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# Health Canada's Proposed Policy Intent for Revising Canada's Gluten-Free Labelling Requirements

**Bureau of Chemical Safety**  
**Food Directorate**  
**Health Products and Food Branch**

A PAHO/WHO Collaborating Centre for  
Food Contamination Monitoring



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**Canada**

# Health Canada’s Proposed Policy Intent for Revising Canada’s Gluten-Free Labelling Requirements

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## Executive Summary

Gluten is a family of proteins found in some cereal grains including wheat, barley and rye. For sensitive individuals, including those with celiac disease (CD) and gluten sensitivity (GS), the consumption of dietary gluten results in adverse health effects, many of which may be serious. Celiac disease is a chronic immune-mediated condition in which gluten in the diet damages the small intestine. This damage prevents the body from absorbing the nutrients it needs to be healthy. Other serious health consequences such as certain cancers and infertility are also related to CD. Gluten sensitivity is another condition triggered by the consumption of gluten, in which individuals present many of the same symptoms as those with CD, but without the autoimmune response observed in individuals with CD. Currently, the only treatment for these conditions is to follow a strict gluten-free diet (GFD) for life.

The understanding of CD has advanced greatly since it was first identified. Historically, oats have been excluded from the GFD, which also excludes wheat, barley, rye and other closely related cereals. However, whether or not individuals with CD can safely consume oats as part of a GFD has recently been an issue of interest and scientific investigation. In 2007, based on an extensive review of the scientific literature related to the safety of oats in a GFD, Health Canada concluded that the majority of people with CD can tolerate moderate amounts of oats that are uncontaminated with gluten proteins from other cereal grains such as wheat, barley and rye. The term uncontaminated oats is used throughout this document to refer to oats that have been specially produced to be free of gluten from other cereals. Health Canada's systematic review of the scientific literature also suggested that the consumption of these uncontaminated oats can be beneficial to those individuals with CD who tolerate it, and that their palatability may help to increase compliance with a GFD. However, section B.24.018 of Canada's *Food and Drug Regulations* (FDR), promulgated in 1995, prohibits the use of the term gluten-free on prepackaged food products containing oats, even if the oats are uncontaminated with other cereal grains.

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This hinders the ability of consumers following a GFD who choose to consume food products containing uncontaminated oats to easily identify prepackaged foods that they can consume while avoiding gluten. In addition, section B.24.018 of the FDR does not reflect the current scientific understanding that it is the protein portion of the cereal grains which is of concern for individuals with CD and GS.

In light of this, Health Canada is reviewing Canada's current gluten-free labelling policy in order to minimize the risk of inadvertent consumption of gluten by sensitive individuals and to maximize the choice of gluten-free foods for consumers following a gluten-free diet. The following principles have been proposed in order to guide this work:

- Canada's gluten-free labelling policy should reflect the fact that consumers following a GFD 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 CD who do not tolerate the consumption of uncontaminated oats.
- This policy should reflect that Health Canada recommends that those individuals and/or practitioners interested in introducing oats to people with CD or dermatitis herpetiformis are advised to consult physicians, dietitians and health practitioners before the introduction of oats to the gluten-free diet.
- Health Canada's gluten-free labelling policy should take into consideration the proposed regulatory amendments to enhance the labelling of allergens, gluten sources and added sulphites in pre-packaged foods as well as Health Canada's ongoing review of precautionary labelling of pre-packaged foods in order to promote consistency and minimize consumer confusion.

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Health Canada is currently seeking feedback from the public on these proposed principles. In addition, we would like to know if there are other issues that should be considered with regards to potential changes to Canada's gluten-free labelling policy.

The feedback received through this consultation will be considered by Health Canada as it moves forward with developing options for potential revisions to Canada's gluten-free labelling policy. Health Canada will undertake further consultation with stakeholders once potential options have been developed.

### **I. Introduction**

Health Canada is reviewing its gluten-free labelling policy in order to minimize the risk of inadvertent consumption of gluten by sensitive individuals and to maximize the choice of gluten-free foods for consumers following a gluten-free diet. In particular, Health Canada would like its gluten-free labelling policy to better reflect current scientific knowledge related to the triggers of celiac disease (CD), and, the safety of consuming oats that are uncontaminated with gluten from other cereal grains, such as wheat, barley and rye, for the majority of celiac individuals. This work is being undertaken as part of Health Canada's Allergen program objectives:

- 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

The purpose of this document is to provide background information and to outline the considerations that have led to the proposed principles that will frame Health Canada's policy direction with respect to changes to its gluten-free labelling policy.

