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# Summary of Health Canada's Assessment of a Health Claim about Sugar-Free Chewing Gum and Dental Caries Risk Reduction

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Bureau of Nutritional Sciences  
Food Directorate  
Health Products and Food Branch



Canada 

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### Background

In September 2011, Health Canada's Food Directorate received an application for a disease risk reduction claim about sugar-free chewing gum and dental caries risk reduction. The submission was based on a file that was originally prepared for the European Food Safety Authority (EFSA). The information below is a summary of Health Canada's review based on the [Guidance Document for Preparing a Submission for Food Health Claims Using an Existing Systematic Review](#).

Health Canada recently reconsidered the classification of food products with disease risk reduction claims or therapeutic claims in light of clarified principles for the classification of foods at the Food-Natural Health Product interface. Health Canada's position is that when food products are marketed for a disease risk reduction or therapeutic benefit which comes as a result of the food's normal use as part of the diet, these products may be classified and regulated as foods. In other words, the use of a disease risk reduction claim or a therapeutic claim alone is not sufficient to classify the product as a natural health product.

### Scientific Evidence Supporting the Claim

The petitioner provided 12 studies to support the claim. A search by the Food Directorate identified 3 additional studies, bringing the total number of relevant studies to 15 (31 relevant trial arms). All of the studies were conducted in generally healthy school children. Six studies (20 test arms) reported selecting children from populations at higher risk for dental caries. The daily amount of gum tested ranged from 1 stick, 2 times per day to 2 pellets, 5 times per day. Sugar alcohols used to bulk sweeten the gum included xylitol (11 test arms), a combination of xylitol and sorbitol (9 test arms), sorbitol (7 test arms), or a combination of sorbitol and mannitol (3 test arms). Daily sugar alcohol loads ranged from 1.9 g to 12.4 g. The gum was always given following snacks or meals. Children were often asked to discard the gum after a fixed length of time, usually 5 or 20 minutes. The duration of the studies ranged from 2 to 3 years. To assess the effect of sugar-free chewing gum on dental caries risk, the decayed, missing, or filled tooth surface (DMFS) index was measured. Preventive fraction was calculated to identify the percentage of DMFS that was prevented in the children given sugar-free chewing gum, relative to those who did not receive gum.

Overall, the direction of the effect was highly consistent, with 91% of the test arms favouring sugar-free chewing gum over no gum. When only statistically significant associations were taken into account, the direction of the effect was favourable in 74% of the sugar-free chewing gum test arms. These findings did not change when only higher-quality studies were taken into account.

The median preventive fraction was 42%, meaning children in the sugar-free chewing gum groups experienced 42% fewer dental caries over the duration of the study, compared with children who received no gum. When subgroups of gum containing xylitol, xylitol and sorbitol,

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sorbitol, or sorbitol and mannitol were looked at separately, the median prevented fractions were 63%, 49%, 13%, and 8%, respectively. When studies conducted in high-risk children were excluded, the overall median prevented fraction decreased from 42% to 13%, which is still considered a biologically relevant reduction in the rate of dental caries. Aside from one study that administered 1.9 g per day, the lowest daily amounts of sugar alcohols clustered around 2.4 g.

### Health Canada's Conclusion

Health Canada has concluded that scientific evidence exists to support a claim about sugar-free chewing gum and dental caries risk reduction. This claim is considered relevant and applicable to the general population of Canada, since: a) dental caries often begin to develop during childhood and continue into adulthood, b) the prevalence of dental caries is much higher in adults than in children, and c) the process of caries development is the same in adults and children.

### Health Claim

The following statements may be made in the labelling and advertising<sup>1</sup> of food products meeting the qualifying criteria.

*Primary statement<sup>2</sup>:*

“Chewing [serving size from Nutrition Facts table in metric and common household measures] of (brand name) sugar-free gum, 3 times per day after eating/meals, helps reduce/lower the risk of dental caries/tooth decay/cavities.”

For example<sup>3</sup>:

“Chewing 1 piece (2.7 g) of sugar-free gum, 3 times per day after meals, helps reduce the risk of tooth decay.”

In the case of labels on single small packages, the additional statement below could be placed on one area of the package label, in letters up to twice the size of the primary claim, and followed by an asterisk, which would take the consumer to the primary claim statement on another area of the same package label. In the case of advertising material and package labels that are not single packages or generally considered small, the additional statement below could be placed adjacent

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<sup>1</sup>The information in this document complements the [labelling information](#) published by the Canadian Food Inspection Agency. It is the responsibility of all manufacturers and importers to ensure that their products comply with all relevant Canadian legislation.

<sup>2</sup>[ ] = mandatory; ( ) = optional; / = acceptable alternate wording.

<sup>3</sup>Examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

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to the primary statement in letters up to twice the size and prominence of those in the primary statement.

*Additional statement*<sup>4</sup>:

- “(Sugar-free chewing gum)\* helps lower/reduce the risk of dental caries/tooth decay/cavities.”  
or
- “(Sugar-free chewing gum)\* helps protect teeth from dental caries/tooth decay/cavities.”

### Conditions for Foods to Carry the Claim

The food is a sugar-free chewing gum that:

- a) Contains at least 0.8 g sugar alcohol bulk sweetener per serving of stated size and per reference amount;
- b) Meets the conditions for “free of sugars” (item 37 in the table following B.01.513 in the *Food and Drugs Regulations*);
- c) Contains 0.25% or less starch, dextrans, mono-, di- and oligosaccharides or other fermentable carbohydrates combined or, if it contains more than 0.25% fermentable carbohydrates, does not lower plaque pH below 5.7 by bacterial fermentation during 30 minutes after consumption as measured by the indwelling plaque pH test, referred to in “Identification of Low Caries Risk Dietary Components” by T.N. Imfeld, Volume 11, *Monographs in Oral Science*, 1983.

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<sup>4</sup>( )\* = optional only on labels of single packages with a small available display surface.

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