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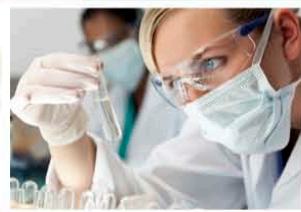
*Your health and
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sécurité... notre priorité.*

The Use of Food Allergen Precautionary Statements on Prepackaged Foods

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

The Use of Food Allergen Precautionary Statements on Prepackaged Foods

Health Canada's policy for enhancing the protection of food-allergic consumers in Canada is based on two guiding principles:

1. prevent the inadvertent consumption of undeclared allergens by sensitive consumers; and
2. enable a variety of safe and nutritious food choices for the allergic consumer.

The policy supports the appropriate use of food allergen precautionary statements on pre-packaged foods, as a risk management tool, where warranted.

A food allergen precautionary statement is a declaration on the label of a prepackaged food of the possible inadvertent presence of an allergen in the food. Precautionary statements are made by food manufacturers and importers on a voluntary basis above and beyond the basic ingredient and nutrition labelling requirements stipulated in the *Food and Drug Regulations* (FDR) and other related legislation. There is no regulatory requirement for, or prohibition of, precautionary labelling. However, like all labelling statements, precautionary statements are subject to section 5(1) of the *Food and Drugs Act* (FDA).

The current policy on the use of food allergen precautionary statements was set in 1994 by Health Canada's Food Directorate. When used, precautionary statements aim to: (1) alert the consumer to the possible presence of an allergen in a food, and (2) prevent the consumption of products labelled with a precautionary statement by persons having a food allergy. Health Canada's policy has been non-prescriptive with respect to the wording of precautionary statements, requiring only that such statements be **truthful, clear and non-ambiguous, and that they not be a substitute for Good Manufacturing Practices**.

Health Canada and the Canadian Food Inspection Agency (CFIA) have committed to reviewing the current policy, because:

1. The use of food allergen precautionary statements on pre-packaged foods has substantially increased since the mid-1990s.
2. A variety of statements are being employed, some of which are no longer providing food allergic consumers with meaningful information on the potential presence of allergens in pre-packaged foods hence misleading consumers on the possible occurrence, levels and risks associated with allergens in food¹.

¹ The Bureau of Chemical Safety's Food Research Division (FRD) recently surveyed chocolate bars and granola bars for precautionary statements and analysed for the presence of certain allergens such as peanut and tree nuts. According to the survey results, the most commonly used statement was "may contain trace(s) of . . .", which implies that the amount of allergen present, if any, is very small. Analytical results generated by Health Canada and CFIA's laboratories for such products have shown that levels of an allergen have reached up to 6,500 parts per million (ppm) or 0.65% in a chocolate product with a precautionary statement that the product may contain only "traces" of the allergen.

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To inform and support policy development, the Food Directorate's [Bureau of Chemical Safety](#) (BCS) has partnered with research teams at McGill University, McMaster University, the Network of Centres of Excellence (AllerGen), and consumer associations representing Canadians having food allergies and sensitivities, to [assess Canadian consumers' current attitudes toward precautionary labelling](#). Research of this kind has also been conducted in the United States² and the United Kingdom³ where general circumstances surrounding the use of precautionary labelling are similar to those in Canada.

In addition to research that has been undertaken, Health Canada and the Canadian Food Inspection Agency conducted Canada-wide on-line and face-to-face consultations in 2009-2010 to seek feedback from a wide range of stakeholders, and engage them in discussion of proposed actions to improve food allergen precautionary labelling. These research activities and public consultations each confirm that Canadian allergic consumers currently perceive themselves to be at risk because of the overuse of food allergen precautionary labelling by the food industry; also, these same consumers find it difficult to interpret the level of risk posed by a product due to the variety of precautionary statements being used. Consultations indicate that the vast majority of stakeholders support the use of a single, preferred precautionary statement over multiple precautionary statements.

Conditions for the Use of Food Allergen Precautionary Statements and Future Directions:

Health Canada still considers the use of allergen precautionary statements to be a useful tool in mitigating adverse reactions to priority food allergens if the statements are used appropriately. Precautionary labelling should only be used when, despite all reasonable measures, the inadvertent presence of allergens in food is unavoidable. It must not be used when an allergen or allergen-containing ingredient is deliberately added to a food. Furthermore, the use of a precautionary statement where there is no real risk of an allergen being present in the food is contrary to the Department's goal of enabling a variety of safe and nutritious food choices for the allergic consumer.

There is consensus among the various stakeholders that further guidance is needed regarding the use of allergen precautionary labelling. To address the potential risks associated with mis-use or misinterpretation of food allergen statements, Health Canada is recommending a single food allergen precautionary statement.

² Hefle SL, Furlong TJ, Niemann L, Lemon-Mule H, Sicherer S, Taylor SL. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. Article in Press. J Allergy Clin Immunol.

³ Food Standards Agency. 2002. Nut allergy labelling: report of research into the consumer response. <http://www.foodstandards.gov.uk/multimedia/pdfs/nutallergyresearch.pdf>

The Use of Food Allergen Precautionary Statements on Prepackaged Foods

Health Canada and the CFIA are therefore recommending that, food manufacturers and importers begin to use **only one precautionary statement** on food labels:

"may contain [X]"

where X is the name by which the allergen is commonly known.

Health Canada continues to collaborate with food allergy consumer groups and the food industry with the aim of publishing a revised policy and guideline for the use of food allergen precautionary statements on pre-packaged foods, upon completion of current research activities.

Annex I

- [Health Risk Assessments in Support of Mitigating Food Allergy Incidents in Canada](#)

Other information

Health Canada is reviewing its policy on the use of food allergen precautionary statements on prepackaged foods.

- [Consultation on Health Canada's Food Allergen Precautionary Labelling Policy Renewal - Summary of Comments from the Online and Face-to-Face Consultation Sessions](#)
- [Consultation on Precautionary Labelling of Food Allergens](#)