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Psyllium Products and Blood Cholesterol Lowering

Summary of Health Canada's Assessment of a Health Claim about Food Products Containing Psyllium and Blood Cholesterol Lowering

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Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch



Canada 

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Background

In July 2007, Health Canada's Food Directorate received a submission from industry requesting approval for the use of a disease risk reduction claim on food products containing psyllium. This claim would stipulate a linkage between the consumption of psyllium fibre and a reduced risk of heart disease by lowering blood cholesterol levels. The information below is a summary of the review that was conducted based on Health Canada's [*Interim Guidance Document, Preparing a Submission for Foods with Health Claims*](#) (IGD).

Health Canada has 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. The current position of Health Canada 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 would not be sufficient in itself to classify the product as a natural health product.

Scientific Evidence Supporting the Claim

In 1998, the US Food and Drug Administration (FDA) approved a health claim under the Nutrition Labelling and Education Act linking psyllium fibre and a reduced risk of coronary heart disease. While the US petition was not provided as evidence by the petitioner, as has been the case with other health claims approved by the US FDA, Health Canada decided to accept, as the evidence base, an update of the literature since the time of the US approval of the claim, provided that a systematic review of this evidence was part of the submission. The evidence provided by the petitioner includes a systematic review prepared by the Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA) of the University of Toronto that spanned the literature published from 1996 to 2005. In the PFSNRA review, 21 human studies were identified that investigated psyllium fibre and its cholesterol lowering properties. LDL-cholesterol and total cholesterol were the endpoints measured in the reviewed studies, which are recognized risk factors or biomarkers for heart disease.

Overall, in the PFSNRA literature review (2006), an intake of 7 grams of psyllium soluble fibre resulted in a physiologically meaningful LDL-cholesterol reduction, ranging from 0.047% to 0.86% LDL-cholesterol reduction on a per gram of fibre basis. Most of the studies were carried out with mildly to highly hypercholesterolemic subjects. The PFSNRA review did not identify any evidence contrary to the previous findings upon which FDA based its final health claim rule on psyllium fibre and reduced risk of heart disease (by lowering blood cholesterol).

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Health Canada's Conclusions

Health Canada has concluded that scientific evidence exists in support of the therapeutic claim linking the consumption of psyllium fibre to a reduction of blood cholesterol. The claim is relevant and generally applicable to the Canadian population given that a high proportion of the population (approximately 44%) is hyperlipidemic and that adults with normal or mildly elevated blood cholesterol concentrations could also benefit from increased psyllium intake.

Based on the evidence available, as well as consumer research, preliminary feedback from industry and consideration of decisions made in other jurisdictions, it is Health Canada's opinion that the therapeutic claim statements set out below are substantiated in relation to psyllium products when specific conditions for the food carrying the claim are met.

Health Claim

The following statements may be made in the labelling and advertising¹ of food products meeting the qualifying criteria. These statements are intended for the general population who wants to maintain or lower their blood cholesterol.

Primary statement:

“[serving size from Nutrition Facts table in metric or common household measures]² of (Brand name) [name of food] with psyllium supplies/provides X % of the daily amount of the fibres shown to help reduce/lower cholesterol.”

For example:

1 cup (30 g) of Brand X cereal with psyllium supplies 50 % of the daily amount of fibre shown to help lower cholesterol.

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

- 1) Psyllium fibre helps reduce/lower cholesterol.**
- 2) High cholesterol is a risk factor for heart disease.**
- 3) Psyllium fibre helps reduce/lower (LDL) cholesterol, a risk factor for heart disease.**

¹ The information in this document complements the guidance on using health claims on food labels and in advertising in the [Guide to Food Labelling and Advertising](#) available on the Canadian Food Inspection website. It is the responsibility of all manufacturers and importers to ensure that their products comply with all relevant Canadian legislation.

² [] = mandatory; () = optional; / = or

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The “**daily amount**” referred to in the primary statement is 7 grams psyllium fibre. This amount is based on the evidence available concerning the lowest observed efficacious daily intake for lowering cholesterol. In this statement, the percentage of the daily amount of psyllium fibre provided in one serving should be expressed to the nearest multiple of 5%.

Conditions for Foods to Carry the Claim

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

The food:

- 1) contains at least 1.75 g psyllium soluble fibre per reference amount and per serving of stated size;
- 2) contains at least 10% of the weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient per reference amount and per serving of stated size;
- 3) contains 100 mg or less of cholesterol per 100 g of food;
- 4) contains 0.5% or less alcohol;
- 5) contains 480 mg or less 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;
- 6) meets the definition of “free of saturated fatty acids” or “low in saturated fatty acids”.

In previous consultations with stakeholders, there was strong support from all sectors that foods carrying a health claim should meet certain nutritional criteria. For example, in the case of health claims about blood cholesterol lowering, it is expected that limits are set on those nutrients associated with risks of high blood cholesterol and heart disease. Conditions 2 to 6 above have already been outlined in section B.01.603 of the Food and Drug Regulations for foods carrying a heart disease risk reduction claim.

Currently, there are a limited number of psyllium-containing products in the Canadian marketplace. This could make it difficult for the daily amount of 7 grams to be achieved from a combination of products with amounts of psyllium husk less than 3.5 grams while maintaining a nutritious, well-balanced diet. However, Health Canada has agreed to consider 1.75 grams of psyllium soluble fibre per reference amount and per serving of stated size so long as a sufficient number of psyllium-containing products, other than breakfast cereals, are introduced on the Canadian market. The introduction of new psyllium-containing products on the market as well as their uptake will need to be monitored and data provided to Health Canada, in order to determine the feasibility of consuming 1.75 grams of psyllium soluble fibre over 4 eating occasions to

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obtain the daily amount of 7 grams. Depending on the outcome of this monitoring, Health Canada may need to revisit the conditions for foods carrying psyllium soluble fibre claims to ensure consuming the lowest observed efficacious daily intake in the context of a healthy eating pattern is feasible.

Health Canada will propose regulatory amendments to consolidate the conditions for the use of the above stated health claims and to confirm that foods which are subject of such claims are not governed by the provisions of the *Food and Drugs Act* with respect to drugs; nor do they contravene subsections 3(1) and (2) of the Act.