Health Canada Santé Canada

*Your health and safety… our priority.* *Votre santé et votre sécurité… notre priorité.*

# Summary of Health Canada's assessment of a health claim about a polysaccharide complex (glucomannan, xanthan gum, sodium alginate) and cholesterol lowering

**May 2016**

Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch

Canada

## Background

In April 2013, Health Canada's Food Directorate received an application for a therapeutic claim about a polysaccharide complex (glucomannan, xanthan gum, sodium alginate) and blood cholesterol lowering. The information below is a summary of Health Canada's review based on the *Guidance Document for Preparing a Submission for Food Health Claims*.

In 2010, Health Canada 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 food that is the subject of the health claim is a soluble 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 June 2014. A total of four relevant references were identified, including three published references [1-3] as well as one unpublished reference for which the petitioner provided the full report [4].

The four relevant studies were randomised, double-blind, controlled, parallel studies conducted in normo- and hypercholesterolemic males and females ranging from 18 to 68 years of age. Studies were carried out in France, Japan and Australia; included 54 to 84 subjects; and lasted from 2 weeks to 12 months. The daily intake of PGX® ranged from 10 to 15 g per day.

PGX® was consumed in the context of the usual diet in three studies [2-4] and with a low-fibre diet in one study [1]. PGX® powder or granules were consumed with foods in two ways: premixed with breakfast cereals and combined with plain yogurt prior to ingestion with main meals [1-3]; or mixed with water and consumed 5-10 min before the main meals [4]. Control foods for PGX® consisted of skim milk powder, inulin powder and rice flour.

The primary outcomes considered were changes in total cholesterol and low-density lipoprotein (LDL) cholesterol levels between intervention and control groups. Change in high-density lipoprotein (HDL) cholesterol levels was used as an additional outcome.

The direction of effect was highly consistent towards a reduction in total cholesterol (100% of

studies) and LDL cholesterol (100% of studies) levels when PGX® was consumed. In addition, a high proportion of studies showed statistically significant reductions in total (75%) and LDL cholesterol (100%) levels. These results did not change when only higher quality studies were considered since the four relevant studies 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 direction of effect was not consistent for HDL cholesterol with half of the studies being in a favourable direction (increase in HDL cholesterol levels) and the other half being in an unfavourable direction. In addition, none of the studies showed a statistically significant increase in HDL cholesterol levels.

The minimum effective daily intake of PGX® was determined to be 10 g per day because it is the lowest intake that resulted in a statistically significant cholesterol-lowering effect when consumed for at least 2 weeks.

The reduction in total and LDL cholesterol levels ranged from -0.20 to -0.37 mmol/L (-4 to -7.5%) and -0.25 to -0.46 mmol/L (-8.4 to -14.6 %), respectively.

No evidence was available to support a cholesterol lowering effect for PGX® when 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 blood cholesterol lowering. The claim is relevant and generally applicable to the Canadian population on the basis that 19% of Canadians aged from 18 to 79 had unhealthy LDL cholesterol levels (>3.5 mml/L) during the time period 2012 -2013[1].

## Health claim

The following statements may be made in the labelling and advertising[2] 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.

[1] Statistics Canada. 2014. Cholesterol Levels of Adults, 2012 to 2013. Available from: http://www.statcan.gc.ca/pub/82-625-x/2014001/article/14122-eng.htm. Last accessed on October 28, 2015.

[2] 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.

The primary statement would be structured as follows[3]:

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

   [*serving size from Nutrition Facts table in metric and common household measures*] of (Brand name) [name of food] after the addition of PGX® supplies/provides X% of the daily amount of PGX® shown to help reduce/lower cholesterol.

   For example[4]:
   1 container (100 g) of yogurt after the addition of PGX® supplies 50% of the daily amount of PGX® shown to help lower cholesterol.

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] supplies/provides X % of the daily amount of PGX® shown to help reduce/lower cholesterol.

   For example:
   1 pouch (35 g) of Brand X drink mix with PGX® supplies 50% of the daily amount of PGX® shown to help reduce cholesterol.

The "daily amount" referred to in the primary statement is 10 g of PGX®. This amount is based on the evidence available concerning the amount of PGX® shown to help reduce cholesterol. In this statement, the percentage of the daily amount of PGX® provided in one serving should be rounded to the nearest multiple of 5%.

The following additional statements 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/lower cholesterol
- High cholesterol is a risk factor for heart disease
- PGX® helps reduce/lower cholesterol, (which is) a risk factor for heart disease

## Conditions for foods to carry the claim

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

[3] [ ] = mandatory; ( ) = optional; / = acceptable alternate wording.
[4] Examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

The food with PGX® added:

a) contains at least 3.3 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) contains at least 10% of the weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient
   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;
c) contains 0.5% or less alcohol;
d) contains
   i. less than 15% of the Daily Value (DV) of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or
   ii. less than 15% of the Daily Value (DV) of sodium per serving of stated size, if the food is a nutritional supplement or a meal replacement, or
   iii. less than 25% of the Daily Value (DV) of sodium per serving of stated size, if the food is a prepackaged meal;
e) meets the conditions for "free of saturated fatty acids" or "low in saturated fatty acids" (Items 18 and 19, respectively, in the table following section B.01.513 of the *Food and Drug Regulations*).

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.

## References

1. Carabin IG, Lyon MR, Wood S, Pelletier X, Donazzolo Y, Burdock GA. Supplementation of the diet with the functional fiber PolyGlycoplex® is well tolerated by healthy subjects in a clinical trial. Nutr J. 2009;8(1):1-11.

2. Lyon M, Wood S, Pelletier X, Donazzolo Y, Gahler R, Bellisle F. Effects of a 3-month supplementation with a novel soluble highly viscous polysaccharide on anthropometry and blood lipids in nondieting overweight or obese adults. J Hum Nutr Diet. 2011;24(4):351-359.

3. Reimer RA, Yamaguchi H, Eller LK, Lyon MR, Gahler RJ, Kacinik V, et al. Changes in visceral adiposity and serum cholesterol with a novel viscous polysaccharide in Japanese adults with abdominal obesity. Obesity. 2013;21(9):E379-E387.

4. Pal S, Wood S, and M. Lyon. Comparison of two different fibre supplements on body weight, body composition, metabolic and cardiovascular risk factors in overweight and obese individuals. Unpublished.