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The Bureau of Chemical Safety Food Directorate Health Canada

Health Canada Reviews and Answers Comments Received on Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites

June 2010



Health Canada Reviews Comments Received on Regulatory Project 1220 - Enhanced Labelling for Food Allergens, Gluten Sources and Added Sulphites

I. Background

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 (CGI) on July 26th, 2008. The proposed amendments would require 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 require 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. Health Canada's proposed amendments to the *Food and Drug Regulations* 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.

II. Summary of Comments

More than 140 comments were received from stakeholders including consumers, health professionals, patient groups, industry associations, industries and other governments. Of these comments, sixty e-mails were received from consumers. During the comment period, Health Canada also met with a number of patient and consumer groups, as well as industry associations. These groups included: Anaphylaxis Canada, Canadian Celiac Association, l'Association québécoise des allergies alimentaires, la Fondation québécoise de la maladie coéliquaie, Option consommateurs, Canadian Council of Grocery Distributors, Flavouring Manufacturer's Association of Canada, Spirits Canada, Canadian Brewers Association, La Société des alcools du Québec, Food & Consumer Products of Canada and the Bakers Association of Canada. Some of these meetings were held following specific requests from stakeholders.

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 the overall objective of the project. 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 present document highlights the key issues identified by stakeholders and Health Canada's response to the issues.

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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.*

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • Some stakeholders requested the addition of specific foods such as mustard seeds, onions, and garlic to the list of foods included in the proposed regulatory definition of food allergen. • A comment was received regarding the necessity to regularly review the list of foods in the definition of food allergen. 	<p>Health Canada will review the current scientific evidence and will develop clear criteria for considering the inclusion of foods in the regulatory definition of food allergen.</p>	<p>Health Canada has developed criteria to determine the scientific validity of including new foods to the list of foods identified in the definition of food allergen. See: http://www.hc-sc.gc.ca/fn-an/pubs/label-etiquet/crit/index-eng.php</p> <p>Health Canada undertook a systematic review of the existing literature on mustard seeds, onions and garlic against these criteria.</p> <p>Based on the conclusions of these systematic reviews, HC will be adding mustard seeds as one of the foods listed in the definition of "food allergen".</p>
<ul style="list-style-type: none"> • The inclusion of oats in the definition of gluten raised questions about the distinction between regular oats and pure and uncontaminated oats. The latter can be tolerated by many people with celiac disease. • Some stakeholders recommended that Health Canada make the distinction between the two oats in the proposed amendments and re-examine the criteria for enabling gluten-free claims. 	<p>Health Canada will consider potential regulatory options to update the gluten-free definition prescribed in B.24.018 of the <i>Food and Drug Regulations</i> to better reflect the current scientific knowledge related to the safety of pure and uncontaminated oats for the majority of celiac individuals. Health Canada will review and may consider changes to the definition of gluten which is included in the current regulatory proposal.</p>	<p>Health Canada will maintain the list of cereal grains identified in the definition of gluten as proposed in the CG 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.</p> <p>Health Canada will consider potential options to update the gluten-free definition prescribed in B.24.018 of the <i>Food and Drug Regulations</i> to better reflect the current scientific knowledge related to the safety of pure and uncontaminated oats for the majority of celiac individuals.</p>

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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.)

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • Concerns were expressed regarding the option to declare food allergens and gluten sources in two different places (in either the list of ingredients or in the 'Allergy and Intolerance Information Contains' statement). • Some stakeholders preferred a mandatory declaration of food allergen and gluten sources in the list of ingredients. • Some other stakeholders preferred that the declaration always appear in a "contains statement". 	<p>Health Canada will assess the options for declaring the food allergen and gluten sources 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.</p>	<p>No changes will be made to the proposal since it was determined the proposed approach was the best option that fulfills the policy objectives of enhancing the protection of consumers with food allergies and celiac disease, while not unduly restricting their food choices.</p>
<ul style="list-style-type: none"> • Most of the stakeholders agreed with the proposed name by which a food allergen and/or gluten sources would be declared. • Other stakeholders provided alternatives for the terms or the manner to declare some food allergens. It was suggested that the species name for fish, shellfish and crustaceans be followed by the appropriate term "fish", "shellfish" or "crustaceans" in parenthesis e.g. halibut (fish). • A similar suggestion was made for tree nuts. The specified name of the tree 	<p>Health Canada will review possible alternatives for the declaration of fish, shellfish, crustaceans and tree nuts that would best fulfill the policy objectives.</p>	<p>No changes will be made to the proposal since it was determined the proposed approach was the best option that fulfills the policy objectives of enhancing the protection of consumers with food allergies and celiac disease, while not unduly restricting their food choices.</p>

