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Health Canada's Modifications to Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites

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Canada

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I. PURPOSE

This document outlines Health Canada's modifications to the proposed regulatory amendments to the *Food and Drug Regulations* on Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites published in *Canada Gazette*, Part I on July 26th, 2008. The modifications take into account comments received following the publication of the proposed amendments in *Canada Gazette*, Part I.

II. BACKGROUND

The proposed regulatory amendments to the *Food and Drug Regulations*, on Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites, were published in *Canada Gazette*, Part I on July 26th, 2008. Health Canada's proposed amendments to the *Food and Drug Regualtions* are summarized at: http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/project_1220_info-eng.php. The comment period ended November 28th, 2008. Health Canada accepted comments until early December 2008.

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.

The amendments, as proposed, would have required that the food allergen and gluten source be declared on a label of prepackaged foods, having a list of ingredients, whenever the protein, modified protein or protein fractions of the food allergen or gluten source are added to the product. The proposed amendments would also have required the labelling of added sulphites, in a statement following the list of ingredients, when sulphites are present in the finished product at levels of 10 ppm or more.

III. MODIFICATIONS TO THE PROPOSAL

The summary document on the comments received entitled: *Health Canada Reviews Comments Received on Regulatory Project 1220 – Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites* is posted at: http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/sum-comm-exa-eng.php

Overall, the comments received indicated a general support for the proposed amendments. Health Canada also received suggestions on how specific aspects of the proposed

amendments could be improved. On some other issues, divergent views were expressed. Health Canada analysed all the comments received against the emerging scientific evidence and assessed the options available which would best fulfill the policy objectives of enhancing the protection of consumers with food allergies and celiac disease, while not unduly restricting their food choices.

The present document highlights HC's key modifications to the proposed regulatory amendments published in *Canada Gazette*, Part I.

1) Definition of "food allergen" and "gluten"

In the proposed amendments, food allergen and gluten are defined as:

- *Food allergen: any protein or modified protein, including any protein fraction, 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 or fish.*
- *Gluten: any gluten protein or modified protein, including any protein fraction derived from the grains of the following cereals: barley, oats, rye, triticale, wheat, kamut or spelt. The definition would also apply to the grains of hybridized strains of the cereals listed above.*

Health Canada's revised approach:

a) Addition of mustard seeds in the regulatory definition of food allergen

Following the publication of the proposed amendments in *Canada Gazette*, Part I, stakeholders requested that other foods such as mustard seeds, onions, and garlic be added to the list of foods included in the regulatory definition of food allergen cited above.

In Canada, for a food to be considered for inclusion in the list of priority allergens, the information obtained from a systematic review of available literature regarding the potential allergenicity of a food must fulfill the following criteria. The first three criteria are in accordance with the Joint Expert Committee on Food Additives (JECFA) guidelines, the last two criteria are specific to the Canadian legislative context. The criteria are:

1. The existence of a credible cause-effect relationship, based upon positive Double-Blind, Placebo-Controlled (DBPC) food challenges or unequivocal reports of reactions with typical features of severe allergic or intolerance reactions.
2. Reports of severe systematic reactions following exposure to the foodstuff.
3. The assessment of all available Canadian prevalence data in children and adults, supported by appropriate clinical studies or alternatively data from other countries supported as per criterion 1.

4. The presence, in prepackaged food, of protein from the food allergen under consideration or any modified protein, including any protein fraction that is derived from the food allergen under consideration.
5. The possibility that the current food application of the food allergen under consideration may lead to the presence of the food allergen being hidden within certain foods.

Health Canada undertook a systematic review on the allergenicity of mustard seeds, onions, and garlic in order to determine the scientific validity of including those foods on the list of priority food allergens in Canada and within the definition of food allergen for the purpose of these regulatory amendments. The relevant information was assessed using the criteria described above.

