

# A Review of the Health Benefits of Pulses

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

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October 2011



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# **Executive Summary**

In 2010 FRID commissioned a systematic scientific literature review of the relationship between the consumption of pulses 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 pulses and pulse-containing foods without a pre-market submission.

#### **Literature Review Filtering and Quality Appraisal**

From the initial 5,774 references identified, filtering resulted in a total of 12 references that met all of the inclusion criteria. All 12 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 pulses (whole pulses or as a food constituent) demonstrated:

- a highly consistent effect on LDL-cholesterol and total cholesterol, and low consistency of effect on HDL-cholesterol and triglycerides;
- a moderate strength of association with changes in total cholesterol, and low strengths of association for all other parameters.

The literature review and quality appraisal process identified some research gaps that need to be addressed to substantiate the relationship of pulses and cardiovascular disease. For example, research is needed to determine existing patterns of pulse consumption in Canada, sustainability of effects over the long term, minimum effective intake, beneficial constituents, and effects of different pulses.

While additional research is required to substantiate a health claim for pulses and cardiovascular disease, other nutrition and health claim options can be provided on product labels for pulses and pulse-containing foods. For example, nutrient content claims can be used to promote pulses as a source of vitamins, mineral nutrients and fibre while being low in fat, particularly saturated and *trans* fat. 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 pulses 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 pulses in Canada that do not require pre-market approval, and investigated whether any pulse-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 pulses and CVD based on a systematic scientific literature review;
- a summary of the research gaps;
- information on the availability of pulse-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 pulses.

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 pulses. Furthermore, it provides direction to researchers interested in contributing to the body of evidence addressing the relationship between the consumption of pulses and CVD.

# Systematic Scientific Literature Review

FRID commissioned a systematic scientific literature review of the relationship between the consumption of pulses and CVD. The literature review was based on Health Canada's *Guidance Document for Preparing a Submission for Food Health Claims*. (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 pulses and CVD.

#### **Databases and Search Parameters Used for Literature Retrieval**

All fields of Medline (PubMed), Agricola, and Scholar's Portal, as well as the topic field of Web of Knowledge (Web of Science, Current Contents Connect, BIOSIS Previews, Food Science and Technology Abstracts, and Journal Citation Reports), were used to search for relevant peer-reviewed literature. Unpublished studies were not considered. The 'limit to human studies' parameter was used

<sup>&</sup>lt;sup>1</sup> The literature review was conducted by Nutrasource Diagnostics Inc., Guelph, Ontario, and completed in February 2010.

<sup>&</sup>lt;sup>2</sup> www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims\_guidance-orientation\_allegations-sante-eng.php

in the Medline search; this parameter is not available in the other databases. The search was also limited to literature published in English in Medline, Agricola and Web of Knowledge (no language limit is available in Scholar's Portal), and to articles published between 1980 and 2009 (search conducted in November 2009), 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:**

- Pulses OR puls
- Legumes OR leguminous seeds OR legumen
- Dry beans OR Phaseolus vulgaris
- Kidney beans OR lima beans OR pinto beans
- Dry peas OR split peas OR Pisum sativum
- Chickpeas OR Cicer arietinum
- · Lentils OR Lens culinaris
- Soluble fibre OR dietary fibre

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# 1. Final Health Effect

# Keywords used:

- CVD OR cardiovascular disease
- CHD OR coronary heart disease
- Myocardial ischemia
- Myocardial infarction OR heart attack
- Atherosclerosis
- Hypercholesterolemia
- Hyperlipidemia

# 2. Biomarker/Surrogate marker of health effect

#### Keywords used:

- · Cholesterol OR cholesterol reduction
- Lipids
- Homocysteine
- Blood pressure
- Total cholesterol OR TC
- LDL cholesterol OR LDL-C
- HDL cholesterol OR HDL-C

#### C. Combinations of Keywords Used

• 'food' [from section A] + 'final health effect OR biomarker/surrogate marker of health effect' [from section B]