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<p>nut should be followed by the term "tree nut" in parenthesis e.g. Brazil nut (tree nut).</p>		
<p>Stakeholders expressed varying views on which term should be used when the source of gluten is declared:</p> <ul style="list-style-type: none"> • Some stakeholders requested the use of the term "gluten"; • Other stakeholders would prefer the term "gluten" in addition to the common name of the grain of the cereal, and; • Others agreed with the suggestion in the proposed amendments. 	<p>Health Canada will review the possible alternatives for the declaration of gluten sources that would best fulfill the policy objectives.</p>	<p>No changes will be made to the proposal since it was determined the proposed approach was the best option that fulfills the policy objectives of enhancing the protection of consumers with food allergies and celiac disease, while not unduly restricting their food choices.</p>
<ul style="list-style-type: none"> • Some stakeholders recommended that all varieties of wheat, including spelt and kamut, be declared by the term "wheat" for the purpose of these amendments. 	<p>Health Canada will strive to propose a simple option to identify the different varieties of wheat, such as, spelt and kamut on food labels.</p>	<p>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 <i>Triticum</i>. This interpretation will include kamut and spelt.</p> <p>This approach is similar to the approach used by the US in the Food Allergen Labelling and Consumer Protection Act (FALCPA)</p>

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<ul style="list-style-type: none"> • One patient group expressed a desire to have gluten declared only when the amount of 20 parts per million or more is present in the product. • A health professional group expressed a desire for gluten to be labelled when present in food at any level. 	<p>Once finalized, Health Canada and the Canadian Food Inspection Agency will aim to develop guidance, and compliance policy that clearly reflects the intent of the amendments with respect to gluten declaration.</p>	<p>No changes will be made to the proposal since it was determined the proposed approach was the best option that fulfills the policy objectives of enhancing the protection of consumers with food allergies and celiac disease, while not unduly restricting their food choices.</p>
<p>Concerns were raised that the proposed format for common name of hydrolyzed protein (proposed modification to paragraph B.01.010 (3) (a)) would apply to hydrolyzed protein from both plant and animal sources. It was noted that if those modifications proceed as proposed, a number of the common names for animal based hydrolyzed protein (as hydrolysed casein or whey protein hydrolysate) could no longer be used.</p>	<p>Health Canada will review the possible alternatives for the declaration of hydrolyzed protein that would best fulfill the policy objectives.</p>	<p>Since the proposed amendments would require the identification of the source of any food allergen or gluten, Health Canada believes the currently used common names for animal based hydrolyzed protein, with the additional requirement of the proposed amendments would be sufficient to protect the consumers with food allergies.</p> <p>Consequently, Health Canada will proceed only with the modification that 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”.</p>

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:".

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Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> The majority of the stakeholders, including consumers, patient groups and industry associations, found the prefix "Allergy and Intolerance Information - Contains:" too long. It was also noted that the longer statement could be confusing and misleading for consumers. 		
<ul style="list-style-type: none"> The majority of stakeholders preferred a short "Contains" statement as currently required by other jurisdictions including as the United States and the European Commission. Some stakeholders noted that the term "Contains" has been widely used on a voluntary basis by Canadian food processors and importers for several years. Stakeholders also indicated that the term "Contains" is well understood by consumers. 	<p>Health Canada will examine various options to determine a specific statement for the declaration of food allergen and gluten sources, and sulphites that will best fulfill Health Canada's policy objectives, and meet its trade agreement obligations.</p>	<p>Health Canada will shorten the wording of the prescribed prefix to: "Contains:".</p> <p>Health Canada recognizes that wording "Contains:" statement would be more practical for industry and consumers and would harmonize with international trade practice.</p>
<ul style="list-style-type: none"> Industry and industry associations indicated that the proposed prefix would be too long for small labels as well as products with limited panel space. Comments received from industry, industry associations as well as international jurisdictions indicated that the wording of the statement would pose a trade barrier for labelling of certain foods and, in particular, alcoholic beverages. 		

4) Sulphites

When sulphites are present in a prepackaged product in a total amount of 10 parts per million or more, the proposed amendments would require that sulphites be declared in a statement starting with the words "Allergy and Intolerance Information

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- Contains:" followed by one of its common names: sulphites, sulfites, sulphiting agents, sulfiting agents.

If the "Allergy and Intolerance Information - Contains:" statement is used on the label of a prepackaged product it must be comprehensive. Thus, the source of each food allergen and the source of any 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 sulphites are present in a total amount of 10 parts per million or more.

