the food allergen or gluten source are

- in the list of ingredients, in parentheses, immediately following the common name of the ingredient or component in which it is present; or
- in a statement, beginning with the words “Allergy and Intolerance Information – Contains:” which would immediately follow the list of ingredients when a list of ingredients is provided.

In order to provide manufacturers and importers some flexibility in the labelling of their products, both options for declaring food allergens and gluten were developed and incorporated into the proposed regulatory amendments.

Based on the recommendations of a joint committee of scientists and officials of Health Canada and the CFIA, which included consultation with representatives of the medical community, Health Canada also decided to include regulatory amendments to require the declaration of the name of the plant for all forms of starch and modified starch, as well as the source of hydrolyzed protein and lecithin. As indicated in the report of this committee, this recommendation would ensure that sensitive consumers would have the essential information to assist them in avoiding ingredients or components that may trigger adverse reactions. (see footnote 17)

With regard to sulphites, the selected option was to maintain the current regulatory regime for declaring sulphites in the list of ingredients and amend the Regulations to require the declaration of added sulphites in a statement beginning with the words “Allergy and Intolerance Information – Contains:” when added sulphites are present in a prepackaged product in a total amount of 10 ppm or more.

This option was considered the best alternative to achieve the intent. This option would readily identify products that contain added sulphites in a total amount of 10 ppm or more. This labelling requirement would enable sensitive consumers to be informed of the presence of added sulphites in the product when they are present at a level likely to cause an adverse reaction. This labelling would specifically address the health and safety concerns. Finally, this option would have no impact on the current provisions regarding the declaration of sulphites in the list of ingredients.

In terms of developing the proposed amendments, there was no rationale for removing the current and long-standing exemption for a list of ingredients on the label of standardized alcoholic beverages and vinegars identified in Divisions 2 and 19, respectively, of the Regulations. For these products, the declaration of the presence of substances known to cause adverse effects would be accomplished through the use of a statement on their labels beginning with the words “Allergy and Intolerance Information – Contains:”.

In addition, based on discussions with the food industry and the current state of scientific evidence, fining agents derived from egg, fish and milk used in the manufacture of standardized alcoholic beverages would not require declaration under the proposed amendments. However, this exemption may be revisited, if warranted, once the results of research being conducted in Canada and other countries become available.

The mandatory declaration of food allergen and gluten sources and added sulphites when present in an amount of 10 ppm or more, as proposed by Canada, is in line with the approach taken by other countries, including the United States, the European Union and Australia/New Zealand. These countries have implemented legislation or regulations for the declaration of the substances specified in the *General Standard for the Labelling of Prepackaged Foods* established by the Codex Alimentarius Commission. The proposed Canadian regulations address the Codex recommendations by including the list of substances specified in the *General Standard for the Labelling of Prepackaged Foods.* In order to meet the specific needs of the Canadian population, sesame seeds and shellfish would be added to the list of substances requiring mandatory declaration. The Canadian list of food allergens and gluten sources to which

mandatory declaration would apply will be reviewed on a regular basis and amended based on new scientific findings.

In developing the specific labelling requirements of these proposed amendments, Health Canada attempted to align as much as possible with the U.S. labelling requirements for food allergens. However, these proposed amendments build on Canada's existing labelling and food safety legislation, and only partial harmonization of the labelling requirements could be achieved. For example, consideration was given to using the wording "Contains:" as the prefix for the statement that would be used to list the food allergen and gluten sources and added sulphites. However, for products that contain 10 ppm or more of sulphites, the sulphites would be required to be declared in the statement and would also be required to be declared in the list of ingredients if the sulphite is an ingredient or component that is not subject to subsections B.01.009(1) and (2) of the Regulations. The prefix "Contains" would not be considered appropriate in this case as it does not explain why the sulphites are declared in the statement in addition to the declaration in the list of ingredients. Based on this concern, a more descriptive prefix was deemed necessary. The wording "Allergy and Intolerance Information – Contains:" prevents any confusion as to why the information is being provided to the consumer.

A brief summary of the legislation implemented by some other countries is provided below.