## D. Justification for Exclusion of Potentially Relevant Terms

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	Published in a peer-reviewed journal	Published in a non-peer-reviewed source
Report Type	Full-text articles	<ul> <li>Published abstracts, published opinion letters, anecdotal data, consumer testimonials</li> </ul>
	Original Research	Review papers
	Human Data	Non-human data
	<ul> <li>Human intervention studies</li> </ul>	o In vitro data
	Observational studies	o Animal data
	<ul><li>Cohort studies</li><li>Nested case-control studies</li></ul>	
	Systematic reviews or meta-	Retrospective cohort, case–control,
	analyses [human data]	cross-sectional, ecological, time-
		series, or demographic studies
	Authoritative statement position	, 3 1
	papers by credible scientific bodies [i.e., WHO, IOM, etc]	
Language	• English	All but English
Publication	1980 to date of search (November	All before 1980
year	11, 2009)	
Duplicate	• N/A	Publication is a duplicate
Treatment	Observational studies in which food intake was calculated	Observational studies in which food intake was not calculated
	Intervention studies in which food intake was quantified	<ul> <li>Intervention studies in which food intake was not quantified</li> </ul>
	<ul> <li>Intervention studies in which food was independently consumed [i.e. food was not administered in combination with drugs or with other foods]</li> </ul>	<ul> <li>Intervention studies in which foods was not independently consumed [i.e. food was administered in combination with drugs or with other foods]</li> </ul>
	Selected biomarkers of the food— health relationship are biologically and/or methodologically relevant	Selected biomarkers of the food— health relationship are not biologically and/or methodologically relevant
	<ul> <li>Duration of food exposure is adequate (e.g. ≥4 weeks in intervention studies)</li> </ul>	<ul> <li>Duration of food exposure is not adequate (e.g. &lt;4 weeks in intervention studies)</li> </ul>
	Follow-up time (to measure health effect) adequate (cohort studies)	Follow-up time (to measure health effect) not adequate (cohort studies)
Control	Study included a control group     OR	Study did not include a control group
	Study utilized a placebo	AND
Route of	Oral	Study did not utilize a placebo     Non-oral
Exposure	- Olai	- Non-oral

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

Factor	Inclusion Criteria	Exclusion Criteria
Health	Direct	Direct
Effect	The health effect of interest has been accurately measured (CVD OR cardiovascular disease, CHD OR coronary heart disease, myocardial ischemia, myocardial infarction OR heart attack, atherosclerosis, hypercholesterolemia, hyperlipidemia)	The health effect of interest has not been accurately measured
	Indirect • Selected biomarkers of the health effect are biologically and/or methodologically relevant (cholesterol OR cholesterol reduction, lipids, homocysteine, blood pressure, total cholesterol OR TC, LDL cholesterol OR LDL-C, HDL cholesterol OR HDL-C)	<ul> <li>Indirect</li> <li>Selected biomarkers of the health effect are not biologically and/or methodologically relevant (e.g. glucose, body composition, weight)</li> </ul>
Population health status/study setting <sup>1</sup>	Representative of the target population     Generally healthy adults, including hypercholesterolemic and borderline hypercholesterolemic adults     Free living or controlled feeding	<ul> <li>Not representative of health status of target population</li> <li>Hospitalized or free-living sick or diseased individuals</li> </ul>
Ages	<ul> <li>Representative of target population</li> <li>o Adults ≥ 18 years</li> </ul>	<ul> <li>Not representative of target population</li> <li>Individuals &lt;18 years</li> </ul>
Statistical significance	Reported	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 5,774 references identified, filtering resulted in a total of 12 references that met all of the inclusion criteria (see Table 3, based on Table 9 in the HC Guidance Document). The 12 references are listed in <a href="Appendix A">Appendix A</a>. These 12 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	5774
References excluded at title-filtering stage	5590
References excluded at abstract-filtering stage	128
References excluded at full-text filtering stage	44
TOTAL References Excluded	5762
(after applying inclusion/exclusion criteria)	
TOTAL References Included	12
(after applying inclusion/exclusion criteria)	

#### **Quality Appraisal Process**

Two investigators independently applied the quality appraisal tool provided in the HC Guidance Document to each of the 12 included publications. All of the 12 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 <u>Step 9a of the HC Guidance Document</u>, 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 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 pulses (whole pulses or as a food constituent) was found to have a highly consistent effect on LDL-cholesterol and total cholesterol.
- The data for the effect of pulse consumption on HDL-cholesterol and triglycerides had a **low consistency** rating.

#### **Strength of Association**

The objective, as described in <u>Step 9b of the HC Guidance Document</u>, 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.

- Pulse consumption had a moderate strength of association with changes in total cholesterol.
- All other parameters had low strengths of association.

