



A Review of the Health Benefits of Flaxseed

- Systematic literature review on flaxseed and reduced risk of cardiovascular disease
- Options for promoting the health benefits of flaxseed

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Executive Summary

In 2010 FRID commissioned a systematic scientific literature review of the relationship between the consumption of milled or ground flaxseed and cardiovascular disease. This report summarizes the findings including direction for future research required to substantiate the relationship. Furthermore, the report outlines the nutrition and health claim options that could be provided on product labels for flaxseed and flaxseed-containing foods without a pre-market submission.

Literature Review Filtering and Quality Appraisal

From the initial 1,630 references identified, filtering resulted in a total of 7 references that met all of the inclusion criteria. All seven were rated as being of higher quality (i.e. scoring at least 8 out of a possible 15 points).

Consistency of Effect and Strength of Association

The data describing the effects of the consumption of milled or ground flaxseed demonstrated:

- a **highly consistent** effect on total cholesterol, LDL-cholesterol, lipoprotein A* and apolipoprotein B**, a **moderately consistent** effect for C-reactive protein**, and a **low consistency** of effect for HDL-cholesterol, triglycerides and apolipoprotein A1**;
- a **weak strength of association** with changes in total cholesterol and LDL-cholesterol, and **no association** for HDL-cholesterol.

**Note that only 4 of the publications had measured lipoprotein A.*

***Note that only 3 publications had measured apolipoprotein A1, apolipoprotein B and C-reactive protein.*

The literature review and quality appraisal process identified some research gaps that need to be addressed to substantiate the relationship of milled or ground flaxseed and cardiovascular disease. For example, research is needed to establish a minimum effective intake, the health impact on male participants and on pre-menopausal women, whether milled or ground partially defatted flaxseed provides the same cardio-protective effects as milled or ground whole flaxseed, and to demonstrate a statistically significant effect of flaxseed on biomarkers of cardiovascular disease.

While additional research is required to substantiate a health claim for flaxseed and cardiovascular disease, other nutrition and health claim options can be provided on product labels for flaxseed and flaxseed-containing foods. For example, nutrient content claims can be used to promote flaxseeds as a source of vitamins, mineral nutrients and fibre, and to highlight their low saturated and *trans* fat content. This report identifies some of these options, as well as their conditions of use, as outlined in the Canadian Food Inspection Agency's [Guide to Food Labelling and Advertising](#).

Introduction

The Food Regulatory Issues Division (FRID) of Agriculture and Agri-Food Canada provides the agri-food sector with information and advice on food policy and regulatory issues. This role includes helping stakeholders understand and navigate the regulatory system, including scientific requirements, particularly with regard to innovative foods with health benefits.

In 2010 FRID commissioned a systematic scientific literature review of the relationship between the consumption of milled or ground flaxseed and cardiovascular disease (CVD). The evidence obtained from this literature review was used to assess the strength of the food–health relationship, identify gaps in scientific knowledge, and focus future investments in research and product development.

FRID also reviewed current nutrition and health labelling options for flaxseed in Canada that do not require pre-market approval, and investigated whether any flaxseed-related health claims are permitted in other jurisdictions.

This report provides:

- an assessment of the state of the science on the relationship between the consumption of milled or ground flaxseed and CVD based on a systematic scientific literature review;
- a summary of the research gaps;
- information on the availability of flaxseed-related health claims approved in other jurisdictions; and
- an outline of the labelling options available within the current Canadian regulatory context to promote the nutritional and health benefits of flaxseed.

This report will be useful to the agri-food industry and commodity groups as they develop their business and marketing plans for promoting the nutritional and health benefits of flaxseed. Furthermore, it provides direction to researchers interested in contributing to the body of evidence addressing the relationship between the consumption of milled or ground flaxseed and CVD.

Systematic Scientific Literature Review

FRID commissioned a systematic scientific literature review of the relationship between the consumption of milled or ground flaxseed and CVD.¹ The literature review was based on Health Canada's *Guidance Document for Preparing a Submission for Food Health Claims*² (1) (HC Guidance Document). The HC Guidance Document serves as the basis for preparing any food health claim submission to Health Canada.