United States

In the United States, the *Food Allergen Labeling and Consumer Protection Act of 2004* (FALCPA), establishes labelling requirements for packaged foods that contain certain food allergens. The food allergens identified by FALCPA are milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans. These food allergens can be declared in either of two ways. The first option is to declare the food allergen in the list of ingredients by the common or usual name of the major food allergen followed in parentheses by the name of the food source from which the major food allergen is derived. The second option is to use the word "Contains", followed by the name of the food source from which the major food allergen is derived, immediately after or adjacent to the list of ingredients.

Under separate regulation, the Food and Drug Administration requires that companies list, on their product labels, sulfiting agents that occur at concentrations of 10 ppm or higher, and any sulfiting agents that had a technical or functional effect in the food regardless of the amount present. The companies have to disclose the presence of sulphites on labels of packaged foods, although they do not need to specify the particular agent used. This information is included in the ingredient portion of the label, along with the function of the sulfiting agent in the food.

Australia and New Zealand

In December 2002, the *Australia New Zealand Food Standards Code* came into force. Standard 1.2.3, clause 4 of the Code, requires the declaration of certain substances in the list of ingredients on labels of food products or, if the food is not required to bear a label, then the information must be displayed on or in connection with the display of the food or provided to the purchaser upon request. These substances are an ingredient; an ingredient of a compound ingredient; a food additive or component of a food additive; or a processing aid or component of a processing aid. This requirement applies if the substances fall within one of the following categories: cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridized strains other than where these substances are present in beer and spirits standardized in Standard 2.7.2 and Standard 2.7.5 respectively; crustaceans and their products; fish and fish products; milk and milk products; peanuts and soybeans, and their products; added sulphites present in food in concentrations of 10 mg/kg or more; and tree nuts and sesame seeds and their products.

European Union

Directive 2003/89/EC was published on November 25, 2003. The substances covered by this Directive are cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof; crustaceans and products thereof; eggs and products thereof; fish and products thereof; peanuts and products thereof; soybeans and products thereof; milk and products thereof (including lactose); nuts i.e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut [*Carya illinoiesis (Wangenh.) K. Koch*], Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof; celery and products thereof; mustard and products thereof; sesame seeds and products thereof; and sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in the food expressed as SO_2 . The Directive requires that any ingredient from the above-noted list used in the

production of a foodstuff and still present in the finished product be indicated on the label. For alcoholic beverages, provision is made for the use of a “Contains” statement followed by the name of the appropriate ingredients. On December 22, 2006, Directive 2006/142/EC was issued amending the list of substances to which Directive 2003/89/EC would apply. The following substances were added to the list: lupin and products thereof and molluscs and products thereof.

In conclusion, implementation of this regulatory proposal would align Canada’s approach to the labelling of food allergens with those general requirements of its major trading partners. The key differences between this proposal and those currently implemented by other countries are a result of existing labelling requirements within the various countries.

Consultation

During the development of these proposed regulatory amendments, the following consultations were conducted:

- Prepublication of a regulatory proposal in the *Canada Gazette*, Part I, on October 15, 1994. These regulatory amendments proposed the mandatory declaration of sulphites on the label of all foods when present at a level of 10 ppm 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 BIT in 2002 to seek input from industry on potential costs of implementing regulations for the labelling of allergens. Subsequent to the invitation, several industry organizations met with Health Canada and the CFIA to discuss specific issues.
- Issuance of a letter to various stakeholders, including industry, industry associations, patient groups, health professionals and consumer groups and publication on Health Canada’s Web site regarding the final policy recommendations in February 2004. See www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/index_e.html.

In addition to the above-noted consultations, Health Canada is engaged in ongoing discussions with affected patient groups. Health Canada continues to work collaboratively with the international and the academic communities in refining and advancing its overall allergen strategy and the technical tools to support the proposed amendments and the broader strategy.

The following key issues were raised during the consultation process, and the updated responses are provided.

