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Summary of Comments Received on Health Canada's Proposed Policy Intent for Revising Canada's Gluten-Free Labelling Requirements

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Food Directorate

Health Products and Food Branch



Canada 

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Note: For the purposes of this document, the term “uncontaminated oats” refers to oats that have been specially produced to be free of gluten from other cereals.

Background

Canada's *Food and Drug Regulations* (FDR) currently prohibit the use of gluten-free claims on prepackaged food products containing wheat, including spelt and kamut, oats, barley, rye or triticale or any part thereof (Section B.24.018 of the FDR).

The safety of oats in a gluten-free diet has been the subject of study in the recent past.

The *Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (revised in 2008) and a Canadian Celiac Association position paper have recently supported the safety of oats for most individuals with celiac disease.

In 2007, Health Canada published its [*Position on the Introduction of Oats to the Diet of Individuals Diagnosed with Celiac Disease*](#). Based on an extensive review of the scientific literature, Health Canada concluded that the majority of people with celiac disease can tolerate the consumption of limited amounts of uncontaminated oats. The scientific literature also suggests that the consumption of uncontaminated oats can be nutritionally beneficial to celiac individuals who are able to tolerate their consumption, and their palatability may help to increase compliance with a gluten-free diet. Uncontaminated oats are an important source of proteins and carbohydrates, especially fibre, and their consumption would permit a wider choice of foods for celiac individuals when selecting foods within the grains and cereals category.

In light of the evolving scientific evidence, Health Canada undertook a review of the current policy on gluten-free labelling. In the summer of 2010, Health Canada published a [*Proposed Policy Intent for Revising Canada's Gluten-Free Labelling Requirements*](#) which outlined the principles proposed to guide Health Canada's review of the gluten-free labelling policy. Stakeholders were invited to provide Health Canada with input on these principles via an online consultation, which focused on the safety of oats, and to identify other issues that should be considered with regards to potential changes to Canada's gluten-free labelling policy.

The following principles were proposed in the 2010 policy intent document:

- Canada's gluten-free labelling policy should reflect the fact that consumers following a gluten-free diet for medical reasons must not consume the protein fraction of certain cereal grains.
- Health Canada's gluten-free labelling policy should be mindful and protective of the minority of individuals with celiac disease who do not tolerate the consumption of uncontaminated oats.

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- The policy should reflect Health Canada's recommendation that those individuals with celiac disease or dermatitis herpetiformis interested in consuming oats should consult physicians, dietitians or health practitioners beforehand.
- Health Canada's gluten-free labelling policy should take into consideration the newly adopted regulatory amendments to *enhance the labelling of allergen and gluten sources and added sulphites in prepackaged foods* as well as Health Canada's ongoing review of precautionary labelling of prepackaged foods in order to promote consistency and minimize consumer confusion.¹

Summary of Comments

In total, comments were received from 131 stakeholders [individuals (99), health professionals/health professional associations (9), patient/consumer associations (6), industry (12), industry associations (3), government (1) and academia (1)].

What We Heard On the Proposed Principles:

Only a limited number of stakeholders directly addressed the proposed principles in their comments. Those that did address the proposed principles expressed support for them. Based on the overall substance of the comments received, there was general support for the proposed policy direction.

¹ It should be noted that since the publication of the gluten free policy intent document, Health Canada published regulatory amendments (1220 — *Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites*) which update the FDR to better reflect the current scientific understanding regarding the trigger of celiac disease (*i.e.*, that it is the protein portion of cereal grains which is of concern for individuals with celiac disease). In these amendments, gluten is defined as “(a) any gluten protein from the grain of any of the following cereals or from the grain of a hybridized strain that is created from at least one of the following cereals: (i) barley,(ii) oats,(iii) rye, (iv) triticale,(v) wheat; 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 paragraph (a) or from the grain of a hybridized strain referred to in that paragraph. (Subsection B.01.010.1(1) of the FDR). The amendments will come into force August 4th, 2012. The move to focus on the protein fraction does not affect the proposed policy principles for the review of Canada's gluten-free labelling policy.

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What Else We Heard:

As noted above, the majority of stakeholders did not address the principles in their comments, but provided a number of other comments. General support for harmonization with other jurisdictions was indicated. The following tables summarize the other specific comments received from stakeholders in response to the online consultation (*i.e.*, comments that are not in direct response to the proposed principles), and Health Canada’s considerations with respect to these comments. These general comments were grouped into the following themes: the threshold for gluten-free claims; gluten-free claims for products specially processed to remove gluten and naturally gluten-free foods; the use of “reduced gluten”, “low gluten” or “very low gluten” claims; permitting gluten-free claims for products containing oats; precautionary labelling statements; enforcement concerns; advertising fortified gluten-free foods, and education.