The literature review assessed the strength of the evidence for a food–health relationship as well as identified gaps in scientific knowledge and suggested where future research investments should be focused. The level of scientific substantiation revealed by this literature review is also essential in defining the scope of commitment (e.g. time, money and effort) required to prepare a regulatory submission seeking approval for a new food health claim in Canada.

The scope of the commissioned review was to:

- conduct a comprehensive literature review of scientific articles that could be used to substantiate a food health claim;
- calculate the consistency of effect and strength of association of the data using the HC Guidance Document tool; and
- identify any research gaps that affect a possible health claim.

The process also served to build sector capacity in conducting, managing and analyzing the information retrieved from a literature review.

In keeping with HC Guidance Document requirements, the review focused on intervention and/or prospective observational studies in humans. The available literature was systematically searched, filtered, rated for quality, and analyzed to evaluate the validity of the potential food health claim.

The review addressed Section 5.0 Evaluation of Claim Validity (steps 1 to 9b) of the HC Guidance Document. As a systematic literature review can only be conducted on a clearly defined topic, Sections 3 and 4 of the HC Guidance Document—the characterization of the food and the characterization of the health effect—were also completed.

It is important to note that a systematic literature review is only one part of a food health claim submission. A petitioner would need to complete all other sections of the HC Guidance Document, including steps 9c through 13 of Section 5, to assess generalizability (i.e. applicability of the food–health relationship to the target group), as well as the biological relevance of the health effect and the feasibility of consuming an effective intake of the food. A petitioner would also need to provide a full list of references cited in the submission and gather any missing information. Also note that systematic literature reviews used in a submission need to be current (i.e. completed within six months to one year prior to a submission).

The present report gives an overview of the parameters used in conducting the literature review and the conclusions from the review for flaxseed and CVD.

¹ The literature review was conducted by the Richardson Centre for Functional Foods and Nutraceuticals, Winnipeg, Manitoba, and completed in June 2010.

² www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php

Databases and Search Parameters Used for Literature Retrieval

All fields of Medline (PubMed) and Scopus, as well as the topic field of Web of Science, were used to search for relevant peer-reviewed literature. Hand searching was used for one known publication that was noticeably absent from the electronic search. Unpublished studies were not considered. The 'limit to human studies' parameter was used in the Medline search; this parameter is not available in Scopus or Web of Science. The search was also limited to literature published in English in Medline and Web of Science (no language limit is available in Scopus), and to articles published between 1980 and 2010 (search conducted in April 2010), to be inclusive of recent and relevant research.

Keywords Used for Literature Retrieval

Table 1 (based on Table 6 of the HC Guidance Document) provides an outline of the keywords used in the search strategy.

Table 1: Keywords and their combinations used to retrieve literature on the food–health relationship from electronic databases

A. Food	
Keywords used:	
<ul style="list-style-type: none"> • flax • “linum usitatissimum” 	
B. Health Effect	
1. Final Health Effect	2. Biomarker/Surrogate marker of health effect
Keywords used:	Keywords used:
<ul style="list-style-type: none"> • “cardiovascular disease” • CVD • “heart disease” 	<ul style="list-style-type: none"> • cholesterol, TC, lipoproteins, LDL, HDL, triglycerides • hypertension, “blood pressure” • atherosclerosis, angina, arrhythmia, ischemia, • “heart attack”, “myocardial infarction” • inflammation, “inflammatory biomarker”, homocysteine
C. Combinations of Keywords Used	
<ul style="list-style-type: none"> • (flax OR “linum usitatissimum”) AND (“cardiovascular disease” OR CVD OR “heart disease”) • (flax OR “linum usitatissimum”) AND (cholesterol OR TC OR lipoproteins OR LDL OR HDL OR triglycerides) • (flax OR “linum usitatissimum”) AND (hypertension OR “blood pressure”) • (flax OR “linum usitatissimum”) AND (atherosclerosis OR angina OR arrhythmia OR ischemia) • (flax OR “linum usitatissimum”) AND (“heart attack” OR “myocardial infarction”) • (flax OR “linum usitatissimum”) AND (inflammation OR “inflammatory biomarker” OR homocysteine) 	
D. Justification for Exclusion of Potentially Relevant Terms	
<ul style="list-style-type: none"> • Not applicable 	