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## II. Current Situation – The Case for Action

### **Celiac Disease is a Common Genetic Condition With Serious Symptoms Triggered by the Consumption of Gluten**

Celiac Disease (CD), also known as celiac sprue or gluten-sensitive enteropathy, is an adverse reaction observed in genetically susceptible individuals when they consume certain cereal grains<sup>1</sup>. Scientific evidence indicates that it is the protein fraction of these grains, known as gluten, which triggers the adverse reactions in individual with CD (Zarkadas, 1999; Shan *et al.*, 2002, Rashid *et al.*, 2007). The immune system of a celiac reacts negatively to the presence of gluten in the diet causing damage to the inner lining of the small intestine. This damage reduces the person's ability to absorb nutrients including: iron, folate, calcium, Vitamin D, protein, fat and other food compounds. Other serious health consequences such as certain cancers and infertility are also related to CD (Pulido, in press).

CD is now recognized as one of the most common chronic diseases in the world. It is estimated that it affects as many as 1 in every 100 - 200 people in North America (Fasano *et al.*, 2003; National Institutes of Health, 2004). As many as 300,000 Canadians could have this disease; however, many remain undiagnosed. Closely related family members of celiacs have a greater risk (10-20%) of developing the disease than others (Jolobe, 2008).

The symptoms of CD vary greatly from one person to another both in extent and severity, making diagnosis difficult. While CD has been regarded primarily as a disease of the gastrointestinal tract, only some individuals with CD suffer typical gastrointestinal symptoms

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<sup>1</sup>Cereal grains that are known to trigger celiac disease/dermatitis herpetiformis reactions include the following: wheat (including durum wheat or "durum", spelt wheat or "spelt", kamut), barley, rye, triticale, atta, bulgur, einkorn, emmer and farro. (Case, 2006).

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(abdominal pain, flatulence, and diarrhea). Individuals with CD may suffer from a range of symptoms including fatigue or anemia, while others display no visible symptoms. A serious skin condition called dermatitis herpetiformis, characterized by an itchy rash with bumps and blisters, is also triggered by the ingestion of gluten in genetically susceptible individuals and is considered the dermatological form of CD. In this document, unless otherwise indicated, the term CD includes dermatitis herpetiformis. Undiagnosed or untreated CD can be associated with serious complications including osteoporosis, cancer, reproductive problems in adults, as well as failure to grow and delayed puberty in children (Ciclitira *et al.*, 2005; Green and Jabri, 2006; Helm, 2005; Koning 2005; Lee and Green, 2006; Lowichik and Book, 2003; McGough and Cummings, 2005; Rashid *et al.*, 2005).

### **The Only Treatment for Celiac Disease is a Gluten-Free Diet**

Currently, the only treatment for CD is to continually maintain a gluten-free diet (GFD) (Case, 2006; Zarkadas *et al.*, 2006). The diet requires a strict lifelong exclusion of wheat, rye, barley, and other related cereal grains from the diet (Fasano & Catassi, 2001; Catassi *et al.*, 2007; Ciclitira *et al.*, 2005; Kupper, 2005; Case, 2006; Zarkadas *et al.*, 2006). Despite the fact that consuming a GFD ultimately brings about greater well-being in most people with CD, following a GFD is complex and requires a significant amount of effort and commitment. As a result, compliance with a GFD is a problem for many individuals with CD (Ciclitira *et al.*, 2005). Gluten is widely used in the production of many processed and prepackaged foods. In addition to the obvious sources of gluten such as breads, pastas, and most common breakfast cereals, gluten is often found in a wide variety of products such as seasonings, sauces, soy sauce, marinades, salad dressings, soups, prepared meats, corn- and rice-based cold cereals, candy and flavoured coffee/teas (Raymond *et al.*, 2006). For individuals with CD, careful review of food labels to determine if gluten-containing ingredients are present is essential to avoid acute and chronic adverse health effects.