Definition of food allergen

As presented in 2002 in the BIT, the term “food allergen” would have referred to either the whole food or any derivative of a list of specified foods. Stakeholders raised the concern that the declaration of a food allergen would have been required even if the ingredient or component did not contain any protein of the specified foods, although it is the protein which is responsible for the allergic reaction. For example, soybean oil would have had to be declared as a food allergen even if it did not contain soy protein.

Health Canada has adjusted the proposal so that the declaration of a food allergen would only be required if the prepackaged product contains a protein, or a modified protein, including a protein fraction, derived from the specified foods. This option allows enhanced food choices to consumers with food allergies as the information provided on the label is more precise.

List of food allergens — Use of the term “tree nuts”

Stakeholders expressed concern that the term “tree nuts,” as it appeared in the 2004 policy recommendations, would not adequately identify the specific tree nuts of concern and requested that the tree nuts that were intended to be covered by the regulatory amendments be identified in a regulated list.

Health Canada agrees with the concern. The list of tree nuts is specifically identified in the proposed amendments and would include only the following tree nuts: almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts. The term “tree nut” is not used in the proposed amendments.

List of food allergens — Inclusion of sesame seeds

The requirement to declare sesame seeds as a food allergen was questioned by some stakeholders.

Severe anaphylactic reactions to sesame seeds have been reported in the scientific literature, and one death in Canada has been attributed to anaphylaxis from sesame seeds. (see footnote 18) Sesame seeds have been included for these reasons.

List of food allergens — Inclusion of gluten sources

The requirement to declare gluten sources such as wheat, spelt, kamut, rye, barley, oats and triticale and hybridized strains of these grains was also questioned.

Health Canada responded that these grains represent the sources of gluten that may be of concern to individuals with celiac disease. With the proposed labelling requirements, these individuals would benefit by being able to ascertain the actual source of gluten present in the prepackaged product.

Labelling of the source of hydrolyzed protein

Industry stakeholders questioned the recommendation to label the protein source of hydrolyzed protein.

Hydrolyzed plant proteins, which are widely used as ingredients in prepackaged products, are made from wheat, soybeans and corn but may be made from other protein sources including peanut. Partially hydrolyzed plant proteins, starches or modified starches may also be made from these plant sources and may contain residual protein. Consumers with allergies to any of these foods are advised to avoid products containing hydrolyzed protein, partially hydrolyzed plant protein, starches and modified starches when the ingredient name does not specify the plant source. Similarly, soybean lecithin has been reported to contain soybean protein and may be problematic for allergic consumers.

In addition, Health Canada responded that under the current Regulations, item 8 of the Table to paragraph B.01.010(3)(*a*) of the Regulations requires that the source of protein be declared in hydrolyzed plant protein prepared by an enzymatic process. Hydrolyzed proteins prepared by other processes do not have to declare the source of the protein. This inconsistency means that consumers cannot always determine the source of hydrolyzed protein in a prepackaged product.

The proposed requirement to include the protein source of hydrolyzed proteins, the plant source of starches and modified starches and the source of lecithin in the common names of these ingredients would remove uncertainty for consumers with food sensitivities and would better enable them to make safe and informed food choices from a wider variety of foods.

Naturally occurring sulphites

Concerns were raised over the presence of naturally occurring sulphites which may cause interference during laboratory analysis but are not associated with the triggering of adverse effects in sulphite-sensitive individuals.

To clarify that the amendments would address only added sulphites and not naturally occurring sulphites, for the purposes of the proposed Regulations, the term “sulphites” would refer specifically to the group of food additives composed of sulphurous acid and its salts that are currently regulated under the Regulations.

Sulphites and the determination of a 10 ppm limit

The appropriateness of using a 10 ppm limit for sulphites was raised.

The establishment of the 10 ppm limit as the trigger for labelling of sulphites is supported by the scientific evidence to date. The limit of 10 ppm is a “threshold” below which the probability of an adverse reaction in a sensitive individual is minimal. This proposed amendment for sulphites would harmonize the Canadian requirements with those established by the Codex Alimentarius *General Standard for the Labelling of Prepackaged Foods*.

Scope of products to be included in proposed amendments

In the BIT, a number of retail level products were included in the scope of the proposal. Industry expressed concern about their ability to ensure accurate labelling on products prepared at retail level in-store facilities.