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • Most stakeholders agreed with the requirement to declare added sulphites when present in a total amount of 10 parts per million or more given that such a requirement, at the indicated threshold, is supported by a health and safety rationale. 	<p>Health Canada will review potential regulatory options for sulphites to ensure that sulphites, present in a total amount of 10 parts per million or more, be identified on the food label in the simplest manner possible.</p>	<p>Health Canada will no longer be requiring that sulphites present at levels of 10 ppm or more be declared in a separate statement. HC will permit sulphites, that are present in a total amount of 10 ppm or more and not already shown in the list of ingredients in accordance with sections B.01.008-B.01.010 to be shown either in the list of ingredients or in the "Contains:" statement. HC will be maintaining the requirement for the "Contains:" statement to be complete for all food allergen and gluten sources as well as added sulphites present in the prepackaged product at a total amount of 10 ppm or more. Thus, sulphites required to be shown in the list of ingredients, in accordance with sections B.01.008 to B.01.010, will continue to be shown in the list of ingredients. However, if a "Contains:" statement appears on the label, sulphites present in the amount of 10 ppm or more would also be required to be shown in the "Contains:" statement.</p>
<ul style="list-style-type: none"> • Industry associations expressed concern with the requirement to exclusively use the "Allergy and Intolerance Information - Contains:" statement to declare sulphites when they are present at 10 ppm and above. 		
<ul style="list-style-type: none"> • Some stakeholders suggested that sulphites be shown in the list of ingredients followed by a simple statement that provides additional information about the amount of sulphites present and that the "Allergy and Intolerance Information - Contains:" statement be made optional. 		
<ul style="list-style-type: none"> • Some stakeholders requested clarity as to whether sulphites that are formed as a result of certain processing condition would be addressed by the proposed amendments. 	<p>Health Canada is reviewing the possible need to address process-induced sulphites with the same labelling requirements for prepackaged foods, such as added sulphites, when present in the food in a total amount of 10 parts per million or more. Consideration will be given to the fact that such process-induced sulphites may lead to the same</p>	<p>HC will not be addressing process induced sulphites in these regulatory amendments. Health Canada may re-examine the issue as part of a separate initiative at a later date.</p>

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	health concerns as added sulphites, when inadvertently consumed by sulphite sensitive individuals at the indicated threshold.	
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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.*

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • Patient groups, health professionals and consumers questioned the safety of some fining agents and wax coatings (derived from food allergen and gluten sources) for allergic consumers or individuals with celiac disease. They questioned the rationale used by Health Canada to exempt such substances from the proposed amendments. • It was suggested that the safety of these products be evaluated on a case by case basis. • 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. 	<p>Health Canada will review the scientific evidence and the recent rulings made by other food regulatory agencies on the exemption of fining agents and wax coatings (derived from food allergen or gluten sources) from ingredient declaration.</p>	<p>As indicated in the document (http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/proj1220-exempt-eng.php) posted on HC's website on September 11th, 2009, Health Canada will remove the proposed exemptions for wax coating compounds and their components. Therefore, any allergen or gluten present in the wax coating compounds or their components will be required to be declared on the label of prepackaged fruits and vegetables.</p> <p>Health Canada will remove the exemption for fining agents. Thus, if a food allergen from milk, egg or fish is present in a standardized alcoholic beverage as a result of the use of fining agents, the allergen source will need to appear on the label of the prepackaged product unless it has been established, based on accepted scientific principles that the consumption of the product will not result in an immune mediated adverse response in persons who are allergic to the food allergen.</p>
<ul style="list-style-type: none"> • Some stakeholders indicated that highly refined oils do 	<p>Health Canada will consider possible options to establishing an</p>	<p>Health Canada is committed to developing a process under which</p>

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<p>not contain significant amounts of protein. It was suggested that highly refined oils be given an exemption similar to the proposed exemptions for fining agents and wax coatings.</p> <ul style="list-style-type: none"> • Industry suggested that exemptions for fining agents and wax coatings be eliminated and that their potential exemption be part of a regulatory mechanism that is similar to those developed by other jurisdictions which could: <ul style="list-style-type: none"> • Based on current scientific and clinical evidence, exempt the requirement to label certain ingredients as per the proposed amendments. • Be used to address ingredients derived from a food allergen or gluten source that have been processed in a manner to remove the protein source, and thus, not posing a risk to allergic consumers or individuals with celiac disease. 	<p>approach that will provide guidance on food labelling requirements when the protein or protein fractions may be present at very low amounts in the product as a result of a manufacturing process. Health Canada will consider its current regulatory framework and will also consider the approach used by other countries such as those developed by the United States Food and Drug Administration (US FDA) and the European Food Safety Authority / European Commission.</p>	<p>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.</p> <p>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.</p>
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6) Methods and methodology