Inclusion and Exclusion Criteria Used for Literature Filtering

Table 2 (based on Table 8 in the HC Guidance Document) outlines the inclusion and exclusion criteria used for literature filtering.

Table 2: Inclusion and exclusion criteria used for literature filtering

Factor	Inclusion Criteria	Exclusion Criteria
Source	<ul style="list-style-type: none"> Published or in press in a peer-reviewed journal 	<ul style="list-style-type: none"> Published in a non-peer-reviewed source
Report type	<ul style="list-style-type: none"> Full length article/study report of original research in humans: <ul style="list-style-type: none"> Human intervention studies (parallel or cross-over design) Prospective observational studies (cohort and nested case-control studies) 	<ul style="list-style-type: none"> Animal and in vitro studies Published abstract, short communication, opinion letter, consumer letter, testimonials Authoritative statements (position papers by a credible scientific body, e.g. Institute of Medicine, World Health Organization) Abbreviated unpublished study report Retrospective cohort, case-control, cross-sectional, ecological, time-series, or demographic studies Systematic reviews, meta/pooled analysis of original research or unsystematic literature review articles
Language	<ul style="list-style-type: none"> English 	<ul style="list-style-type: none"> All but English
Publication year	<ul style="list-style-type: none"> 1980 to 2010 	<ul style="list-style-type: none"> All before 1980
Duplicate	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> Publication is a duplicate
Treatment	<ul style="list-style-type: none"> Food of interest quantified: dose of food known (intervention studies); amount of food calculated (prospective observation studies) or adequate information provided to calculate dose Form of food described as or assumed to be milled or ground flaxseed, or partially defatted flaxseed meal (or foods made with milled or ground flaxseed or partially defatted flaxseed meal, e.g. baked goods, cereals, snack foods) For intervention studies, food of interest administered independently of other nutritional and/or pharmacological interventions Treatment duration at least 2 weeks 	<ul style="list-style-type: none"> Food of interest not quantified: dose of food not known; amount of food not calculated or insufficient information provided to calculate dose Form of food described as or assumed to be whole flaxseed or extracts of flaxseed including flaxseed oil, totally defatted flaxseed meal, flaxseed lignans or flaxseed mucilage or flaxseed fibre or foods made from whole flaxseed or flaxseed extracts For intervention studies, food of interest not administered independently of other nutritional and/or pharmacological interventions Treatment duration less than 2 weeks

Table 2: Inclusion and exclusion criteria used for literature filtering (*continued*)

Factor	• Inclusion Criteria	• Exclusion Criteria
Control	<ul style="list-style-type: none"> • Use of control group/placebo appropriate to design including control/comparison group (e.g. wheat bran, wheat germ, wheat flour, oat bran, ground nuts or seeds) 	<ul style="list-style-type: none"> • No control or comparison group or inappropriate/inadequate control used
	<ul style="list-style-type: none"> • Duration of control diet at least 2 weeks 	<ul style="list-style-type: none"> • Duration of control diet less than 2 weeks
	<ul style="list-style-type: none"> • Duration of washout period at least 2 weeks with background diet (cross-over studies) 	<ul style="list-style-type: none"> • Duration of washout period less than 2 weeks (cross-over studies) or duration not reported
Route of exposure	<ul style="list-style-type: none"> • Oral 	<ul style="list-style-type: none"> • Non-oral
Health effect	<ul style="list-style-type: none"> • Health effect of interest measured (cardiovascular-related health outcomes; e.g. heart disease, cardiovascular disease, coronary heart disease, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, blood pressure, arrhythmia, ischemia, angina, atherosclerosis, heart attack, myocardial infarction, inflammatory biomarkers, such as C-reactive protein or homocysteine) 	<ul style="list-style-type: none"> • Health effect of interest not measured (non-cardiovascular-related health outcomes; e.g. blood glucose, body composition, weight, bowel function)
Population health status/study setting	<ul style="list-style-type: none"> • Representative of target population - e.g. generally healthy adults, possibly hypercholesterolemic adults (total cholesterol < 8.0 mmol/L but who are not on cholesterol-lowering drugs) 	<ul style="list-style-type: none"> • Not representative of target population - e.g. hospitalized or free-living sick or diseased individuals; hypercholesterolemic adults who are on cholesterol lowering drugs
Ages	<ul style="list-style-type: none"> • Representative of target population (adults ≥ 18 years) 	<ul style="list-style-type: none"> • Not representative of target population (individuals < 18 years)
Statistical significance	<ul style="list-style-type: none"> • Reported 	<ul style="list-style-type: none"> • Not reported

