

Summary of Health Canada's Assessment of a Health Claim about Barley Products and Blood Cholesterol Lowering

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Background

In February 2009, Health Canada's Food Directorate received a submission requesting approval for the use of a therapeutic claim linking barley beta-glucan to blood cholesterol lowering. 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

The petitioner provided a literature review up to July 2008 to substantiate the proposed health claim. The petitioner's literature review was updated by Health Canada's Food Directorate, bringing the total number of relevant studies to 13 (19 relevant trial arms).

All of the studies were conducted in relatively healthy normocholesterolemic and hypercholesterolemic men and women ranging from 18 to 73 years old. Treatment duration ranged from 4 to 12 weeks, and the quantity of beta-glucan consumed ranged from 3 g/day to about 12 g/day.

Total cholesterol and low-density lipoprotein cholesterol (LDL-cholesterol) were the endpoints measured in the reviewed studies. These are recognized as risk factors or biomarkers for heart disease.

The direction of effect (without taking statistical significance into account) was highly consistent towards a reduction for total cholesterol (100%) and LDL-cholesterol (94%) when barley beta-glucan was consumed. In addition, a high proportion (78%) of trial arms showed a statistically significant reduction in total and LDL-cholesterol levels when barley beta-glucan was consumed. These conclusions were similar when only the higher-quality studies were taken into account.

Inconsistencies and conflicting results were reported in some clinical trials using extracted beta-glucans. Differences in consistency of the direction of effect between trials using barley grain products and trials using barley beta-glucan extracts were minimal. However, when statistical significance was taken into account, a high proportion (91%) of trial arms using barley grain products showed significantly lower total and LDL-cholesterol levels, while only 57% of trial arms using barley beta-glucan extracts reported significantly lower total and LDL-cholesterol levels.

A daily intake of a minimum of 3 g of beta-glucan from barley grain products resulted in a physiologically relevant LDL cholesterol lowering comparable to the LDL cholesterol lowering effect of oat beta-glucan. The magnitude of the cholesterol-lowering effect in the relevant studies was variable. When only the higher-quality studies using barley grain products (no extracts) were taken into account [Anonymous, 2005; Behall, 2004a; Behall 2004b; Rondanelli, 2011; Shimizu, 2008; Sundberg, 2008], the reduction in total cholesterol levels ranged from -0.06 to -0.50 mmol/L (-1.1% to -7.5%) while the reduction in LDL-cholesterol levels ranged from 0 to -0.32 mmol/L (0% to -8.5%). In addition, subgroup analyses in a meta-

analysis conducted by the petitioner showed that consumption of beta-glucan from barley grain products lowered total cholesterol by 0.29 mmol/L and LDL cholesterol by 0.26 mmol/L compared to control.

Health Canada's Conclusions

Health Canada has concluded that scientific evidence exists in support of the therapeutic claim linking barley grain products 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 40% of Canadian adults aged 20 to 79) ^{Footnote 1} has unhealthy total cholesterol levels (>5.2 mmol/L), putting them at an increased risk for heart disease. Based on the scientific evidence available, feedback from the petitioner 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 barley grain products when specific conditions for the food carrying the claim are met.

Health Claim

The following statements may be made in the labelling and advertising ^{Footnote 2} of food products meeting the qualifying criteria.

Primary statement ^{Footnote 3}:

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

For example ^{Footnote 4}:

125 ml (1/2 cup) of cooked pearled barley supplies 60% of the daily amount of the fibre shown to help lower cholesterol

The "daily amount" referred to in the primary statement is 3 grams of barley beta-glucan. 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 barley beta-glucan provided in one serving should be expressed to the nearest multiple of 5%.

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

- **"Barley fibre helps reduce/lower cholesterol"**
- **"High cholesterol is a risk factor for heart disease"**
- **"Barley fibre 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.

