

 This content was archived on June 24, 2013.

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-Notice- Labelling of Natural Health Products Containing Gluten

January 2010

The purpose of notice is to communicate labelling guidelines for natural health products containing sources of gluten as medicinal and/or non-medicinal ingredients. Labelling of gluten sources would enable consumers with celiac disease (CD) or wheat allergies to make an informed choice when purchasing or consuming natural health products and enable them to avoid gluten in quantities that may trigger an adverse reaction.

Following responses to Health Canada's proposed amendments to the *Food and Drug Regulations* (Government of Canada 2008) on enhanced labelling of food allergen and gluten sources and added sulphites, "Gluten" is proposed to be defined as 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: wheat, oats, barley, rye and triticale. Note that the term "wheat" includes spelt and kamut. The proposed amendments would require that if gluten is present in a prepackaged food, the source of the gluten must be shown on the label of the product in the list of ingredients or in a "contains" statement. These amendments do not apply to a food allergen or gluten source that is present in the prepackaged product as a result of cross-contamination.

Similarly, natural health products containing intentionally added sources of gluten such as wheat or wheat starch should not be labelled as "gluten-free". The product should be clearly labelled with the gluten-containing ingredient, or where the gluten is present as a result of processing (e.g. with wheat- or barley-derived enzymes), a statement should appear on the label indicating the presence of gluten. Acceptable statements would be "Contains: Gluten" or a statement equivalent to those proposed in the Regulatory Project 1220 – Enhanced Labelling for Food Allergens and Gluten Sources and Added Sulphites or in subsequent amendments to the *Food and Drug Regulations*. The optional statement "Do not use if you have celiac disease or a wheat allergy" may also appear on the label. For products containing a processed ingredient which contains trace amounts of gluten confirmed by testing to be < 20 ppm, the above cautionary "Contains: Gluten" or similar statement is not required; however, a gluten-free claim cannot be made.

Gluten Present in NHPs as a Contaminant

Tolerance to gluten varies among individuals with CD and there are limited clinical scientific data on a threshold for the amount of gluten required to initiate or maintain an immunological reaction in CD patients. Therefore, there is no clear consensus on a safe gluten threshold level.

Currently, as per section B.24.018 of the *Food and Drug Regulations* (Government of Canada 2009), a food cannot be labelled as "gluten-free" if it contains wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof. For compliance

purposes, for food products labelled as “gluten-free”, Health Canada uses a maximum limit of 20 ppm. Based on current scientific evidence, this generally represents a maximum level which can be used to interpret Section B.24.018 of the *Food and Drug Regulations* where a food is prepared under good manufacturing conditions aimed at achieving the lowest possible levels of gluten resulting from cross-contamination. This action level is consistent with the Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118 – 1979) established by Codex Alimentarius (Codex 2008) and is subject to periodic review as new data become available regarding emerging analytical techniques and a possible gluten threshold. This maximum limit will be applied to “gluten-free” natural health products which may contain gluten as a contaminant.

Where claims which relate to other food allergens (e.g. dairy free) are being made on the label of natural health products, Health Canada’s approach for food allergens will be used to assess whether or not these claims are false or misleading.

References

Codex: Codex Alimentarius Commission. 2008. Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten. CODEX STAN 118 - 1979. Rome: FAO/WHO. Available from: http://www.codexalimentarius.net/web/standard_list.do?lang=en [Accessed 2009-09-02].

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Health Canada. 2007. Celiac Disease and the Safety of Oats. Available from: www.hc-sc.gc.ca/fn-an/securit/allerg/cel-coe/oats_cd-avoine-eng.php [Accessed 2009-04-29].