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### **Other Consumers May Also Follow a Gluten-Free Diet For Medical Reasons**

Following a GFD is essential for individuals with CD. While the gold standard for the diagnosis of CD is presently a biopsy to check for characteristic changes to the small intestine, there is some literature to suggest that the development of CD is a continuum and that changes to the intestine may take years to develop (Marsh, 1995, Kurpa *et al.*, 2009). In addition, there has been some discussion in the scientific literature that some individuals with gluten sensitivity do not progress to fully expressed CD (Bai *et al.*, 1997). More recent research has indicated that gluten sensitivity and CD could be defined as two distinct conditions that are both triggered by the consumption of gluten. Gluten sensitivity could be defined as a non-allergic, non-autoimmune reaction to gluten that can cause symptoms similar to those of CD but without the autoimmune response (Sapone *et al.*, 2009). As a result, in addition to individuals with CD, there are other consumers who may also need to follow a GFD for medical reasons.

### **The Majority of Celiac Individuals Can Safely Consume Uncontaminated Oats**

Historically, oats have been excluded from the GFD. Recently, whether or not those with CD can safely consume oats has been an issue of interest and scientific investigation. Of the gluten proteins found in wheat and other related cereals, it is the alcohol soluble fractions, known as the prolamins, which are of the most concern to individuals with CD (Pulido *et al.*, 2009). The prolamins found in these cereals contain a high amount of the amino acid proline, making them resistant to complete digestive breakdown. It is the undigested portions of these proteins that are considered to elicit the immune response in individuals with CD (Shan *et al.*, 2002, Wieser and Kohler, 2008). In comparison, the prolamins found in oats, known as avenin, have a substantially lower content of proline. In addition, avenin accounts for only 5-15% of the total protein in oats, whereas in wheat, barley and rye, prolamins constitute 40-50% of the total protein (Pulido *et al.*, 2009, Shan *et al.*, 2002, Vader *et al.*, 2003).

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However, oats, wheat and barley are usually grown next to each other in the fields, stored in the same grain elevators, milled and processed with the same equipment, and transported using the same containers. Inevitably, the grains co-mingle and the oats become contaminated with gluten from other grains.

In 2007, based on an extensive review of the scientific literature related to the safety of oats in a GFD, Health Canada concluded that the majority of people with CD can tolerate moderate amounts of oats uncontaminated with gluten from other cereal grains such as wheat, barley and rye (Pulido *et al.*, 2009). This finding concurs with the position of the Canadian Celiac Association (CCA). Health Canada's systematic review of the scientific literature also suggested that uncontaminated oats can be beneficial to those individuals with CD who tolerate it, and their palatability may help to increase compliance with a GFD. Oats are an important source of proteins and carbohydrates, especially fibre, and would permit a wider choice of foods for celiac individuals when selecting foods within the grains and cereals category.

When introducing uncontaminated oats into the GFD, Health Canada recommended that individuals with CD have proper follow up by a health professional, including initial and long term assessments. Oats should be limited to 20-25 grams/day (65 ml - or 1/4 cup dry rolled oats) for children and 50 -70 grams/day (125 to 175 ml - or 1/2 to 3/4 cup dry rolled oats) for adults, as recommended by the CCA (Pulido *et al.*, 2009; Professional Advisory Board of the Canadian Celiac Association, 2007, Rashid *et al.*, 2007).

In its review of the safety of uncontaminated oats as part of a GFD, Health Canada also recognized that there are limitations in the available scientific literature regarding the safety of uncontaminated oats for individuals with CD, including: limited information on long-term consumption, small numbers of subjects tested, limited information on reasons for patients dropping out without completing study protocols, reports that some

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individuals may be intolerant to even uncontaminated oats, and an indication from some *in vitro* studies of an immunological response in the absence of clinical manifestations (Pulido *et al.*, 2009).

Despite these limitations, the possible benefit for the majority of individuals with CD is supported by Health Canada's current position regarding uncontaminated oats. Although some uncontaminated oat products may be available in Canada, the desire from the CD community and manufacturers to have these labelled as "gluten-free" and expand their availability and variety warrant the review of Canada's existing gluten-free regulation. Any changes made to Canada's existing gluten-free labelling policy should be mindful and protective of those individuals with CD who do not tolerate even uncontaminated oats.