Health Canada and the CFIA recognized that the issue in question in these situations was one of cross-contamination. In view of the fact that these proposed amendments are not intended to address cross-

contamination, prepackaged products that are sold only in the retail establishment where the product is prepared and processed from its ingredients have been exempted from the requirements of these proposed amendments. However, in order to balance the needs of the consumer, the requirements of the proposed amendments would apply to these products if the manufacturer/retailer chooses to voluntarily provide a list of ingredients on the product's label.

Products sold in bulk for further processing

Clarification was requested on the intent of the term "bulk foods," as described in the policy recommendations of 2004, since bulk foods would be exempted from the requirements of these proposed regulatory amendments.

The bulk products that are not intended to be covered by these proposed requirements are foods sold out of bins in grocery or food stores which require that the shopper scoop out the quantity of the product desired into a bag and secure it with a twist-tie or other closure.

Food sold in large containers to grocery stores for resale from "bulk" bins is considered to be a prepackaged product when shipped from the manufacturer to the grocery store and must be labelled in compliance with the requirements of the Regulations. This would include the proposed requirements for the declaration of food allergen and gluten sources and added sulphites. Similarly, ingredients sold in bulk packages for further processing in commercial or industrial facilities would also be subject to the proposed requirements for declaration of food allergen and gluten sources and added sulphites.

Alcoholic beverages — Effect on the labelling of alcoholic beverages

In response to the 2004 consultation, stakeholders inquired whether these proposed regulatory amendments would affect the labelling of alcoholic beverages. Under the current Regulations, alcoholic beverages that are subject to standards specified in Division 2 of the Regulations are not required to have a list of ingredients on their labels.

These proposed amendments would require a statement entitled "Allergen and Intolerance Information – Contains:" to appear on the label of alcoholic beverages followed by the identification of the sources of food allergens and gluten or added sulphites (if present in the amount of 10 ppm or more). However, Health Canada indicated that these proposed amendments would not require that a list of ingredients appear on the label of alcoholic beverages subject to standards specified in Division 2 of the Regulations.

Fining agents used in the manufacture of standardized alcoholic beverages

Health Canada received comments concerning the labelling requirements applicable to alcoholic beverages subject to standards of composition set out in Division 2 of the Regulations with regard to specific fining agents used during the manufacture of wine and beer.

Based on the nature of these alcoholic beverage products and their manufacturing processes, Health Canada concluded that fining agents derived from milk, eggs and fish that are used during the manufacture of standardized alcoholic beverages should be exempted from the proposed regulatory amendments. Fining agents have been used for many years in the preparation of certain standardized alcoholic beverages and, to date, Health Canada is not aware of documented clinical evidence of allergenic reactions in sensitive individuals resulting from the consumption of these products. However, Health Canada may reconsider its position in view of any new data developed by the scientific community, nationally and internationally, related to possible residues resulting from the presence of such fining agents in finished products and associated allergic reactions.

Threshold levels for food allergens and action levels for enforcement purposes

Industry expressed concerns related to the lack of threshold levels for food allergens (i.e. a level below which there will not be clinical manifestations of an allergic response in sensitive individuals). This lack of thresholds would necessitate the declaration of allergenic proteins present at very low levels.

Health Canada recognizes that the absence of threshold levels for food allergens is a challenge for regulatory agencies, industry and sensitive consumers. In the absence of established threshold levels, the proposed regulatory amendments would require the declaration of a food allergen when it is present in the prepackaged product as determined by the best available analytical methods. The current proposal specifically excludes the requirement to declare food allergens that would be present in the prepackaged product as a result of cross-contamination. Based on knowledge of the ingredients and components that

are used in the manufacture of the prepackaged product and the food allergen control programs implemented by the manufacturer and ingredient suppliers, the manufacturer would be able to determine if the proposed requirements would apply to its product.

Testing methodology and the application of requirements to imported products

The industry raised concerns about the application of these labelling requirements equally to domestic and imported products and how the analysis of products would be conducted.