N/A = not applicable

References Included after Literature Filtering

Two investigators independently applied the inclusion/exclusion criteria described in Table 2 to all retrieved references. A three-step filtering process was followed: 1) title filtering; 2) abstract filtering; and 3) full text filtering.

From the initial 1,630 references identified, filtering resulted in a total of 7 references that met all of the inclusion criteria (see Table 3, based on Table 9 in the HC Guidance Document). The seven references are listed in [Appendix A](#). These seven publications form the totality of relevant evidence on the food–health relationship and were used to assess causality (i.e. the consistency of effect and strength of association related to whether intake of the food causes the health effect of interest).

Table 3: Results of literature filtering

Factor	Number of References
References prior to applying inclusion/exclusion criteria	1630
References excluded at title-filtering stage	1568
References excluded at abstract-filtering stage	46
References excluded at full-text filtering stage	9
TOTAL References Excluded (after applying inclusion/exclusion criteria):	1623
TOTAL References Included (after applying inclusion/exclusion criteria):	7

Quality Appraisal Process

Two investigators independently applied the quality appraisal tool provided in the HC Guidance Document to each of the seven included publications. All of the seven included publications were rated as being of higher quality, scoring at least 8 out of a possible 15 points.

Conclusions from the Literature Review

To assess causality, the included publications were classified according to the effect of the treatment on each biomarker (i.e. the direction of the effect and whether this effect reached statistical significance) and the quality rating. Based on the results of this classification, the consistency of effect and the strength of the association were calculated for each biomarker.

Consistency of Effect

The objective, as described in [Step 9a of the HC Guidance Document](#), is to rate the consistency of findings across publications, per health outcome with regard to the direction of effect of the food on the health outcome with consideration given to the quality rating. As all of the included publications were rated as being high quality, no distinction was required for the effect of quality rating on consistency of outcome.

- The consumption of milled or ground flaxseed was found to have a **highly consistent** effect on total cholesterol, LDL-cholesterol, lipoprotein A* and apolipoprotein B**, and a **moderately consistent** effect on C-reactive protein**.
- The data for the effect of milled or ground flaxseed consumption on HDL-cholesterol, triglycerides and apolipoprotein A1** had a **low consistency** rating.

**Note that only 4 of the publications had measured lipoprotein A.*

***Note that only 3 publications had measured apolipoprotein A1, apolipoprotein B and C-reactive protein.*

Strength of Association

The objective, as described in [Step 9b of the HC Guidance Document](#), is to assess the strength of the association between the food and health outcome by considering the proportion of studies that showed statistical significance at $p < 0.05$ among all included publications.

- Milled or ground flaxseed consumption had a **weak strength of association** with changes in total cholesterol and LDL-cholesterol.
- For HDL-cholesterol, **no association** was seen.

