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Food and Nutrition

Summary of differences between the proposed regulatory amendments as published in *Canada Gazette*, Part I and the amendments being published to *Canada Gazette*, Part II: entitled "Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites".

1. Addition of mustard seeds in the regulatory definition of food allergen

This is a change to the list of food allergens covered by the regulations. Mustard was not on the list in the Canada Gazette, Part I (CGI) proposal, but a number of comments were received requesting that Health Canada consider adding mustard to the list. Health Canada developed criteria for addition of allergens to the list and undertook a systematic review of the available information on allergenicity of mustard seeds.

Based on the conclusions of the systematic review, mustard has been added to the list of foods in the definition of food allergen in the Canada Gazette, Part II (CGII), (final version of the regulations).

2. Declaration of the common name for hydrolyzed protein from plant sources

The CG I proposal indicated modifications pertaining to the format of the common name for hydrolyzed protein. The proposed modification applied to hydrolyzed protein from both plant and animal sources.

After review, Health Canada recognized 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, so only hydrolyzed plant proteins will be specifically required to identify their source.

3. Spelt and kamut being declared as wheat for the allergen source

In the CG I proposal the list of food allergens included "wheat, spelt, kamut". HC will be interpreting the term "wheat" to include all cereal grains from the species Triticum. This interpretation will include kamut and spelt. Based on this the list of food allergens was shortened by removing the reference to spelt and kamut.

Consequently, when present in a prepackaged product, the term "wheat" will need to be declared in parenthesis beside spelt and kamut (or any other grains from the species Triticum) or, if a "Contains" statement is used the term "wheat" will need to be declared in the statement.

4. Wording of the contains statement.

The CG I proposal required the statement "Allergy and Intolerance Information - Contains" to be used.

Based on numerous comments this has been changed to "Contains" only.

5. Health Canada's Revised Approach to Declaration of Added Sulphites

In the CG I proposal, when sulphites were present at 10 ppm or higher, they had to be declared using the separate contains statement.

In the CG II publication sulphites above 10 ppm or higher will be treated the same as other priority allergens and use of a separate contains statement will be optional.

6. Fining Agents

The CG I proposal included an exemption for "fining agents derived from eggs, fish or milk that are used in the manufacture of" standardized alcoholic beverages. This exemption has been removed in the CG II publication. If 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. Mandatory <u>declaration of allergens</u>, <u>gluten sources and sulphites on standardized beer labels</u> is not included in the current amendments, and any additional amendments dealing with the labelling of beer will be dealt with once further consultations and discussions can be held.

7. Wax Coating

The CG I proposal included an exemption for "wax coating compounds and their components that are used on prepackaged fresh fruits or vegetables". This exemption has been removed in the CG II publication. 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.

8. Transition period

The CGI proposal included a 12 month transition period from the date of publication. The CG II publication changed this to an 18 month "coming into force" period which means the regulations will only start to be enforced 18 months after the CG II publication.

9. Declaration of allergens, gluten sources and sulphites on standardized beer

Health Canada has heard from numerous stakeholders, including various industry groups, patient associations and the general public with respect to the inclusion of beer labelling in these regulations. While the bulk of the comments received have been addressed, there remain some outstanding concerns about the best way to handle the labelling of allergens, sulphites and gluten sources when it comes to <u>standardized beer</u>.

Rather than delay the publication of the regulations any further, the department is moving forward with a phased approach. The bulk of the regulations are being published now, while any additional amendments dealing with enhanced labelling of beer will be dealt with once further consultations and discussions can be held.

While the current amendments do not require standardized beer to be labelled with a list of ingredients, it is important to note that if a list of ingredients is voluntarily provided on beer, that this list will have to be complete in accordance with the new food allergen labelling regulations.

10. Section B.24.018 of the Food and Drug Regulations (FDR) has been updated

In order to better reflect the <u>variationally adopted scientific description of 'gluten'</u>, Health Canada has updated B.24.018 for the regulations to describe gluten as 'any gluten protein, including any gluten protein fraction, referred to in Canada's definition of gluten', which can be found in subsection B.01.010.1(1) of the FDR.

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