Other comments on:

1) Threshold for “Gluten-free” claims

Questions/Comments	Health Canada’s consideration
<p>There were suggestions from some stakeholders for alignment with the “gluten-free” threshold established internationally by <i>Codex Alimentarius</i>. Most stakeholders who provided comments on this issue supported a 20 ppm threshold. A few stakeholders favoured zero tolerance while others favoured a label declaration of actual test results for gluten. One stakeholder suggested < 10 ppm as a threshold.</p>	<p><u>Health Canada's Position on Gluten-Free Claims</u> was recently published. The position states that based on the available scientific evidence, Health Canada considers that gluten-free foods, prepared under good manufacturing practices, which contain levels of gluten not exceeding 20 ppm as a result of cross-contamination, meet the health and safety intent of B.24.018 when a gluten-free claim is made.</p>

2) Specially processed and naturally gluten-free products

Questions/Comments	Health Canada’s consideration
<p>A few comments were received regarding products specially processed to remove gluten. Within the received comments, there was a divergence of opinion with some supporting a gluten-free claim for products containing wheat, barley or rye specially processed to remove gluten, while others did not.</p> <p>In addition, some stakeholders expressed</p>	<p>Regulations amending the <i>Food and Drug Regulations</i> (1220 — <i>Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites</i>), which come into force August 4, 2012, will enable Canadians with food allergies, sensitivities and celiac disease to make more informed choices about the foods they buy. Among other things, these regulations update Section B.24.018 of the FDR to better reflect the</p>

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<p>the view that the regulation must enable and encourage the use of gluten-free labelling for naturally gluten-free grains and cereals and their flours and starches such as: amaranth, buckwheat, millet, sorghum, teff, rice, quinoa, corn and tapioca, as well as naturally gluten-free, seeds, legumes and nuts and their flours if properly manufactured and tested so as to meet the < 20 ppm gluten threshold. One industry member suggested that the gluten-free claim should be allowed for wheatgrass juice.</p>	<p>current internationally adopted scientific description of gluten. With this updated terminology, companies that manufacture products made with barley, oats, rye, triticale or wheat that do not contain gluten protein will have the option of labelling them as gluten-free in Canada (<i>e.g.</i>, products containing pure maltodextrin derived from wheat will now be able to label themselves as gluten free). It is considered that this change will be of benefit to celiac patients, since it could further expand the availability of healthy food choices for this group.</p> <p>Health Canada will also consider various policy options with respect to allowing naturally gluten-free foods to carry gluten-free claims.</p>
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3) “Reduced gluten”, “low gluten” or “very low gluten” claims

Questions/Comments	Health Canada’s consideration
<p>A few comments were received on this issue; however, one patient association and one health professional did not support such claims as they stated that the data to support safety of reduced gluten products containing > 20 ppm gluten are inconsistent and there is potential to confuse consumers.</p>	<p>For foods specially processed to reduce gluten, the Codex standard allows for claims such as "very low gluten" to be used for foods that contain more than 20 ppm gluten, but less than 100 ppm gluten. However, due to potential health risks for some individuals with celiac disease and the potential to confuse consumers, Health Canada does not propose the use of such claims at this time.</p>

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4) Oats

Numerous comments were received around a number of issues pertaining to oats. These have been grouped and summarized below.

Questions/Comments	Health Canada’s consideration
a) Allowing gluten-free claims for uncontaminated oats and products containing uncontaminated oats	
<p>Consumer/patient groups, health professionals and industry generally supported allowing gluten-free claims for uncontaminated oats and products containing uncontaminated oats. Although some consumers expressed support, others cited concerns, including:</p> <ul style="list-style-type: none"> • scientific basis for the safety of oats for individuals with celiac disease • need to ensure purity of oats • potential impact on availability of products for individuals who cannot tolerate uncontaminated oats. 	<p>Health Canada’s position statement “Celiac Disease and the Safety of Oats” is based on an extensive review of the scientific literature related to the safety of oats in a gluten-free diet. As a result, Health Canada proposes to continue to support the safety of uncontaminated oats in a gluten-free diet, consistent with the position of the Canadian Celiac Association.</p> <p>Health Canada is considering amending the regulatory requirement for “gluten-free” foods to account for the findings of its assessment of the “safety of oats for celiac individuals”.</p>
b) Related labelling issues	
<p>Declaration of presence of oats</p> <p>Many respondents indicated that the presence of oats should be declared on the label of gluten-free foods in order to inform consumers, including those who cannot tolerate uncontaminated oats.</p>	<p>In general, oats which are used as ingredients in a food would appear in the list of ingredients. The likelihood of oats being present as a component of an ingredient exempted from component declaration is very small. Nevertheless, regulations amending the <i>Food and Drug Regulations</i> (1220 – <i>Enhanced Labelling for Food Allergen and Gluten Sources and Added Sulphites</i>), which come into force on August 4, 2012, will require the mandatory declaration of oats, either in the list of ingredients or in a “Contains” statement, whenever protein from oats is added to a prepackaged product as an ingredient or component.</p>