Research Gaps

Research gaps need to be addressed to validate the relationship of milled or ground flaxseed and CVD. For example, additional research is needed to determine:

- the minimum effective intake;
- the health impact in male participants and pre-menopausal women;
- whether milled or ground partially defatted flaxseed provides the same cardio-protective effects as milled or ground whole flaxseed; and
- a statistically significant effect of flaxseed on CVD biomarkers (through research designed to have an adequate numbers of participants).

Related Health Claims in Other Jurisdictions

The HC Guidance Document (Section 2.3) requests information about the regulatory status of the potential health claim in other jurisdictions, along with the claim wording and conditions for use of approved claims. Currently, no scientifically substantiated health claims regarding flaxseed consumption and reduced risk of CVD are approved for use in any other jurisdiction.

Nutrition and Health Claim Options in Canada

The current regulatory system in Canada allows for several types of claims to promote the nutritional value or health benefits of foods:³

- nutrient content claims;
- nutrient function claims;
- comparative claims;
- disease risk reduction or therapeutic claims.

The requirements for using these options are outlined in the [Guide to Food Labelling and Advertising](#) by the Canadian Food Inspection Agency (CFIA Guide) (2) and summarized briefly in this report. When determining whether a product meets the criteria for a particular claim, the producer or manufacturer must have the nutrient composition data for the food available (see Table 4 for sample data on flaxseed), and know the reference amount or the serving of stated size (serving size) of the food.

- Schedule M of the *Food and Drug Regulations* (3) indicates that the standard “**reference amount**” for “nuts and seeds, not for use as snacks: whole, chopped, sliced, slivered or ground” is “30 g shelled”. Consequently, the **reference amount** for flaxseed, either milled or ground, is **30 g**.
- The **reference amount** and the **serving size** for a food containing flaxseed will vary depending on the food; see [Section 6.2 of the CFIA Guide](#) or Schedule M of the *Food and Drug Regulations*.

Nutrient Content Claims

Nutrient content claims are statements or expressions which describe, directly or indirectly, the level of a nutrient in a food or group of foods. Only claims permitted by the *Food and Drug Regulations* may be used. Nutrient content claims can be made without pre-market approval, provided there is a specific percentage Daily Value (DV) for the nutrient per serving of stated size. The DV is equivalent to either the **Recommended Daily Intake (RDI)** (for vitamins and minerals) or the **Reference Standard** (for other nutrients) (see the CFIA Guide, [Section 6.3.2](#) and [Section 6.3.4](#)). The % DV of the nutrient in one serving, rounded as indicated in the CFIA Guide ([Table 6-1](#) and [Table 6-2](#)) must be declared in the Nutrition Facts table.

Vitamin and Mineral Nutrient Content Claims

The CFIA Guide ([Table 7-14](#)) lists nutrient content claims with respect to vitamins and mineral nutrients, along with the conditions for their use. For example, if the reference amount of flaxseed, or stated serving of a food containing flaxseed, provides $\geq 5\%$ of the RDI of the nutrient it would qualify as a “source” of that nutrient. The CFIA Guide ([Table 7-11](#) and [Table 7-15](#)) outlines the minimum amounts of the nutrients per serving of stated size required to make a claim. To determine a product’s eligibility to use such claims, a producer or manufacturer would compare the product’s nutrient composition to the criteria.

³ For information on other nutrition communication activities, see *Best Practices in Promoting Food Health Benefits: Insights from an Environmental Scan*; www.agr.gc.ca/food-regulatory-issues (Reports and Reviews)