### **Uncontaminated Oats are Available in Canada**

In Canada, uncontaminated oats are now being produced to eliminate cross contamination with other gluten sources and certain food products made from these oats are being sold. Every level of their production (seed, planting, growing, harvesting, transport, storage, processing, packaging) must be controlled to eliminate cross contamination. The producers follow the same procedures that have been developed for pedigreed seed growers. Uncontaminated oats are harvested, transported, stored, processed and manufactured under Good Manufacturing Practices to minimize the presence of wheat, including spelt and kamut, barley, rye or triticale, or any part thereof, so as not to exceed 20 ppm of gluten. Throughout this document, the term uncontaminated oats is used to refer to oats that have been produced in this manner.

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### **Canada's *Food and Drug Regulations* Limit Options for Celiac Consumers**

Currently, section B.24.018 of Canada's FDR define a gluten-free food as follows:

No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or *oats*, barley, rye or triticale or *any part thereof*.”[emphasis added].

As a result, the term "gluten-free" is not permitted on packaged food products containing oats, even if the oats are uncontaminated with gluten from other cereal grains. This hinders the ability of consumers with CD who choose to consume food products containing uncontaminated oats to easily identify packaged foods that they can consume while avoiding gluten from wheat, rye and barley.

In addition, as a matter of industry policy outside of regulation, any gluten-free manufacturer who brought oats into their facilities could no longer be considered a gluten-free facility. For this reason many gluten-free manufacturers are reluctant to make products using uncontaminated oats as ingredients.

### **Health Canada Has Proposed Regulatory Amendments to Enhance the Labelling of Food Allergen and Gluten Sources in Canada**

Health Canada recently proposed regulatory amendments intended to enhance the labelling of allergens, gluten sources and added sulphites in Canada (Canada 2008). Among other things, the proposed amendments would require labelling of food allergen and gluten sources on the label of pre-packaged foods having a list of ingredients, whenever the protein or protein fractions of the gluten source are added to the product. The proposed amendments define gluten as 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 these cereals. This definition takes into account the scientific

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evidence which indicates that the protein is the portion of the food which will trigger the adverse reaction in an individual with CD (Zarkadas, 1999; Shan et al., 2002; Rashid et al., 2007).

The list of cereal grains identified in the definition of gluten included in the proposed regulatory amendments, published in the *Canada Gazette*, Part I (CGI) in July 2008, is consistent with the cereal grains identified in section B.24.018 of the FDR (*i.e.*, a gluten-free food cannot contain oats). Following publication of the proposed regulatory amendments in CGI, the inclusion of oats in the definition of gluten prompted comments from stakeholders regarding the distinction between regular oats and oats that are uncontaminated with gluten from other cereals which can be tolerated by many people with CD. This is one of the reasons that Health Canada is considering changes to its current gluten-free labelling policy, including potential amendments to section B.24.018 of the FDR in order to permit products containing uncontaminated, gluten-free oats to carry a gluten-free label.

### **Gluten-Free Labelling is Evolving Internationally**

Canada is currently one of the few countries in the world with a regulation regarding the use of the term gluten-free. However, the science has evolved since the existing gluten-free regulation was promulgated in 1995.

At the international level, the *Codex Alimentarius Commission* revised its *Codex Standard For Foods For Special Dietary Use For Persons Intolerant to Gluten* in 2008 (Codex Alimentarius Commission, 2008). The revised standard includes oats in the list of grains which may not be present in foods that are gluten free, but notes that: "Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level." This standard applies to gluten-free foods (foods containing less than 20ppm) as well as to foods that have been processed to

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remove gluten to a level between 20ppm and 100ppm. According to this standard, only foods containing less than 20ppm may be labelled as gluten-free, however, labelling terms and marketing decisions for foods specially processed to reduce gluten content to a level between 20ppm-100ppm (*e.g.*, low gluten, reduced gluten) may be determined at the national level.

