



Summary of Health Canada's Assessment of a Health Claim about a Polysaccharide Complex (Glucomannan, Xanthan Gum, Sodium Alginate) and a Reduction of the Post-Prandial Blood Glucose Response

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Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch



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Background

In February 2014, Health Canada's Food Directorate received an application for a voluntary pre-market review of a [function claim](#) about a polysaccharide complex (glucomannan, xanthan gum, sodium alginate) and a reduction of the post-prandial blood glucose response. The information below is a summary of Health Canada's review based on the [Guidance Document for Preparing a Submission for Food Health Claims](#) and the [Draft Guidance Document on Food Health Claims Related to the Reduction in Post-Prandial Glycaemic Response](#).

Scientific evidence supporting the claim

The food ingredient that is the subject of the health claim is a soluble and viscous polysaccharide complex (glucomannan, xanthan gum, sodium alginate) which is sold under the brand name PGX[®] (PolyGlycopleX[®]). PGX[®] is a [dietary fibre](#) as per Health Canada's [Policy for Labelling and Advertising of Dietary Fibre-Containing Food Products](#).

The petitioner provided a literature review covering the period from 2008 to 2013. The literature search was updated by Health Canada's Food Directorate to encompass studies published to October 2014. A total of six relevant references comprising 31 relevant treatment arms were identified [1-6].

The six relevant studies were randomised, controlled trials with a crossover design. One study [6] was double-blinded, two studies [1, 2] were open label and three studies [3-5] reported participants' blinding only. Three studies were carried out in Canada and the other three studies in Australia. The studies included 10 to 19 normal or overweight but otherwise healthy men and women whose group mean age ranged from 24 to 39 years. PGX[®] in granular form was used in all six studies and the dose tested ranged from 2.5 to 7.5 g. PGX[®] was consumed with a standard meal at one eating occasion following a 10-12 h overnight fast. Subjects consumed control and test foods on separate days with a wash out period of at least 1 day between tests.

PGX[®] was sprinkled on or mixed with carbohydrate-containing foods including a glucose drink, white bread, rice, yogurt, cornflakes, granola, boiled potatoes, fries, oat porridge and bagels. In all studies, the control foods were the same as the test foods without PGX[®]. Two of these studies [3, 5] added inulin, a non-viscous fibre, to the control foods in the same manner as PGX[®].

The primary outcome considered was the post-prandial glucose response measured by determining blood glucose concentrations over at least a two-hour period after a test or control meal is consumed, and calculating the incremental area under the curve (iAUC). The iAUC is the area over the baseline and under the glucose curve, ignoring area beneath the baseline concentration [7]. The post-prandial insulin response, also calculated as the iAUC, was used as an additional outcome.

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The direction of effect was highly consistent (100% of treatment arms) towards a reduction of blood glucose iAUC when PGX[®] was consumed, and a high proportion (80%) of the treatment arms showed statistically significant reductions in glucose iAUC. These conclusions did not change when only higher quality studies were considered. Five of the six studies, representing 25 out of 31 treatment arms, were rated as higher quality using the Food Directorate's quality appraisal tool for intervention studies published in the [*Guidance Document for Preparing a Submission for Food Health Claims*](#).

The consumption of 2.5 to 7.5 g of PGX[®] with foods resulted in a reduction of blood glucose iAUC in the range of 12 to 69%. A reduction of the post-prandial glucose response by at least 20% is considered to be physiologically relevant as per the [*Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them*](#).

The minimum effective dose of PGX[®] was determined to be 5 g because it is the amount that consistently resulted in statistically and physiologically significant reduction in blood glucose iAUC following the consumption of meals containing carbohydrates.

The decrease in postprandial glucose response following the consumption of PGX[®] with a meal containing carbohydrates was accompanied by a reduction ($P < 0.05$) in the insulin iAUC compared to the control food in one higher quality study [6]. Therefore, Health Canada's Food Directorate has concluded that the reduction in the post-prandial glucose response following the consumption of PGX[®] is not due to an increase in insulin levels, but is likely due to a decrease in glucose absorption.