Table 4: Nutrient composition data for whole, milled or ground flaxseed

Nutrient	Reference Standard or RDI (adults; children ≥2 years)(2)*	Flaxseed, whole, milled or ground (reference amount, 30 g)	
		Amount(4) [†]	% Daily Value [‡]
Total Fat	65 g	12.48 g	20%
Saturated FA	Sum of saturated + <i>trans</i> FA 20 g	1.234 g	6%
<i>Trans</i> FA		0.002 g	
Monounsaturated FA	N/A	2.262 g	N/A
Polyunsaturated FA	N/A	8.877 g	N/A
Omega-6	N/A	1.927 g	N/A
Omega-3	N/A	6.941 g (ALA)	N/A
Cholesterol	300 mg	0 mg	0%
Carbohydrate	300 g	8.67 g	3%
Fibre, total dietary	25 g	8.37 g	33%
Sugars, total	N/A	0.465 g	N/A
Folate	220 µg	83.4 µg	40%
Niacin	23 NE	2.42 NE	10%
Vitamin B ₆	1.8 mg	0.278 mg	15%
Pantothenic acid	7 mg	0.459 mg	6%
Calcium	1100 mg	100.2 mg	10%
Magnesium	250 mg	109.8 mg	45%
Phosphorus	1100 mg	149.4 mg	15%
Iron	14 mg	1.5 mg	10%
Zinc	9 mg	1.29 mg	15%
Copper	2 mg	0.57 mg	30%
Manganese	2 mg	2.22 mg	110%
Potassium	3500 mg	249.3 mg	7%

ALA = alpha-linolenic acid; N/A = not applicable; RDI = Recommended Daily Intake

* see the CFIA Guide, [Table 6-5](#) (vitamins and mineral nutrients) and [Table 6-7](#) (other nutrients)

[†] Source: Canadian Nutrient File 2007b (4), food code #4528: seeds, flaxseeds (linseeds), whole and ground

[‡] % Daily Value has been calculated using the Canadian Nutrient File data, and rounded according to the rounding rules for labelling purposes outlined in the CFIA Guide ([Table 6-1](#) and [Table 6-2](#)).

Based on the nutrient composition data found in Table 4 above, and the CFIA Guide (Tables 7-11 and 7-15), examples of vitamin and mineral nutrient content claims that could be used on a package of whole, milled or ground flaxseed are:

- “Flaxseeds contain potassium”
- “Flaxseeds are a source of calcium”
- “Ground flaxseed is an excellent source of folate”
- “Flaxseeds contain 12 essential nutrients”⁴

⁴ The number indicated is not necessarily the maximum that could be claimed. It is based on the 12 nutrients chosen as key nutrients in flaxseed and determined to be present in sufficient amounts for flaxseed to qualify as a “source” of each of the nutrients..

Other Nutrient Content Claims

Table 5 provides examples of other nutrient content claims that could be used for whole, milled or ground flaxseed. If the claim is to be made for a product that includes flaxseed as an ingredient, the conditions for use of the claim must be met by the final product. Refer to [Sections 7-16 to 7-20](#) and [Section 7-24](#) of the CFIA Guide for a complete list of the permitted wording for each claim.

Table 5: Other nutrient content claims that could be associated with whole, milled or ground flaxseed

Claim	Condition(s)	Examples of approved wording
Low in saturated fatty acids	Flaxseed contains 2 g or less of saturated fatty acids and <i>trans</i> fatty acids combined per reference amount and serving of stated size	- "low in saturated fatty acids" - "contains only [X] g of saturated fatty acids per serving" - "contains less than [X] g of saturated fatty acids per serving"
Free of <i>trans</i> fatty acids	Flaxseed contains less than 0.2 g of <i>trans</i> fatty acids per reference amount and serving of stated size, and is low in saturated fatty acids	- "trans fatty acids-free" - "zero trans fatty acids" - "contains no trans fat"
Source of omega-3 polyunsaturated fatty acids	Flaxseed contains 0.3 g or more of omega-3 polyunsaturated fatty acids per reference amount and serving of stated size	- "source of omega-3 polyunsaturated fatty acids" - "contains omega-3 polyunsaturated fat"
Free of cholesterol	Flaxseed contains less than 2 mg of cholesterol per reference amount and serving of stated size, and is low in saturated fatty acids	- "cholesterol-free" - "zero cholesterol" - "contains no cholesterol"
Very high source of fibre [†]	Flaxseed contains 6 g or more of fibre per reference amount and serving of stated size	- "very high source of fibre" - "rich in fibre" - "very high in dietary fibre"

[†] Note that CFIA guidelines state that producers or manufacturers are **not** permitted to include the terms "good" and "excellent" sources of fibre because these statements imply a judgment regarding the nature and value of the fibre in addition to the quantity. Nutrient content claim guidelines with respect to fibre are fully explained in the CFIA Guide ([Table 7-13](#)).