#### **Research Gaps**

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

- existing patterns of pulse consumption in Canada, detailed according to the specific variety of pulse consumed;
- the sustainability of effect over the long-term;
- the minimum effective intake (i.e. dose-response clinical trials);
- the beneficial constituents of pulses (e.g. soluble fibre, plant protein, oligosaccharides); and
- the effect of different pulses (e.g. beans vs. peas vs. chickpeas vs. lentils) on CVD.

## **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 pulse 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: <sup>3</sup>

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

The requirements for using these options are outlined in the <u>Guide to Food Labelling and Advertising</u> 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 pulses), 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 beans, peas, lentils and chickpeas is "100 g dry or 250 mL cooked or canned".
   This report will base claims on a reference amount of 250 mL of cooked pulses as this is considered to be a reasonable amount to consume within a meal.
- The reference amount and the serving size for a food containing pulses will vary depending on the food; see <u>Section 6.2 of the CFIA Guide</u> 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, <u>Section 6.3.2</u> and <u>Section 6.3.4</u>). The % DV of the nutrient in one serving, rounded as indicated in the CFIA Guide (<u>Table 6-1</u> and <u>Table 6-2</u>), must be declared in the Nutrition Facts table.

#### **Vitamin and Mineral Nutrient Content Claims**

The CFIA Guide (<u>Table 7-14</u>) 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 pulses, or stated serving of a food containing pulses, provides ≥5% of the RDI of the nutrient it would qualify as a "source" of that nutrient. The CFIA Guide (<u>Table 7-11</u> and <u>Table 7-15</u>) outlines the minimum amounts of the nutrient 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.

<sup>&</sup>lt;sup>3</sup> 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 kidney beans, split peas, lentils and chickpeas

	Reference	Type of pulse (reference amount, 250 mL)				
Nutrient	Standard  or RDI (adults; children	Kidney beans	Split peas	Lentils	Chickpeas	
	≥2 years) (2)*	Amount (4) †	Amount (4) †	Amount (4) †	Amount (4) †	
Total fat	65 g	0.94 g	0.81 g	0.80 g	4.49 g	
%Daily Value <sup>‡</sup>		1%	1%	1%	7%	
Saturated FA	Sum of saturated	0.131 g	0.112 g	0.111 g	0.466 g	
Trans FA	+ <i>tran</i> s FA 20 g	0 g	0 g	0 g	0 g	
%Daily Value <sup>‡</sup>		0%	0%	0%	2%	
Monounsaturated FA	N/A	0.056 g	0.168 g	0.134 g	1.010 g	
Polyunsaturated FA	N/A	0.505 g	0.342 g	0.366 g	2.003 g	
Cholesterol	300 mg	0 mg	0 mg	0 mg	0 mg	
%Daily Value <sup>‡</sup>		0%	0%	0%	0%	
Carbohydrate	300 g	42.64 g	43.70 g	42.11 g	47.52 g	
%Daily Value <sup>‡</sup>		14%	15%	14%	16%	
Fibre, total dietary	25 g	12.0 g	6.0 g	8.9 g	7.9 g	
%Daily Value <sup>‡</sup>		48%	24%	36%	32%	
Sodium	2400 mg	2 mg	4 mg	4 mg	12 mg	
%Daily Value <sup>‡</sup>		0%	0%	0%	1%	
Potassium	3500 mg	757 mg	750 mg	772 mg	504 mg	
%Daily Value <sup>‡</sup>		22%	21%	22%	14%	
Folate	220 μg	243 µg	135 µg	379 µg	298 µg	
%Daily Value <sup>‡</sup>		110%	60%	170%	140%	
Iron	14 mg	4.15 mg	2.67 mg	6.97 mg	5.01 mg	
%Daily Value <sup>‡</sup>		30%	20%	50%	35%	
Magnesium	250 mg	79 mg	75 mg	75 mg	83 mg	
%Daily Value <sup>‡</sup>		30%	30%	30%	30%	
Phosphorus	1100 mg	258 mg	205 mg	377 mg	291 mg	
%Daily Value <sup>‡</sup>		25%	20%	35%	25%	
Zinc	9 mg	1.87 mg	2.07 mg	2.66 mg	2.65 mg	
%Daily Value <sup>‡</sup>		20.00%	25.00%	30.00%	30.00%	
Copper	2 mg	0.393 mg	0.375 mg	0.525 mg	0.610 mg	
%Daily Value <sup>‡</sup>		20%	20%	25%	30%	
Manganese	2 mg	0.804 mg	0.820 mg	1.034 mg	1.785 mg	
%Daily Value <sup>‡</sup> FA = fatty acids; N/A = not applicable		40%	40%	50%	90%	