The European Union (EU) has based its recently published regulations, which come into effect January 2012, on the Codex standard. Under the EU regulation, gluten is defined as a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives. Food products containing ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten may bear the term 'gluten-free'. Oats contained in food for people intolerant to gluten must have been specially produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties and the gluten content of the oats must not exceed 20mg/kg. As the amount of gluten that is tolerated by gluten intolerant individuals varies from individual to individual, the EU regulations permit products to be labelled either as 'very-low gluten' (less than 100ppm of gluten) or 'gluten-free' (less than 20 ppm of gluten), in order to permit a choice of products with different low levels of gluten.

The US Food & Drug Administration (FDA) is proposing to define the term "gluten-free" for voluntary use in the labelling of foods. The FDA proposal would not prohibit a food product containing oats from carrying a gluten-free claim, provided that it contained less than 20 ppm gluten (FDA, 2007). The FDA's proposal specifies that a food labelled "gluten-free" does not contain any of the following: an ingredient that is any species of the grains wheat, rye, barley, or a crossbred hybrid of these grains (collectively referred to as "prohibited grains"); an ingredient that is derived from a prohibited grain and that has NOT been processed to remove gluten (*e.g.* wheat flour); an ingredient that is derived from a prohibited grain and that has been processed to remove gluten (*e.g.* wheat starch)

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if the use of that ingredient results in the presence of 20 parts per million (ppm or mg/kg) or more gluten in the food; 20 ppm or more gluten. Under the FDA proposal, a food that bears the claim “gluten-free” in its labelling and does not meet these conditions would be deemed misbranded. Foods that are inherently or naturally free of gluten would also be deemed misbranded if the claim does not refer to all foods of that same type (e.g., “milk, a gluten-free food” or “all milk is gluten-free”)

According to the Australia New Zealand Food Standards Code, foods containing oats or their products are prohibited from carrying gluten free claims. They may, however, carry low gluten claims provided they contain no more than 200 ppm of gluten (Food Standards Australia New Zealand, 2009).

### **III. Proposed Policy Intent**

#### **Based on the Above Considerations, Several Principles Can be Derived Regarding Gluten-Free Labelling in Canada**

In order to minimize the risk of inadvertent consumption of gluten by sensitive individuals and to maximize the selection of safe foods suitable for inclusion in a GFD, Canada's policy direction should:

- Canada's gluten-free labelling policy should reflect the fact that consumers following a GFD 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 CD who do not tolerate the consumption of uncontaminated oats.
- This policy should reflect that Health Canada recommends that those individuals and / or practitioners interested in introducing oats to people with CD or

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dermatitis herpetiformis are advised to consult physicians, dietitians and health practitioners before the introduction of oats to the gluten-free diet.

- Health Canada's gluten-free labelling policy should take into consideration the proposed regulatory amendments to enhance the labelling of allergens, gluten sources and added sulphites in pre-packaged foods as well as Health Canada's ongoing review of precautionary labelling of pre-packaged foods in order to promote consistency and minimize consumer confusion.

#### **IV. Conclusion**

Health Canada is proposing to modernize its gluten-free labelling policy in accordance with the principles that have been outlined in this document. It is anticipated that Canadians would benefit from an updated gluten-free labelling policy. Revising Canada's gluten-free labelling policy to reflect the findings stemming from Health Canada's review of the safety of oats uncontaminated with gluten from other cereals for celiac individuals, would minimize risks associated with the inadvertent consumption of undeclared gluten by individuals with CD, while maximizing the selection of safe and nutritious foods suitable for inclusion in a GFD. Revising the current gluten-free labelling policy would also ensure consistency with the proposed regulatory amendments to enhance the labelling of allergens, gluten sources and sulphites in Canada and would also bring the regulations in line with international standards. Health Canada will give careful consideration to feedback from stakeholders on this issue, as it considers its gluten free labelling policy.

Health Canada is currently seeking feedback from the public on these proposed principles. Specifically, we are interested in knowing whether there are other issues that should be considered with regards to potential changes to Canada's gluten-free labelling policy.

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This consultation is open for comment starting May 13, 2010, until July 11, 2010.

Comments may be submitted by email: [bfpi@hc-sc.gc.ca](mailto:bfpi@hc-sc.gc.ca) , mail or courier to:

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The feedback received through this consultation will be considered by Health Canada as it moves forward with developing options for potential revisions to Canada's gluten-free labelling policy. Health Canada will undertake further consultation with stakeholders once potential options have been developed.

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