Nutrient content claims that are made for non-prepackaged foods or claims in advertisements placed by someone other than the manufacturer (such as trade associations or marketing boards) must be accompanied by a quantitative declaration of the energy value or the nutrient(s) as required for the claims.

Nutrient Function Claims

Nutrient function claims (formerly biological role claims) describe the well-established roles of energy or known nutrients that are generally essential for the maintenance of good health or for normal growth and development.

Nutrient function claims are not made for a food per se; they may only be made with respect to the energy value or nutrients in a food. These claims do not require pre-market approval. There are two types of nutrient function claims: general nutrient function claims and nutrient function claims for vitamins and mineral nutrients.

General Nutrient Function Claims

General nutrient function claims are permitted for all nutrients. There are two choices for the wording of a general nutrient function claim:

- "Energy (or Name of the nutrient) is a factor in the maintenance of good health."
- "Energy (or Name of the nutrient) is a factor in normal growth and development."

Nutrient Function Claims for Vitamins and Mineral Nutrients

A nutrient function claim for vitamins and mineral nutrients can only be used if the vitamin or mineral nutrient has an established Recommended Daily Intake (RDI) and the reference serving of the food contains a minimum of 5% of the RDI for that vitamin or mineral nutrient (i.e. the food must be a dietary source of the nutrient). Acceptable nutrient function claims are listed in the CFIA Guide ([Table 8-3](#)). Examples of acceptable nutrient function claims that could be associated with whole, milled or ground flaxseed would be those related to fat, carbohydrate, niacin, vitamin B₆, folate, pantothenic acid, calcium, phosphorus, magnesium, iron and zinc. For products where flaxseed is an ingredient, the nutrient composition of the finished product would need to be compared with the criteria to determine whether claims can be made.

Manufacturers may use any combination of claims for which their product is eligible. For example, a package of whole, milled or ground flaxseed could include a general nutrient function claim or a nutrient function claim for vitamins and minerals, combined with a vitamin and mineral nutrient content claim:

- "Flaxseeds are a good source of vitamin B₆, which is a factor in the maintenance of good health."
- "Vitamin B₆ is a factor in energy metabolism and tissue formation. Flaxseeds are a good source of vitamin B₆."

Nutrient function claims can also be used for other nutrients found in flaxseed at dietary source levels, such as the ones listed in Table 4 of this report.

Comparative Claims

Comparative claims are those that compare the nutritional properties of two or more similar foods. Foods that contain whole, milled or ground flaxseed as an ingredient, such as breads, could possibly make a comparative claim. The nutrient composition data for both products must be available in order to make a comparative claim.

Comparative Claims for Vitamin or Mineral Nutrient Content

When comparing vitamin or mineral nutrient content, as indicated in the CFIA Guide (item (e) of [Table 7-14](#)), the food must:

- a) contain at least a 25% increase in the claimed vitamin or mineral nutrient compared to the reference food; and
- b) have a significant absolute difference in the vitamin or mineral content of at least 10% of the RDI of the vitamin or mineral nutrient.

The following is an example of a potential comparative vitamin or mineral content claim involving flaxseed:

- "Our whole wheat flax bread contains 50% more manganese than our original whole wheat bread."

Comparative Claims for Fibre Content

To make a comparative claim for fibre, as indicated in the CFIA Guide (item (d) of [Table 7-13](#)), the food must:

- a) contain at least 25% more fibre, totalling 1 g or more (of the identified fibre if a fibre source is identified in the statement or claim)
 - per reference amount of the food, as compared to the reference amount of a reference food of the same food group or a similar reference food; or
 - per 100 g, as compared to 100 g of a reference food of the same food group or a similar reference food, if the food is a prepackaged meal; and
- b) contain at least 2 g of fibre (from the identified fibre if a fibre source is identified in the statement or claim) per reference amount and serving of stated size.