Based on the conclusions of these systematic reviews, mustard seeds will be added to the list of foods in the definition of food allergen in the regulatory project 1220: Enhanced Labelling of Food Allergen and Gluten Sources and Added Sulphites. At this point in time, there is insufficient data to support the inclusion of onions and garlic in the list.

b) Inclusion of oats in the list of gluten sources.

The inclusion of oats in the definition of gluten raised concerns among stakeholders about the ability to make a distinction between regular oats and pure and uncontaminated oats. In addition, questions were raised regarding the use the gluten-free claim for food products containing pure and uncontaminated oats. Pure and uncontaminated oats can be tolerated by many people with celiac disease.

Health Canada will maintain the list of cereal grains identified in the definition of gluten as proposed in the *Canada Gazette* Part I. Thus, "oats" will be required to be shown, in accordance with the new amendments, when oat gluten is present in the product. This will alert all individuals with celiac disease of the presence of oat gluten. This will assist those individuals with celiac disease who cannot tolerate oats to avoid those products that may cause an adverse reaction.

Health Canada will consider potential options to update the gluten-free definition in section B.24.018 of the *Food and Drug Regulations* to better reflect the current scientific knowledge related to the safety of pure and uncontaminated oats for the majority of celiac individuals. Pure and uncontaminated oats are grown and handled in a manner to minimize the amount of cross-contamination with other gluten sources such as wheat, rye and barley. Health Canada recently conducted a safety/benefit evaluation regarding the introduction of pure and uncontaminated oats in the gluten-free diet of patients with Celiac Disease (CD). Emerging scientific evidence has demonstrated that these oats can be tolerated by the majority of people with Celiac Disease (CD) and consumption of these oats can have numerous benefits for Celiac individuals. However, there is an unknown proportion of individuals affected with CD that cannot tolerate even pure and uncontaminated oats.

2) Declaration of the food allergen or gluten source

The proposed amendments would require the declaration of food allergens or gluten sources on the label of a prepackaged product, either in the list of ingredients or in a statement beginning with the words "Allergy and Intolerance Information - Contains:". In the case of gluten sources, it would be required that the name of the cereal grain (e.g. wheat, rye, barley, oats, triticale) be declared. For fish, crustacean or shellfish, the proposed amendments would require the species name of the fish, crustacean or shellfish to be declared (e.g. halibut, shrimp, lobster, etc). For the specific tree nuts listed in the definition of food allergen, it is proposed that the specific name of the nut be declared (e.g. Brazil nut, cashew, etc.)

Health Canada's revised approach:

a) Declaration of the common name for hydrolyzed protein from plant sources

The regulatory proposal published in the *Canada Gazette*, Part I indicated modifications to section B.01.010 (3) (a) Item 8 of the *Food and Drug Regulations* pertaining to the format of the common name for hydrolyzed protein. The proposed modification would apply to hydrolyzed protein from both plant and animal sources.

After reviewing possible solutions, Health Canada is of the opinion, when no "Contains:" statement is used, that the currently used common names for animal based hydrolysed protein, with the additional requirement of the proposed amendments, would be sufficient to protect consumers with food allergies.

Consequently, Health Canada will proceed only with the modification to the format of the common names of hydrolyzed plant proteins. The identification of the plant source in the common names will apply to all hydrolyzed plant proteins, not just plant proteins prepared "by enzymatic process".

b) Spelt and kamut being declared as wheat for the allergen source

Based on comments received from a range of stakeholders, HC will be removing kamut and spelt as distinct terms in the definition of "food allergen" and "gluten" and as the prescribed name of the food allergen source and gluten source. HC will be interpreting the term "wheat" to include all cereal grains from the species *Triticum*. This interpretation will include kamut and spelt.

Consequently, when present in a prepackaged product, the term "wheat" will need to be declared in parenthesis beside spelt and kamut or, if a "Contains:" statement is used the term

"wheat" will need to be declared in the statement. This approach is similar to the approach used by the US in the Food Allergen Labelling and Consumer Protection Act (FALCPA).

