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Plant Sterols and Blood Cholesterol Lowering

Summary of Health Canada's Assessment of a Health Claim about Plant Sterols in Foods and Blood Cholesterol Lowering

**Bureau of Nutritional Sciences
Food Directorate, Health Products and Food Branch
Health Canada**

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Canada 

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In August 2007, Health Canada's Food Directorate received a submission requesting the approval of a disease risk reduction or therapeutic claim regarding plant sterols and reduction in LDL cholesterol. This decision document 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).

In this decision document, the term plant sterols¹ refers to both plant sterols and plant stanols, free or esterified, extracted from natural sources (edible vegetable oils or tall oil produced from Kraft wood pulping process), as defined in the [*Notice of Assessment of Certain Categories of foods containing added Phytosterols*](#). The term "phytosterols" is a synonym for "plant sterols".

LDL-cholesterol and total cholesterol were the endpoints measured in the reviewed studies. These are recognized risk factors or biomarkers for heart disease that are relevant to the Canadian population since about 50% of the general adult population is considered to be moderately to highly hypercholesterolemic.

The evidence provided by the petitioner included 84 randomized controlled trials (comprising 141 pertinent trial arms) published from 1994 to 2007. Overall, an 8.8% reduction in LDL-cholesterol was observed with an average intake of 2 g/day of plant sterols. A dose-response relationship was observed up to about 3 g/day in these studies which included doses ranging from about 0.5 g/day to 9.0 g/day. At the average intake of 2 g/day, the effect of plant sterols appeared to be largely independent of the food matrix. Most of the studies were carried out with moderately to highly hypercholesterolemic subjects.

Health Canada has concluded that acceptable scientific evidence exists in support of the claim about the relationship between the consumption of plant sterol-enriched foods as foods and blood cholesterol lowering. Consumption of these foods results in the lowering of total blood cholesterol as well as LDL-cholesterol levels, while having no detrimental effect on HDL-cholesterol levels, resulting in overall improvements in the blood lipid profile.

Health Canada's Conclusions

Based on the evidence available, consumer research, preliminary feedback from industry and consideration of decisions made in other jurisdictions, it is Health Canada's view that the health claims set out below are substantiated in relation to foods containing added plant sterols when the conditions specified below are satisfied. The following statements would be available for all foods meeting the qualifying criteria and that are intended for adults who want to lower their blood cholesterol, *i.e.*, are moderately to highly hypercholesterolemic adults.

¹ Expressed in this document as the equivalent in weights of free plant sterols and stanols.

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Primary statement:

“[serving size from Nutrition Facts table in metric and common household measures] of [naming the product] provides X% of the daily amount* of plant sterols shown to help reduce/lower cholesterol in adults.”

Two additional statements that could be used in combination or alone, adjacent to the primary statement, without any intervening printed, written or graphic material:

- 1) **“Plant sterols help reduce [or help lower] cholesterol.”** This statement when used, shall be shown in letters up to twice the size and prominence as those of the primary statement.
- 2) **“High cholesterol is a risk factor for heart disease.”** This statement when used, shall be shown in letters up to the same size and prominence as those of the primary statement.

* The “daily amount” referred to in the primary statement is 2 grams. This amount is based on the evidence available concerning the amount of plant sterols shown to help reduce cholesterol in adults. In this statement, the percentage of the daily amount of plant sterols provided in one serving should be expressed to the nearest multiple of 5%.

Conditions for foods to carry the claim:

The food

- (a) contains a minimum level equivalent to 0.65 g of free plant sterols or stanols per reference amount and per serving of stated size;
- (b) contains at least 10% of the weighted recommended nutrient intake of a vitamin or mineral per reference amount and per serving of stated size;
- (c) contains 100 mg or less of cholesterol per 100 g of food;
- (d) contains 0.5% or less alcohol;
- (e) 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;
- (f) meets the criterion "low in saturated fatty acids."

The Department anticipates proposing regulatory amendments to confirm that such foods with the above stated health 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.

For additional information please consult: [Plant Sterols \(phytosterols\)](#).