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Summary of Health Canada's Assessment of a Health Claim about Whole Grains and Coronary Heart Disease

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Bureau of Nutritional Sciences
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Canada 

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Background

In 1993, a disease risk reduction health claim for grain products containing fibre, particularly soluble fibre, and heart disease was accepted by the U.S. Food and Drug Administration¹. In 1999, the American Association of Cereal Chemists International (AACCI) established the following definition: "Whole grains shall consist of the intact, ground, cracked or flaked caryopsis, whose principal anatomical components - the starchy endosperm, germ and bran - are present in the same relative proportions as they exist in the intact caryopsis"². In 2006, Health Canada posted its *Position Paper on Five U.S. Health Claims for Use in Canada* for online consultation³. This paper included proposals for adopting the AACCI definition for whole grains and a health claim about whole grains and heart disease.

Since 2006, a considerable amount of additional evidence on whole grains and coronary heart disease has been published. Furthermore, recognition of the AACCI definition of whole grains has changed how research in the area of whole grains is both designed and interpreted. In 2011, Health Canada undertook a systematic review, following the method outlined in its [Guidance Document for Preparing a Submission for Food Health Claims](#), to determine whether or not the evidence to date supported a health claim for whole grain products and coronary heart disease risk reduction. This systematic review only included studies where the grain products met the AACCI definition for whole grains.

Systematic Review of the Scientific Evidence

Studies were eligible for inclusion if they were controlled clinical trials or prospective cohort studies conducted in generally healthy populations. Studies that included participants with a diagnosed disease, such as diabetes mellitus or coronary artery disease, were excluded. Studies were excluded if the AACCI definition for whole grains was not met or if foods with less than 51% whole grain ingredients were included in the measurement of whole grain intake. Also excluded were multi-component clinical trials where the effect of whole grain foods could not be isolated from the effect of other factors, such as dietary fibre. Outcomes of interest included coronary heart disease morbidity and mortality and established biological markers of coronary heart disease risk such as total cholesterol, low density lipoprotein (LDL) cholesterol and blood pressure. The literature search was last updated in January, 2012. Sensitivity analyses were undertaken to evaluate the influence of factors that could undermine the certainty of the findings, including study quality, population health status, type of whole grain tested, and source of funding.

¹ Food and Drug Administration, Department of Health and Human Services. 1993. Federal Register. 58: 3; 2578-2605.

² American Association of Cereal Chemists International. 1999. *Press Release: AACC Members Agree on Definition of Whole Grain*. [Accessed on: 2012 Jan 19]. Available from: <http://www.aacnet.org/news/pdfs/wgPR.pdf>.

³ Health Canada. 2006. *Position Paper on Five U.S. Health Claims for use in Canada*. [Accessed on: 2012 Apr 3]. Available from: http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/position_paper-enonce_position-eng.php.

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Thirty-two studies met the criteria for inclusion; 26 were controlled clinical trials and 6 were prospective cohort studies. Of the 26 trials, 17 were parallel and 9 were crossover designs. Whole grains tested included: oats (12 studies), barley (1 study), wheat (4 studies), rye (1 study), and a mix of grains (8 studies). Eleven parallel and 6 crossover trials reported sufficient information to be included in a meta-analysis. Pooled mean differences suggested that overall, compared with control foods, whole grain foods lowered total and LDL cholesterol. The removal of trials that included participants with elevated lipid or blood pressure levels from the analysis did not change this result. Conversely, no evidence for a cholesterol-lowering effect remained after the trials that tested single grains high in beta-glucan fibre, such as oats and barley (9 studies), and trials that were judged to be of poor quality (2 of the remaining studies) were removed, leaving only 3 parallel and 3 crossover trials in the analysis.

The methods and outcomes in the prospective cohort studies were too heterogeneous to pool statistically. Since two studies were conducted in a cohort of male health professionals (U.S.), 1 in Seventh Day Adventists (U.S.), 1 in rural-dwelling males (Sweden), 1 in individuals "with a special interest in health foods" (U.K.) and 1 in healthy men and women (Norway), the applicability of some of these results to the general Canadian population is limited. Four of the 6 cohort studies reported one or more coronary heart disease outcomes that were significantly improved in individuals who consumed more whole grain products. Of these 4 studies, 2 were judged to be of poor quality because fruit and vegetable intake was not adjusted for in the analysis.

Conclusions

Based on this systematic review, Health Canada concluded that the evidence to date from clinical trials and prospective cohort studies was not sufficient to support a whole grains and coronary heart disease risk reduction claim in Canada. Only six prospective cohort studies were eligible for inclusion and these were limited by potential bias due to confounding factors and poor applicability to the general population of Canada. There was an overall effect of whole grains on total and LDL cholesterol when the results from controlled clinical trials were pooled, but sensitivity analysis showed that the effect was largely attributable to trials that tested single grains high in beta-glucan fibre and trials judged to be of poor quality. Cholesterol-lowering caused by grains high in beta-glucan fibre cannot be generalized to other grains, including wheat, the predominant grain consumed in Canada. A whole grain and coronary heart disease health claim would, therefore, be misleading if applied to grains that are not high in beta-glucan fibre. Health Canada has already accepted a health claim for oats products and cholesterol lowering⁴.

While the current evidence may not be sufficient to support a health claim about whole grains and coronary heart disease, whole grains offer many nutrients important for health, including fibre, vitamins, minerals and trace elements. Canadians are encouraged in [Eating Well with Canada's Food Guide](#) to make at least half of their grain products whole grain each day.

⁴Health Canada. 2010. *Oats Products and Blood Cholesterol Lowering*. [Accessed on: 2012 Apr 27]. Available from: <http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/oat-avoine-eng.php>.