3) The "Allergy and Intolerance Information - Contains:" statement

The proposed amendments would require the declaration of food allergens or gluten sources on the label of a prepackaged product, either in the list of ingredients or in a statement beginning with the words "Allergy and Intolerance Information - Contains:".

For sulphites present in a prepackaged product in a total amount of 10 parts per million or more, the proposed amendments would require that sulphites must always be declared in a statement starting with the words "Allergy and Intolerance Information - Contains:".

Health Canada's revised approach:

Following the publication of the proposed amendments in *Canada Gazette* Part I, Health Canada received numerous comments on the prefix for the statement - "Allergy and Intolerance Information – Contains:". Based on the comments received, there is an overwhelming preference, from both industry and patient groups, to use the prefix "Contains:". Space on label, ease of understanding and familiarity with the terminology were some of the key reasons noted by stakeholders. It was also seen as problematic as our key trading partners allow the prefix "Contains".

After the analysis of the comments received, Health Canada recognizes that removing the words "Allergen and Intolerance Information" and using "Contains:" as the prefix for the statement would be more practical for industry and consumers. This would also harmonize with international trade practice.

4) Sulphites

Background

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

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

Current Situation

Canada's *Food and Drug Regulations* require that the ingredients of prepackaged products be declared in descending order of their proportion in a list of ingredients on the label of most prepackaged products. However, subsections B.01.009 (1) and (2) of the Regulations specifically exempt components of certain ingredients, preparations and mixtures from declaration in the list of ingredients. In addition, some prepackaged products that do not require a list of ingredients may contain food allergens, gluten sources and sulphites, e.g.: certain wines and beer.

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

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

When sulphites are present in a prepackaged product in a total amount of 10 parts per million or more, the regulatory amendments, as proposed in *Canada Gazette*, Part I, would have required that sulphites be declared in a statement starting with the words "Allergy and Intolerance Information - Contains:" followed by one of the common names: sulphites, sulfites, sulphiting agents, sulfiting agents. This statement would have been required even when sulphites were declared in the list of ingredients.

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

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

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

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

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

Health Canada's Revised Approach to Declaration of Added Sulphites

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

However, based on the concerns raised by stakeholders, Health Canada will no longer be requiring added sulphites present at levels of 10 ppm or more to be declared in a separate "contains" statement. The use of a "contains" statement will therefore be optional for sulphites, as it is for declaration of food allergens and gluten sources.

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

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

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

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

5) Exemption for Fining Agents and Wax Coatings and other comments relating to those exemptions

Among few other exemptions, the proposed amendments would not apply in the following situations:

- *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 the alcoholic beverage is a prepackaged product or added to a prepackaged product;*
- *wax coating compounds and their components that are used on prepackaged fresh fruits or vegetables.*

Health Canada's revised approach:

a) Fining Agents

Following the publication of the proposed amendments in *Canada Gazette,* Part I some patient groups, health professionals and consumers raised concerns about the safety of some fining agents for allergic consumers and questioned the rationale used by Health Canada to exempt such substances from the amendments. It was suggested that the safety of these

products be evaluated on a case by case basis. As well, industry expressed confusion as to whether or not fining agents, in non-standardized alcoholic beverages, would need to be declared in view of the proposed exemptions for fining agents in standardized alcoholic beverages.

Based on these concerns, and the evolving scientific knowledge, Health Canada does not wish to proceed with exempting fining agents derived from eggs, fish or milk used in the production of standardized alcoholic beverages.

HC's decision to exempt these fining agents was based on the nature of these alcoholic beverages and their manufacturing processes, which is supposed to lead to the removal of the fining agent protein from the final product. However, Health Canada indicated in the Regulatory Impact Analysis Statement (RIAS) accompanying the *Canada Gazette,* Part I proposal that this exemption may be revisited, if warranted, once the results of research being conducted in Canada and in other countries becomes available.

