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Health Canada's Position on Gluten-Free Claims

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Background

Celiac disease is a lifelong medical condition observed in genetically susceptible individuals. Symptoms and complications occur in response to the ingestion of the gluten protein found in wheat and related grains. Exposure to gluten can lead to a series of immune-mediated adverse reactions and progressive deterioration of the lining of the small intestine. Individuals with celiac disease have an increased risk of developing other diseases, including osteoporosis, lymphoma and type I diabetes mellitus. They are also at increased risk of reproductive problems. In children, celiac disease can be associated with growth failure and delayed puberty. It is estimated that Celiac disease affects approximately 1% of the population, or 340,000 Canadians.

A life-long gluten-free diet is the only way to avoid the symptoms and the complications of celiac disease. As a result, individuals with celiac disease are advised to avoid the consumption of wheat, rye, barley, oats and triticale, as well as their hybridized strains. Gluten can be present in a food as a result of its manufacture using ingredients that are gluten sources themselves, such as wheat or barley. Gluten can also be present in a food due to cross-contamination as a result of manufacturing or distribution practices. As grains containing gluten are widely used in the production of many pre-packaged foods, to avoid acute and chronic adverse health effects, careful review of food labels is essential for individuals with Celiac disease to determine if gluten-containing ingredients are present.

Regulatory Requirements for Gluten-Free Foods

Division 24 of the *Food and Drug Regulations* (FDR) sets out specific regulations that apply to "Foods for Special Dietary Use".

A "food for special dietary use" is defined in B.24.001 of the FDR as a food that has been specially processed or formulated to meet the particular requirements of a person:

a. in whom a physical or physiological condition exists as a result of a disease, disorder or injury; or
b. for whom a particular effect, including but not limited to weight loss, is to be obtained by a controlled intake of foods.

As per section B.24.003(1)(g), a gluten-free food that meets the requirements described in section B.24.018, is one of the types of foods for special dietary use that are covered by the requirements of Division 24.

As of August 4, 2012, section B.24.018 of the *Food and Drug Regulations* will state that:

*It is prohibited to label, package, sell or advertise a food in a manner likely to create an impression that it is a gluten-free food if the food contains **any gluten protein** or modified gluten protein, including any gluten protein fraction, referred to in the definition "gluten" in subsection B.01.010.1(1).*

Subsection B.01.010.1(1) reads:

"gluten"

(a) any gluten protein from the grain of any of the following cereals or the grain of a hybridized strain created from at least one of the following cereals:

(i) barley,

(ii) oats,

(iii) rye,

(iv) triticale, or

(v) wheat, kamut or spelt; 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 subparagraphs (a)(i) to (v) or the grain of a hybridized strain referred to in paragraph (a). (gluten)

Recent advances in the knowledge base about gluten intolerance and Celiac disease

Individuals affected by Celiac disease have been shown to be capable of tolerating a small amount of gluten in their diet. The amount of gluten to which a person with Celiac disease can be exposed before the gluten will have a negative impact on their health is often referred to as a "threshold level". The types of studies required to estimate threshold levels are demanding on study participants, given they require invasive diagnostic procedures to look for signs of intestinal damage. For this reason only a small number of these studies have been conducted usually with a limited number of participants.

Studies have shown that there is variation in the amount of gluten people with celiac disease can tolerate. Therefore, it is difficult to suggest a single definitive threshold. A study published in 2007 looked at the effects of exposure to 0, 10 or 50 mg/day of gluten on people with Celiac disease.

Some signs of damage to the intestinal villi were found in the 50 mg/day group, whereas 10mg/day appeared safe for most of the subjects studied[1]. The authors concluded that "the ingestion of contaminating gluten should be kept lower than 50 mg/day in the treatment of CD"[2]. A systematic review of available information on a tolerable amount of gluten for people with Celiac disease[3] published in 2008 concluded that "a daily gluten intake of less than10 mg is unlikely to cause significant histological abnormalities." In other words, it is anticipated that the majority of people with Celiac disease will not be negatively affected if they limit their gluten intake to less than 10 mg per day.

