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Summary of Health Canada's Assessment of a Health Claim about Ground Whole Flaxseed and Blood Cholesterol Lowering

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Bureau of Nutritional Sciences
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Canada 

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Background

In March 2012, Health Canada's Food Directorate received an application for a therapeutic claim about ground flaxseed 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](#).

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. 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 petitioner provided a literature review up to May 2011 to substantiate the proposed health claim. The petitioner's literature review was updated by Health Canada's Food Directorate to June 2013, bringing the total number of relevant studies to 8.

All relevant studies were clinical trials conducted in normo- and hypercholesterolemic males and females ranging from 8 to 75 years of age. Treatment duration ranged from 4 weeks to 12 months and the quantity of ground flaxseed consumed ranged from 30 g/day to 50 g/day. Ground flaxseed was used in all studies except one (Simbalista et al., 2010), which used partially defatted flaxseed meal at a dose equivalent to 25 g/day of whole seed. The smallest study included 10 subjects, while there were 179 subjects in the largest study. The main endpoints considered were total cholesterol and low-density lipoprotein (LDL) cholesterol. These are recognized as risk factors or biomarkers for heart disease.

The direction of effect was highly consistent towards a reduction in total cholesterol (100%) and LDL cholesterol (100%) levels when flaxseed was consumed. However, a very low proportion of studies showed a statistically significant reduction in total cholesterol (25%) and LDL cholesterol (0%) levels. These conclusions were similar when only higher quality studies were taken into account.

The petitioner conducted a meta-analysis which was reproduced and expanded by Health Canada's Food Directorate. Pooled estimates of both meta-analyses were similar. The estimates from the Food Directorate meta-analysis are reported here. All 8 studies identified as part of the systematic review were included. Baseline and final values for the control and treatment groups were extracted from the studies to calculate the change for each group, except when change was already provided. The pooled effect was -0.21 mmol/L ($p=0.0001$) for total cholesterol levels and -0.22 mmol/L ($p<0.0001$) for LDL cholesterol levels.

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The only study using partially defatted flaxseed meal was included in the meta-analysis, but it was deemed insufficient to demonstrate a cholesterol lowering effect of partially defatted flaxseed meal because of its high risk of bias (total and LDL cholesterol levels at baseline were statistically different between the control and test groups).

The daily intake of ground whole flaxseed in the studies of higher quality in adults ranged from 38 g (Arjmandi et al., 1998) to 40 g (Bloedon et al., 2008; Dodin et al., 2005; Lucas et al., 2002). This includes the study assigned the most weight (most subjects and least dispersion) in the meta-analysis which administered 40 g of ground whole flaxseed per day (Dodin et al., 2005).

Health Canada's Food Directorate Conclusion

The evidence consistently supports a direction of effect towards a reduction in total and LDL cholesterol levels when ground flaxseed is consumed. A low proportion of studies reached statistical significance, but this was addressed by a meta-analysis which showed a statistically significant reduction in total and LDL cholesterol levels with ground flaxseed consumption.

Health Canada's Food Directorate has concluded that scientific evidence exists to support a claim about ground whole flaxseed and blood cholesterol lowering. The claim is relevant and generally applicable to the Canadian population given that a high proportion of the population (39% of Canadians aged 6 to 79)¹ has unhealthy total cholesterol levels, putting them at an increased risk for heart disease.

Health Claim

The following statements may be made in the labelling and advertising² of food products meeting the qualifying criteria.

*Primary statement*³:

[*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 ground (whole) flaxseed]* shown to help reduce/lower cholesterol.

¹ Statistics Canada. 2012. Cholesterol levels of Canadians, 2009 to 2011. <http://www.statcan.gc.ca/pub/82-625-x/2012001/article/11732-eng.htm> [last accessed on November 15, 2013].

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.

³ [] = mandatory; []* = mandatory unless the [*name of food*] is "ground (whole) flaxseed"; () = optional; / = acceptable alternate wording

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For example⁴:

16 g (2 tablespoons) of ground flaxseed supplies 40% of the daily amount shown to help lower cholesterol.

The “daily amount” referred to in the primary statement is 40 g of ground whole flaxseed. This amount is based on the evidence available concerning the amount of ground whole flaxseed shown to help reduce cholesterol. In this statement, the percentage of the daily amount of ground whole flaxseed provided in one serving should be rounded to the nearest multiple of 5%.

Additional statements:

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

- Ground (whole) flaxseed helps reduce/lower cholesterol
- High cholesterol is a risk factor for heart disease
- Ground (whole) flaxseed 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.

The food:

- a) contains at least 13 g of ground whole flaxseed⁵
 - i. per reference amount and per serving of stated size, or
 - ii. per serving of stated size, if the food is ground whole flaxseed, whole flaxseed or a prepackaged meal;
- 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;
- c) contains 100 mg or less of cholesterol per 100 g of food;
- d) contains 0.5% or less alcohol;
- e) 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

⁴ Examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

⁵ Packaged whole flaxseed would be eligible to carry the claim if the label clearly specifies that flaxseeds must be ground before consumption.

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- ii. 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal;
- f) 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*).

References

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