No evidence was available to support a reduction of the post-prandial glucose response when PGX[®] is added to foods requiring further preparation such as cooking (e.g., baking, boiling) or freezing. Therefore, the claim is acceptable only when PGX[®] is sold with a food to which it will be added (sprinkled or mixed) immediately prior to consumption or when PGX[®] is sold mixed with a dry food to which a liquid is added immediately prior to consumption.

Health Canada's Food Directorate conclusion

Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about PGX[®] and a reduction of the post-prandial blood glucose response following consumption of carbohydrate-containing meals.

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Health claim

The following statements may be made in the labelling and advertising¹ of food products meeting the qualifying criteria. These statements are not intended for foods to which PGX[®] is added prior to preparation such as cooking (e.g., baking, boiling) or freezing.

The primary statement would be structured as follows²:

- 1) When PGX[®] is sold with a food to which it will be added (sprinkled or mixed) immediately prior to consumption:

The consumption of the X g of PGX[®] provided with [serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] helps reduce blood glucose rise³ after a meal containing carbohydrates/carbs.

For example⁴:

The consumption of the 5 g of PGX[®] provided with 1 cup (30 g) of cereal helps reduce blood glucose rise³ after a meal containing carbohydrates.

- 2) When PGX[®] is sold mixed with a dry food to which a liquid will be added immediately prior to consumption:

[serving size from Nutrition Facts table in metric and common household measures] of (Brand name) [name of food] contains X g of PGX[®], which helps reduce blood glucose rise³ after a meal containing carbohydrates/carbs.

For example:

One packet (30 g) of cereal contains 5 g of PGX[®], which helps reduce blood glucose rise³ after a meal containing carbohydrates.

The following additional statement may be placed adjacent to the primary statement, in letters up to twice the size and prominence of those in the primary statement:

- PGX[®] helps reduce blood glucose rise³ after a meal containing carbohydrates/carbs.

¹ 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 and regulations.

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

³ "helps slow glucose absorption" could be used in place of "helps reduce blood glucose rise"

⁴ Examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

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Conditions for foods to carry the claim

The following qualifying criteria apply to all food products carrying the above-mentioned health claim.

The food with PGX[®] added⁵:

- a) contains at least 5 g of PGX[®]
 - i. per reference amount and per serving of stated size, or
 - ii. per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement;
- b) contains⁶
 - i. less than 15 g of total sugars per reference amount and per serving of stated size, or
 - ii. less than 15 g of total sugars per serving of stated size, if the food is a prepackaged meal, a nutritional supplement or a meal replacement.

In addition to the claim wording and conditions described above, the label is expected to include directions for use for mixing or sprinkling PGX[®] and for the consumption of water.

Labelling

Claims can be made about PGX[®] on the front of the food package (or elsewhere on the label), provided it is clear that the brand name “PGX[®]” refers to the common name “polysaccharide complex (glucomannan, xanthan gum, sodium alginate)”, which must be used in the list of ingredients and on the principal display panel.

For additional information on labelling, please refer to the [Food Labelling Information for Industry](#) on the Canadian Food Inspection Agency's (CFIA) website.

⁵ PGX[®] is added to the food immediately prior to consumption, or it is already mixed with a dry food to which a liquid will be added immediately prior to consumption.

⁶ To help Canadians manage their sugar intake in a manner consistent with the recommendations of Canada's Food Guide, Health Canada proposed a Daily Value (DV) of 100 grams for sugars as part of its proposed amendments to Nutrition Labelling Regulations, which were published in Canada Gazette, Part 1 in June 2015. Condition b) is based on 15% of the proposed daily value of sugar, which is the threshold for "a lot" based on [Health Canada's guidance](#).

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References

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