The Regulations apply to all foods, domestically produced or imported, that are sold in Canada. Prepackaged products, whether imported or produced domestically, would have to comply with these proposed regulatory amendments. Health Canada and the CFIA are collaborating on the development of suitable methodologies for compliance purposes. The methodology used by the CFIA for compliance testing would be the best available and industry would be informed on the methodology used to assess compliance. The methods of analysis used by the CFIA for these food allergens would be available to manufacturers. Health Canada is documenting the availability and suitability of various analytical methods through publications made in its Compendium of Food Allergen Methodologies, which is Web-enabled, at www.hc-sc.gc.ca/fn-an/res-rech/analy-meth/allergen/index-eng.php.

"May contain" labelling/"allergen-free" claims

Health Canada received inquiries about whether the proposed regulatory amendments would address the use of voluntary "may contain" labelling and "allergen-free" claims.

It is not the intent of these proposed amendments to address these issues. The current policy on the issue of voluntary "may contain" labelling and "allergen-free" claims on labels is being reviewed by Health Canada, the CFIA and stakeholders in order to harmonize industry practices and permit sensitive consumers to make better informed choices.

Size, font and colour of text for declaration

Stakeholders asked if Health Canada was going to specify the size, font and colour of text for declaring food allergens, gluten sources and added sulphites on product labels.

Under the Regulations, the labelling would be required to meet the requirements set out in section A.01.016 which states 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.

Alternatives to labelling

The industry questioned whether alternatives to labelling, such as consumer education or the use of signs, could achieve the same effect and if these were considered as options.

Health Canada and the CFIA considered these options during the policy development process. The use of signage for the wide range of prepackaged products covered by these regulatory amendments would be impractical in grocery stores and other stores where many prepackaged products are sold. In addition, the other problem with signage is that it is effective only at the point of sale and would not provide the necessary information or enhance protection where the prepackaged product is consumed. It was considered that a mandatory labelling requirement was the most effective method of providing this information to consumers regarding the contents of specific prepackaged products. Consumer education would continue to remain an important element of Health Canada's approach to the prevention of food allergy incidents.

Implementation, enforcement and service standards

In recognition of the time required by industry to change their product labels, a 12-month transitional period is being proposed. However, if a manufacturer or importer changes the label to include the new statement beginning with the words "Allergy and Intolerance Information – Contains:", which is referred to in proposed paragraph B.01.010.1(2)(*b*) or subsection B.01.010.2(2), these proposed amendments would then apply immediately.

If these proposed amendments are adopted, compliance would be monitored as a component of the ongoing domestic and import inspection programs conducted by the CFIA. Health Canada would provide ongoing guidance to the CFIA in implementing the new labelling requirements. Health Canada would also

work towards common assessment practices with Canada's major trading partners. As part of its role to develop policies of application for labelling regulations, the CFIA would develop tools for industry to assist in the implementation of the new regulations (e.g. food labelling guide and training sessions).

This regulatory proposal is part of Health Canada's broader Food Allergy Incident Prevention Strategy. This strategy builds upon existing collaborative efforts between federal departments, consumer organizations and the food industry to enhance the protection of consumers with food allergies and celiac disease by addressing public health impacts of food allergies and food intolerance in a pro-active manner. As a result, these regulatory amendments would be supported by other areas and deliverables of the broader strategy. These areas include the development of information tools and education of consumers about food labelling practices related to food allergens as well as national and international collaboration in the development of consistent risk assessment procedures and methods of detection.

Contact

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PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to subsection 30(1) (see footnote a) of the *Food and Drugs Act* (see footnote b), proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1220 — Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites)*.

Interested persons may make representations concerning the proposed Regulations within 90 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to William Ross, Director, Bureau of Food Regulatory, International and Interagency Affairs, Department of Health, 200 Tunney's Pasture Driveway, Address Locator 0702C1, Ottawa, Ontario K1A 0K9 (tel. 613-946-4591; fax: 613-941-3537; e-mail: sche-ann@hc-sc.gc.ca).