- a. The food contains at least 1g of beta-glucan from barley grain products ^{Footnote 5} per reference amount and per serving of stated size;
- b. The food contains at least 10% 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;
- c. The food contains 100 mg or less of cholesterol per 100 g of food;
- d. The food contains 0.5% or less alcohol;
- e. The food contains
 - i. 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, or
 - ii. 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal;
- f. The food meets the conditions for "low in saturated fatty acids" or "free of saturated fatty acids".

References

- Anonymous. 2005. Effects of boiled, flaked, milled barley powder product (Aktiv) on LDL-, HDL- and total cholesterol, triglycerides, glucose, insulin and HS-CRP levels in healthy hypercholesterolemic men and women. Unpublished and confidential clinical study report.
- Behall *et al.* 2004a. Lipids significantly reduced by diets containing barley in moderately hypercholesterolemic men. *Journal of the American College of Nutrition*. 23(1):55-62.
- Behall *et al.* 2004b. Diets containing barley significantly reduce lipids in mildly hypercholesterolemic men and women. *American Journal of Clinical Nutrition*. 80(5):1185-1193.
- Biorklund *et al.* 2005. Changes in serum lipids and postprandial glucose and insulin concentrations after consumption of beverages with beta-glucans from oats or barley: A randomised dose-controlled trial. *European Journal of Clinical Nutrition*. 59(11):1272-1281.
- Keenan *et al.* 2007. The effects of concentrated barley beta-glucan on blood lipids in a population of hypercholesterolaemic men and women. *British Journal of Nutrition*. 97(6):1162-1168.
- Keogh *et al.* 2003. Randomized controlled crossover study of the effect of a highly beta-glucan-enriched barley on cardiovascular disease risk factors in mildly hypercholesterolemic men. *American Journal of Clinical Nutrition*. 78(4):711-718.
- Li *et al.* 2003. Effects of barley intake on glucose tolerance, lipid metabolism, and bowel function in women. *Nutrition*. 19(11-12):926-929.
- McIntosh *et al.* 1991. Barley and wheat foods - influence on plasma-cholesterol concentrations in hypercholesterolemic men. *American Journal of Clinical Nutrition*. 53(5):1205-1209.
- Narain *et al.* 1992. Metabolic responses to a four week barley supplement. *International Journal of Food Sciences and Nutrition*. 43:41-46.
- Newman *et al.* 1989. Hypocholesterolemic effect of barley foods on healthy men. *Nutrition Reports International*. 39(4):749-760.
- Rondanelli *et al.* 2011. Beta-glucan- or rice bran-enriched foods: a comparative crossover clinical trial on lipidic pattern in mildly hypercholesterolemic men. *European Journal of Clinical Nutrition*. 65:864-871.
- Shimizu *et al.* 2008. Effects of high beta-glucan barley on serum cholesterol concentrations and visceral fat area in Japanese men - a randomized, double blinded, placebo-controlled trial. *Plant Foods for Human Nutrition*. 63(1): 21-25.
- Sundberg *et al.* 2008. Cholesterol lowering effects of a barley fibre flake products. *AgroGOOD industry hi-tech*. 19(2 (supplement)):14-17.

Footnotes

Footnote 1

[Statistics Canada. 2010. Heart health and cholesterol levels of Canadians, 2007 to 2009.](http://www.statcan.gc.ca/pub/82-625-x/2010001/article/11136-eng.htm)
<http://www.statcan.gc.ca/pub/82-625-x/2010001/article/11136-eng.htm> [last accessed on May 24, 2012].

Footnote 2

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 Agency website. It is the responsibility of all manufacturers and importers to ensure that their products comply with all relevant Canadian legislation.

Footnote 3

[] = mandatory; []* = mandatory if name of food does not mention the fibre source; () = optional; / = or

Footnote 4

Foods and values used in examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

Footnote 5

Barley grain products include dehulled or hullless barley, pearl barley, barley flakes, grits, meal, flour, bran as well as beta-glucan enriched milling fractions derived from sieving or air classifying ground material or flour fractions, but they exclude extracted barley beta-glucan.

<https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/health-claims/assessments/assessment-health-claim-about-barley-products-blood-cholesterol-lowering.html>