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Questions/Comments	Health Canada’s consideration
<p>Declaration of quantity of oats per serving</p> <p>A few stakeholders inquired as to whether Health Canada would require manufacturers to state the quantity of oats (per serving of product).</p>	<p><u><i>Health Canada’s position on the Introduction of Oats to the Diet of Individuals Diagnosed with Celiac Disease</i></u> states that celiac individuals should limit their consumption of uncontaminated oats to 20–25 grams/day (65 ml – or ¼ cup dry rolled oats) for children and 50–70 grams/day (125 to 175 ml – or ½ to ¾ cup dry rolled oats) for adults. Health Canada will consider how best to communicate this information to consumers, including whether manufacturers should be required to state the quantity of oats per serving of product on the label.</p>
<p>Advisory statement for products containing uncontaminated oats.</p> <p>A few stakeholders expressed support for an advisory statement that would inform consumers about the recommended maximum quantity of uncontaminated oats which is considered safe, and that medical consultation is recommended before the introduction of oats into the diet.</p>	<p>Health Canada acknowledges this comment and will explore how best to address it in the overall context of the gluten-free policy.</p>
<p>Labels should indicate that conventional oats are contaminated.</p> <p>One consumer suggested that labels should indicate that conventional oats are contaminated with other cereals.</p>	<p>Crop contamination of the conventional oat supply with other gluten-containing cereals has recently been confirmed by findings stemming from laboratory analysis conducted by the Bureau of Chemical Safety of Health Canada’s Food Directorate. Health Canada’s policy will give consideration to educating consumers about this adventitious presence which is a result of agricultural practices that are accepted under Canadian agricultural acts and regulations</p>

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5) Precautionary Labelling

Questions/Comments	Health Canada’s consideration
<p>Some stakeholders expressed concern regarding statements such as “May contain gluten” or similar statements (e.g. “Produced in a factory that uses wheat”).</p> <p>Some stakeholders also felt that the label should indicate whether the product is made on the same line as gluten-containing products or whether the facility is gluten-free.</p>	<p>These labelling issues are beyond the scope of this initiative. Note, however, that precautionary labelling statements for wheat (which is both an allergen and a gluten source) and other gluten sources will be addressed in Health Canada’s initiative to review its policy on the use of allergen precautionary statements.</p>

6) Quality Control

Questions/Comments	Health Canada’s consideration
<p>Some stakeholders expressed concerns regarding cross-contamination and the need for Good Manufacturing Practices (e.g. standardized processes for cleaning production lines, ELISA tests, etc.). One consumer/patient group expressed the view that all ingredients should be verified in order for a product to carry a gluten-free claim.</p>	<p>Health Canada recognizes that measures will be needed to ensure the purity of oats used in products that carry gluten-free claims.</p> <p>Health Canada and the CFIA will give consideration to the development of a HACCP generic model, code of practice, or other similar model for gluten-free foods.</p>

7) Enforcement

Questions/Comments	Health Canada’s consideration
<p>A question was asked regarding plans to ensure consistency in enforcement actions for domestic and imported products.</p>	<p>The <i>FDR</i> apply to all foods, domestically produced or imported, that are sold in Canada. Prepackaged products, whether imported or produced domestically, must comply with the <i>FDR</i>.</p> <p>Health Canada will work collaboratively with the CFIA to harmonize our policies to the extent possible and ensure consistent enforcement actions for products labelled gluten-free.</p>

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8) Advertising

Questions/Comments	Health Canada’s consideration
A question was asked regarding the possibility of reviewing the limitations currently in place on the advertising of fortified gluten-free products.	At this time, Health Canada does not intend to undertake a review of section D.03.003 of the <i>FDR</i> , which exempts gluten-free foods from fortification restrictions if the food is not advertised to the general public.

9) Education

Questions/Comments	Health Canada’s consideration
Several stakeholders noted the need to inform and educate consumers and industry.	Health Canada will partner with patient groups, consumer groups and food industry associations to further educate Canadians and industry on any changes to the gluten-free labelling policy.

NEXT STEPS:

Health Canada will continue to give careful consideration to feedback from stakeholders on this issue, as it considers revisions to its gluten-free labelling policy. Health Canada will engage in further consultations with stakeholders once potential options for revisions to Canada’s gluten-free labelling policy have been developed. Stakeholders are invited to visit Health Canada’s website for further updates: <http://www.healthcanada.gc.ca/food>

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