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • The lack of available commercial allergen test kits was identified as a possible concern with certain industries. 	<p>Health Canada will strive to continuously update its current guidance on availability and suitability of food allergen analytical techniques, in its web-enabled compendium of food allergen methodologies: http://www.hc-sc.gc.ca/fn-an/research/analy-meth/allergen/index-eng.php</p>	

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<ul style="list-style-type: none"> • Some stakeholders expressed concern that the declaration of food allergen and gluten sources may possibly be driven by analytical findings. 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. • Refined soy oil was an example mentioned of a product which may contain very low levels of protein without presenting a risk to allergic consumers. 	<p>Health Canada will consider possible options to establishing a process that will provide guidance on food labelling requirements when the protein or protein fractions may be present at very low amount in the product as a result of a manufacturing process. Health Canada will consider its current regulatory framework and will also consider the processes used by other countries.</p>	<p>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.</p> <p>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.</p>
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7) Legibility criteria

No specific criteria regarding the legibility of the information required to be declared on the label of the products has been proposed in the amendments. However, section A.01.016 of the Food and Drug Regulations would apply. This section states that all information, required by the Regulations, must be clearly and prominently displayed on the label and readily discernable to the purchaser or consumer under customary conditions of purchase and use.

Comments	Health Canada's consideration	Health Canada's revised approach
<p>The legibility of the information required by these proposed amendments was identified as a concern for some stakeholders. Suggestions to improve the legibility of the required information included:</p> <ul style="list-style-type: none"> • Requiring food allergen and gluten sources and added sulphites be written 	<p>The improvement of the legibility of information within the list of ingredients is broader than the scope of the current regulatory proposal. The scope of this proposal is to eliminate instances where food allergen and gluten sources and sulphites (above 10 ppm) are not currently declared on the label and to provide a declaration in a simple manner. Legibility issues could be further</p>	<p>HC has noted the concerns about the legibility of the list of ingredients and has identified it as an issue that may be address as part of a broader policy initiative on food labelling.</p>

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<p>in bold faced text in the list of ingredients;</p> <ul style="list-style-type: none"> • Using symbols or pictures on the label, and; • Prohibiting the practice of the use of all capital letters in the list of ingredients. 	<p>addressed as part of a broader policy and regulatory initiative on food labelling.</p>	
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8) Transition period

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

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • Certain stakeholders indicated that a two year transition period would help reduce the cost for label changes on prepackaged foods. • Some stakeholders requested that Health Canada consider extending the transition period to products with a long shelf life, such as, canned food or alcoholic beverages, when developing the transition provisions. 	<p>Health Canada will re-examine the length of the transition period considering both the burden on industry as well as the need to move forward as soon as possible with enhanced protection for consumers.</p>	<p>Considering both the impact on industry as well as the need to move forward as soon as possible with enhanced protection for consumers, Health Canada is recommending that the regulatory amendments come into force 18 months after the date of publication.</p>

9) Precautionary labelling

Comments	Health Canada's consideration	Health Canada's revised approach
<ul style="list-style-type: none"> • The over-use of precautionary labelling and the need for clearer and stricter guidelines for the use of "may contain" or similar statements was raised in a large number of comments. 	<p>This issue, while outside the scope of the present regulatory project, is linked to allergen labelling and to the overall strategy to manage health risks associated with undeclared allergens. Health Canada has taken note of these comments and will be addressing them in its initiative to review the policy in use of allergen precautionary statements (http://www.hc-sc.gc.ca/fn-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette-eng.php).</p>	<p>Health Canada has taken note of these comments and will be addressing them in its initiative to review the policy in use of allergen precautionary statements (http://www.hc-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette-eng.php).</p>

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<ul style="list-style-type: none">• Industry requested that Health Canada align the implementation period of this regulatory proposal with the other initiatives involving labelling changes.	Health Canada will strive to align the implementation period of forthcoming changes in food labelling requirements (in particular those pertaining to allergen precautionary statements) with the proposed transition period associated with this regulatory proposal.	
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10) Need for education

The need to inform and educate consumers and industry regarding the regulatory amendments was noted. Health Canada will partner with patient groups and consumer groups and food industry associations to further educate Canadians and Industry on food allergy incident prevention through improved food labelling practices.

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