Health Canada has conducted exposure estimations[4] to gluten from grain-containing foods and foods with grain-derived ingredients (i.e., flour), taking into consideration the various rates of food consumption by different sex and age groups. These estimates have concluded that if gluten was present at levels not exceeding 20ppm (parts per million or milligrams per kilogram), exposure to gluten would remain below 10 mg per day for all age groups studied. As individuals with celiac disease tend to consume even fewer servings of grain-based products, these estimates further demonstrate that even if all foods labelled as gluten-free food contained 20 ppm gluten, the majority of people with Celiac disease would still be protected (consume less than 10 mg gluten/day). This assessment will be made available in the peer reviewed scientific literature.

In surveys that have been conducted for foods labelled as gluten-free, available for sale in Canada, most samples contained less than 20 ppm of gluten and many of the samples tested had no detectable levels of gluten in them[5]. This would imply that actual exposure to gluten from the consumption of gluten-free foods would likely be much lower than 10 mg/day.

Update on Health Canada's Position Related to the use of Gluten-Free Claims

Division 24 of the *Food and Drug Regulations* is intended to protect the health and safety of individuals who require the use of foods for special dietary use that are covered by these regulations.

With respect to gluten-free foods, only those foods that have been specially processed or formulated to meet the needs of individuals, including individuals with Celiac disease, who need to follow a gluten-free diet in order to protect their health, are considered foods for special dietary purposes and are allowed to carry a gluten-free claim. For example, bread specially formulated with substitute flours from grains that are not identified as one of the gluten sources referred to in section B.24.018

and specifically listed in subsection B.01.010.1(1) (i.e., wheat, rye, barley, oats, triticale) could be labelled gluten-free if it meets all other requirements of the *Food and Drug Regulations*.

If a food is determined to be protective of the health of people with Celiac disease, and meets the other requirements of Division 24 (specially processed and formulated), it follows that such a food should be able to use the claim "Gluten-free", as long as it is being done in a manner that is truthful and not misleading.

While no specific threshold is mentioned in the Regulations themselves, the best currently available scientific evidence indicates that levels of gluten below 20 ppm in gluten-free foods would be protective of the health of the vast majority of people with Celiac disease. This level is recognized internationally in the Codex Alimentarius Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Stan 118-1979) which states that the gluten content of foods labelled gluten free shall not exceed 20 ppm.

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.

Based on the enhanced labelling regulations for allergens and gluten sources, any intentionally added gluten sources, even at low levels (e.g. wheat flour as a component in a seasoning mixture which makes up a small proportion of the final food), must be declared either in the list of ingredients or in a "Contains" statement. In these cases, a gluten-free claim would be considered false and misleading." If, however, a manufacturer using a cereal-derived ingredient includes additional processing steps which are demonstrated to be effective in removing gluten, then the food may be represented as gluten-free.

Related Guidance on Gluten Detection Methodologies

Currently, the most commonly used methods to detect the presence of gluten are ELISA-based methods, which use antibodies to detect proteins or specific parts of proteins (epitopes). In general, these methods are sensitive and specific to the analytes they target and can detect gluten in a wide variety of foods. However, these methods may have difficulty detecting and/or quantifying proteins that have been hydrolyzed, fragmented or otherwise structurally altered, since the antibody will no longer react in the same manner if the epitopes have changed significantly.

However, based on the most recent assessment conducted by Health Canada, methods using the Mendez antibodies (R5 antibodies) allow for the detection and quantification of gluten in processed foods. Health Canada will continue to assess analytical methods that are specific to the detection and quantification of gluten in processed foods and will provide further guidance on the applicability of these methods.

While additional evidence is being gathered to support the establishment of a regulatory 20 ppm threshold for Gluten free claims, including the development of an accepted standard reference material for Gluten, **Health Canada is of the position that at levels not exceeding 20 ppm of gluten as a result of cross-contamination, when Good Manufacturing Practices are followed, a claim suggesting the food is gluten-free would not pose a health risk to individuals with celiac disease and would meet the intent of B.24.018 of the FDR. This would be in keeping with the availability of validated methods (**and their associated limitations, as outlined above**), and would be consistent with the approach being taken internationally.**

Health Canada is continually monitoring the latest scientific evidence on Celiac disease and gluten detection methodologies, and will update its guidance if and when it is required as new information becomes available.

Additional Information

Should you wish to provide feedback or request further information on Health Canada's position on gluten free claims, please contact the Bureau of Chemical Safety.

References

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