The following is an example of a potential comparative fibre claim involving flaxseed:

- “Our blueberry flax muffins have 25% more fibre than our regular blueberry muffins.”

Disease Risk Reduction and Therapeutic Claims

Disease risk reduction claims are generally statements that link a food, a food constituent or the characteristics of a diet to reducing the risk of developing a diet-related disease or condition. Therapeutic claims describe the effect of a food, food constituent or diet in the treatment or mitigation of a health-related disease or condition, including restoring, correcting or modifying body functions.

Existing therapeutic claims would not apply to flaxseed.⁵ According to the CFIA Guide ([Table 8-1](#)), flaxseed meet the criteria for the following disease risk reduction claim:

- “A healthy diet low in saturated and *trans* fats may reduce the risk of heart disease. [Naming the food] is low in saturated and *trans* fats.”

For a product that meets the conditions as set out in the CFIA Guide ([Table 8-1](#)), the above disease risk reduction claim could be applied to whole, milled or ground flaxseed, or a product that contains whole, milled or ground flaxseed, without pre-market approval.

References

1. Health Canada. *Guidance Document for Preparing a Submission for Food Health Claims*. [March 2009]; Available from: www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php
2. Canadian Food Inspection Agency. *Guide to Food Labelling and Advertising*. [Internet] [Accessed: September 20, 2010]; Available from: www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml
3. Department of Justice Canada. *Food and Drugs Act and Food and Drug Regulations*. [updated May 18, 2010]; Available from: <http://laws.justice.gc.ca/en/showtdm/cr/C.R.C.-c.870>
4. Health Canada. Canadian Nutrient File 2007b version; [Accessed: September 20, 2010]. Available from: www.healthcanada.gc.ca/cnf

⁵ See www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php for a list of accepted claims.

Appendix A: References Included in the Literature Review after Filtering

From a literature search that identified 1,630 articles on the relationship between the consumption of milled or ground flaxseed and CVD, the following is a list of the 7 references included in the literature review after filtering.

Arjmandi BH, Khan DA, Juma S, Drum ML, Venkatesh S, Sohn E, et al. Whole flaxseed consumption lowers serum LDL-cholesterol and lipoprotein(a) concentrations in postmenopausal women. *Nutrition Research*. 1998;18(7):1203-14.

Bloedon LT, Balikai S, Chittams J, Cunnane SC, Berlin JA, Rader DJ, et al. Flaxseed and cardiovascular risk factors: results from a double blind, randomized, controlled clinical trial. *J Am Coll Nutr*. 2008;27(1):65-74.

Cunnane SC, Hamadeh MJ, Liede AC, Thompson LU, Wolever TM, Jenkins DJ. Nutritional attributes of traditional flaxseed in healthy young adults. *Am J Clin Nutr*. 1995;61(1):62-8.

Dodin S, Lemay A, Jacques H, Legare F, Forest JC, Masse B. The effects of flaxseed dietary supplement on lipid profile, bone mineral density, and symptoms in menopausal women: a randomized, double-blind, wheat germ placebo-controlled clinical trial. *J Clin Endocrinol Metab*. 2005;90(3):1390-7.

Lucas EA, Wild RD, Hammond LJ, Khalil DA, Juma S, Daggy BP, et al. Flaxseed improves lipid profile without altering biomarkers of bone metabolism in postmenopausal women. *J Clin Endocrinol Metab*. 2002;87(4):1527-32.

Patade A, Devareddy L, Lucas EA, Korlagunta K, Daggy BP, Arjmandi BH. Flaxseed reduces total and LDL cholesterol concentrations in Native American postmenopausal women. *Journal of Women's Health*. 2008;17(3):355-66.

Simbalista RL, Sauerbronn AV, Aldrighi JM, Areas JA. Consumption of a flaxseed-rich food is not more effective than a placebo in alleviating the climacteric symptoms of postmenopausal women. *J Nutr*. 2010;140(2):293-7.

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