Ottawa, June 19, 2008

MARY PICHETTE
Assistant Clerk of the Privy Council

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1220 — ENHANCED LABELLING FOR FOOD ALLERGEN AND GLUTEN SOURCES AND ADDED SULPHITES)

AMENDMENTS

1. Paragraph B.01.008(5)(*a*) of the *Food and Drug Regulations* (see footnote 19) is replaced by the following:

(*a*) subject to subsection B.01.010.1(7), immediately after the ingredient of which they are components in such a manner as to indicate that they are components of that ingredient; and

2. (1) Paragraph B.01.009(3)(*c*) of the Regulations is replaced by the following:

(*c*) hydrolyzed protein;

(2) Subsections B.01.009(4) and (5) of the Regulations are repealed.

3. (1) Item 8 of the table to paragraph B.01.010(3)(*a*) of the Regulations is replaced by the following:

Item	Column I Ingredient or Component	Column II Common Name
8.	hydrolyzed protein	hydrolyzed *plus the name of the source of the protein plus* protein

(2) The table to paragraph B.01.010(3)(*a*) of the Regulations is amended by adding the following after item 19:

Item	Column I Ingredient or Component	Column II Common Name
20.	starch	*the name of the plant plus* starch
21.	modified starch	modified *plus the name of the plant plus* starch
22.	lecithin	*the name of the source of the lecithin plus* lecithin
23.	crustacean	*the name of the crustacean*
24.	shellfish	*the name of the shellfish*

(3) Item 21 of the table to paragraph B.01.010(3)(*b*) of the Regulations is replaced by the following:

Item	Column I Ingredient or Component	Column II Common Name
21.	one or more of the following food additives, namely, potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite, sulphur dioxide and sulphurous acid	sulfites, sulfiting agents, sulphites or sulphiting agents

4. The Regulations are amended by adding the following after section B.01.010:

B.01.010.1 (1) The following definitions apply in this section and section B.01.010.3.

"food allergen" means any protein from any of the following foods or any modified protein, including any protein fraction, that is derived from any of the following foods:

(*a*) almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;

(*b*) peanuts;

(*c*) sesame seeds;

(*d*) wheat, kamut, spelt or triticale;

(*e*) eggs;

(*f*) milk;

(*g*) soybeans;

(*h*) crustaceans;

(*i*) shellfish; or

(*j*) fish. (*allergène alimentaire*)

"gluten" means

(*a*) any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals:

(i) barley,

(ii) oats,

(iii) rye,

(iv) triticale, or

(v) wheat, kamut or spelt; or

(*b*) any modified gluten protein, including any gluten protein fraction, that is derived from the grain of any of the cereals referred to in subparagraphs (*a*)(i) to (v) or the grain of a hybridized strain referred to in paragraph (*a*). (*gluten*)

(2) If a food allergen or gluten is present in a prepackaged product, the source of the food allergen or gluten, as the case may be, must be shown on the label of the product

(*a*) in the list of ingredients; or

(*b*) in a statement entitled "Allergy and Intolerance Information – Contains:", subject to the application of paragraph B.01.010.3(1)(*b*), in which case the source must be shown in the statement.

(3) Subsection (2) does not apply to a food allergen or gluten that is present in a prepackaged product as a result of cross-contamination.

(4) Subsection (2) does not apply

(*a*) to the prepackaged products referred to in paragraphs B.01.008(2)(*a*) to (*e*) unless a list of ingredients is shown on their label;

(*b*) to wax coating compounds and their components that are used on prepackaged fresh fruits or vegetables; and

(*c*) to fining agents derived from eggs, fish or milk that are used in the manufacture of Bourbon whisky or an alcoholic beverage that is subject to a compositional standard in Division 2, whether the Bourbon whisky or alcoholic beverage is a prepackaged product or is added to a prepackaged product.