The scientific perspective has evolved concerning fining agents from eggs, milk and fish used during the manufacture of standardized alcoholic beverages. Based on international incidents and the findings in other countries, there is increasing evidence to indicate that a blanket exemption for all fining agents derived from eggs, fish or milk used in standardized alcoholic beverages may not be warranted.

Internationally, in 2007, the European Food Safety Authority provided opinions to the European Commission that wines fined with milk (casein) and egg products, under specific manufacturing / processing conditions, may trigger adverse reactions in susceptible individuals. In 2010, fining agents from eggs and milk will have to be declared in the EU.

By removing this exemption from the amendments, when a food allergen is present in a standardized alcoholic beverage as a result of the use of fining agents from eggs, fish or milk, the allergen source would be required to be shown on the label of the prepackaged product. HC has concluded that allergic consumers will be better informed when considering the purchase of a standard alcoholic beverage as a result of these changes to the proposed regulatory amendments.

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

Health Canada intends to seek input from Canadians on a process for exemption of specific foods or ingredients from the enhanced labelling regulations for food allergen and gluten

sources. Stakeholders will be invited to make comments once a proposed exemption process is posted on Health Canada's website.

b) Wax Coating are used on prepackaged fresh fruits or vegetables.

Protective edible coatings and waxes are part of the post-harvest and handling technologies routinely used by the fresh produce industry to minimize moisture loss, prolong the shelf life, and to improve the appearance of fresh produce. Currently, there is no requirement to declare coatings or wax components on the label of prepackaged fresh fruits and vegetables.

In the comments received following publication of the proposed amendments in CG Part I, stakeholders pointed out that, over the last few years, there is an increasing diversity of coating formulations which may be used on fresh produce, some of which may contain priority food allergens derived from milk, soy or other allergenic and gluten sources. For example, new edible coatings with improved functionality and performance for fresh fruits and present use of coatings and formulations which may include soy, chitosan (derived from crustaceans) and caseinates (derived from milk) components.

Many fresh fruits and vegetables are commonly sold individually at retail and are not required to carry a label and therefore, a list of ingredients. However, some fruits and vegetables are also sold in prepackaged format where, currently under the Food and Drug Regulations, wax coating compounds and their components are not required to be shown on the label.

After analysis of the situation, Health Canada will remove the exemptions in the proposed amendments. HC will not change subsection B.01.008 (7) for the *Food and Drug Regulations,* the exemption for wax coatings compounds and their components to be shown on the label of prepackaged fresh fruits and vegetables. Thus, although the wax coating compounds and their coating would not be required to be declared on the label, the source of any allergen or gluten present in the wax coating or their compounds would be required to be shown on the label of prepackaged fruits and vegetables.

By not proceeding with the proposed exemptions for wax coatings and their components from the requirements to label food allergen and gluten sources, Health Canada will provide further assurances for allergic consumers, and celiac patient when considering the purchase a prepackaged fresh fruits and vegetables.

6) Methods and methodology

Among the comments received following publication of the proposed amendments in *Canada Gazette*, Part I, some industries expressed concern that the requirement to declare a food allergen and gluten may be driven by analytical findings. They were concerned that, in view of the continued progress in analytical method development and increase sensitivity,

such a situation would lead to a continued change in the requirements to declare for food allergen and gluten sources.

Furthermore, an association representing allergic consumers has pointed out that some highly refined oils may contain very low levels of protein without presenting a risk to allergic consumers. They mentioned the necessity to identify clearly to consumers the products that could represent a risk.

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

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

7) Transition period

In Canada Gazette Part I, a 12-month transitional period was proposed.

Health Canada's revised approach:

In light of the comments received and the time needed for industry to modify labels, as well as the need to move forward as soon as possible with enhanced protection for consumers, Health Canada is recommending that the new regulation come into force in 18 months after the date of publication.

Additional Information

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