(5) The source of a food allergen required to be shown under subsection (2) must be shown by,

(*a*) in respect of a food allergen from a food referred to in one of paragraphs (*a*) to (*c*) and (*e*) of the definition "food allergen" in subsection (1) or derived from that food, the name of the food as shown in the applicable paragraph, expressed in the singular or plural;

(*b*) in respect of a food allergen from a food referred to in paragraphs (*d*) or (*f*) of the same definition or derived from that food, the name of the food as shown in the applicable paragraph;

(*c*) in respect of a food allergen from the food referred to in paragraph (*g*) of the same definition or derived from that food, the name “soy”, “soya”, “soybean” or “soybeans”; and

(*d*) in respect of a food allergen from a food referred to in one of paragraphs (*h*) to (*j*) of the same definition or derived from that food, the common name of the food referred to in column II of item 6, 23 or 24 of the table to paragraph B.01.010(3)(*a*), whichever is applicable.

(6) The source of gluten required to be shown under subsection (2) must be shown by,

(*a*) in respect of gluten from the grain of a cereal referred to in one of subparagraphs (*a*)(i) to (v) of the definition “gluten” in subsection (1) or derived from that grain, the name of the cereal as shown in the applicable subparagraph; and

(*b*) in respect of gluten from the grain of a hybridized strain created from one or more of the cereals referred to in subparagraphs (*a*)(i) to (v) of the same definition or derived from that grain, the name of the cereal or cereals as shown in the applicable subparagraph or subparagraphs.

(7) For the purpose of paragraph (2)(*a*), the source of the food allergen or gluten must be shown in the list of ingredients, in parentheses, as follows:

(*a*) if the food allergen or gluten is an ingredient that is shown in the list of ingredients, immediately after the ingredient;

(*b*) if the food allergen or gluten is a component that is shown in the list of ingredients, immediately after the component;

(*c*) if the food allergen or gluten is a component that is not shown in the list of ingredients, immediately after the ingredient in which it is a component; or

(*d*) in all other cases, except those referred to in subsection (8), immediately after the ingredient or component in which the food allergen or gluten is present.

(8) Despite subsection (2), if the food allergen or gluten is an ingredient that is not shown in the list of ingredients or is present in such an ingredient, the source of the food allergen or gluten, as the case may be, must be shown on the label of the product in the statement referred to in paragraph (2)(*b*).

(9) Despite subsection (7), the source of the food allergen or gluten is not required to be shown in the list of ingredients if the source

(*a*) forms part of the common name of an ingredient or component that is shown in the list of ingredients;

(*b*) appears in parentheses after the common name of an ingredient or component that is shown in the list of ingredients; or

(*c*) appears in the statement referred to in paragraph (2)(*b*).

(10) For greater certainty, showing the source of the food allergen or gluten in accordance with subsection (7) immediately after an ingredient or component that is shown by the common name set out in column II of the table to paragraph B.01.010(3)(*b*) does not have the effect of requiring that ingredients or components that may be shown collectively by that name under that paragraph must be shown separately.

B.01.010.2 (1) In this section and section B.01.010.3, “sulphites” means the food additives listed in Column I of item 21 of the table to paragraph B.01.010(3)(*b*).

(2) If one or more sulphites are present in a prepackaged product in the total amount of 10 parts per million or more, they must be shown on the label of the product in the statement entitled “Allergy and Intolerance Information – Contains:”; however, sulphites must not be shown in the statement if they are present in the product in a total amount less than 10 parts per million.

(3) Subsection (2) does not apply

(*a*) to the prepackaged products referred to in paragraphs B.01.008(2)(*a*) to (*e*) unless a list of ingredients is shown on their label; and

(*b*) to wax coating compounds and their components that are used on prepackaged fresh fruits or vegetables.

(4) Sulphites required to be shown in the statement referred to in subsection (2) must be shown by one of the following common names:

(*a*) "sulfiting agents" or "sulphiting agents"; or

(*b*) "sulfites" or "sulphites".

B.01.010.3 (1) If the label of a prepackaged product includes the statement referred to in paragraph B.01.010.1(2)(*b*) or subsection B.01.010.2(2), the statement must

(*a*) appear after the list of ingredients for the product, if any, without any intervening printed, written or graphic material; and

(*b*) include the following information whether or not all or part of that information is shown in the list of ingredients for the product:

(i) the source of each food allergen present in the product,

(ii) the source of each gluten present in the product, and

(iii) one of the common names referred to in subsection B.01.010.2(4) for the sulphites required to be shown on the label of the product under subsection B.01.010.2(2).

(2) Despite paragraph (1)(*b*), the following information is not required to be shown in the statement more than once:

(*a*) the same source of a food allergen;

(*b*) the same source of gluten; and

(*c*) one of the common names "sulfites", "sulfiting agents", "sulphites" or "sulphiting agents".

5. Section B.13.011 of the Regulations is replaced by the following:

B.13.011.[S] Corn starch shall be starch made from maize and shall contain not less than 84% starch.

TRANSITIONAL PROVISION

6. (1) The following definitions apply in this section.

"former Regulations" means the *Food and Drug Regulations* as they read immediately before the day on which these Regulations come into force. (*règlement antérieur*)

"prepackaged product" has the same meaning as in section B.01.001 of the *Food and Drug Regulations*. (*produit préemballé*)

(2) Despite sections 1 to 5, during the period of 12 months after these Regulations come into force, the former Regulations continue to apply to a prepackaged product if the label does not include the statement referred to in paragraph B.01.010.1(2)(b) or subsection B.01.010.2(2) of the *Food and Drug Regulations* enacted by section 4 of these Regulations.

COMING INTO FORCE

7. These Regulations come into force on the day on which they are registered.

[30-1-o]

Footnote 1
Various references, including Rona, R. J., et al., *J.Allergy Clin Immunol*., 120(3), 638-646, 2007; and Sicherer, S., et al., *J.Allergy Clin Immunol*. 114, 159-165, 2004.

Footnote 2

Canadian Celiac Association Web site: www.celiac.ca/EnglishCCA/eceliac.html

Footnote 3
Allergy Living Web site: www.alergicliving.com/features.asp?copy_id=28

Footnote 4
ServiceOntario E-laws Web site: www.e-laws.gov.on.ca/index.html

Footnote 5
Zarkadas, M., et al., "The impact of a gluten-free diet on adults with coelic disease: results of a national survey," *J Hum Nutr Dietet*, 19(1), 41-49, 2006.

Footnote 6
Anaphylaxis Web site: www.anaphylaxis.org

Footnote 7
Sampson, Hugh, "Update on Food Allergy," *J Allergy Clin Immunol*, 113(5), 805-819, 2004.

Footnote 8
Salter, J., et al., A Study of 32 Food-Induced Anaphylaxis Deaths in Ontario; 1986-2000. Anaphylaxis Canada, Web site: www.anaphylaxis.org/content/ programs/programs_research_ deaths.asp (accessed Dec. 2007).

Footnote 9
Access Economic Pty Limited, The Economic Impact of Allergic Disease in Australia: Not to be Sneezed At. 13 November 2007, Australian Society of Clinical Immunology and Allergy, www.allergy.org.au/content /view/327/274/ (accessed Dec. 2007).

Footnote 10
Mills, E. N. C., et al., "The prevalence, cost and basis of food allergy across Europe," *Allergy* 62(7), 717-722, 2007.

Footnote 11
Access Economic Pty Limited, ibid.

Footnote 12
Zarkadas et al., ibid.

Footnote 13
Rashid, M., et al., "Celiac Disease: Evaluation of the Diagnosis and Dietary Compliance in Canadian Children," *Pediatrics*, 116(6), 754-759, 2005.

Footnote 14
Canadian Food Inspection Agency Web site: www.inspection.gc.ca/english/corpaffr/recarapp /recaltoce.shtml

Footnote 15
Health Canada Web site: www.hc-sc.gc.ca/fn-an/securit/eval/reports-rapports/allergen_paper-evaluation_allergene-01_e.html

Footnote 16
Zarkadas M., et al., Common allergenic foods and their labelling in Canada - A review. *Can J Allergy Clin Immunol*, 4(3), 118-141, 1999.

Footnote 17
Ibid.

Footnote 18
Ibid.

Footnote a
S.C. 2005, c. 42, s. 2

Footnote b
R.S., c. F-27

Footnote 19
C.R.C., c. 870

NOTICE:
The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

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