<sup>\*</sup> see the CFIA Guide, <u>Table 6-5</u> (vitamins and mineral nutrients) and <u>Table 6-7</u> (fat and fibre)

<sup>&</sup>lt;sup>†</sup> Source: Canadian Nutrient File 2007b (4), food codes #3390 Chickpeas (garbanzo beans, bengal gram), boiled; #6366 Beans, kidney, all types, boiled; #3393 Lentils, boiled; #3395 Peas, split, boiled. Note that data on *trans* fats are not available in the Canadian Nutrient File for these foods; the values are shown to be zero based on Nutrition Facts tables on several types of canned pulses. Manufacturers would need to verify the nutrient composition of their particular products.

<sup>&</sup>lt;sup>‡</sup> %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 (<u>Table 7-11</u> and <u>Table 7-15</u>), examples of vitamin and mineral nutrient content claims that could be used for various pulses are:

- "Kidney beans / split peas / lentils / chickpeas are an excellent source of folate"
- "Kidney beans / lentils / chickpeas are an excellent source of iron" or
   "Split peas are a good source of iron"
- "Lentils / chickpeas are an excellent source of zinc" or "Kidney beans / split peas are a good source of zinc"
- "Kidney beans contain 7 essential nutrients"

#### **Other Nutrient Content Claims**

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

Table 5: Other nutrient content claims that could be associated with pulses

Claim	Condition(s)	Examples of approved wording
Low in fat	Kidney beans, split peas and lentils contain 3 g or less of fat per reference amount and serving of stated size	- "low in fat"  - "low fat"  - "contains only (number) g of fat per serving"  - "contains less than (number) g of fat per serving"
Low in saturated fatty acids*	Kidney beans, split peas, lentils and chickpeas contain 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 saturated fatty acids*	Kidney beans, split peas and lentils contain 0.2 g or less of saturated fatty acids and 0.2 g or less of <i>trans</i> fatty acids per reference amount and serving of stated size	- "free in saturated fatty acids"  - "saturated fatty acids-fre"  - "no saturated fatty acids"  - "0 saturated fatty acids"  - "without saturated fatty acids"
Free of <i>trans</i> fatty acids*	Kidney beans, split peas, lentils and chickpeas contain less than 0.2 g of <i>trans</i> fatty acids per reference amount and serving of stated size, and are low in saturated fatty acids	- "trans fatty acids-free" - "zero trans fatty acids" - "contains no trans fat"

<sup>&</sup>lt;sup>4</sup> The number indicated is not necessarily the maximum that could be claimed. It is based on the seven nutrients chosen as key nutrients in pulses and determined to be present in sufficient amounts for pulses to qualify as a "source" of each of the nutrients.

Claim	Condition(s)	Examples of approved wording
Cholesterol free	Kidney beans, split peas, lentils and chickpeas contain less than 2 mg of cholesterol per reference amount and serving of stated size, and are low in saturated fatty acids	- "free of cholesterol" - "cholesterol-free" - "no cholesterol" - "0 cholesterol" - "zero cholesterol" - "without cholesterol" - "contains no cholesterol"
Very high source of fibre <sup>†</sup>	Kidney beans, split peas, lentils and chickpeas contain 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"

<sup>\*</sup> A review of current Nutrition Facts tables on several types of canned pulses suggests negligible amounts of saturated fat and zero *trans* fat, indicating that these nutrient content claims could be used. Producers or manufacturers who want to use these claims should verify that their specific product meets the criteria.

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) <u>and</u> 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 (<u>Table 8-3</u>). Examples of acceptable nutrient function claims that could be associated with various pulses would be those related to folate, phosphorus, magnesium, iron and zinc. For products where a type of pulse 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.

<sup>&</sup>lt;sup>†</sup> 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).

Manufacturers may use any combination of claims for which their product is eligible. For example, a can of kidney beans or lentils 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:

- "Kidney beans are an excellent source of folate, which is a factor in the maintenance of good health."
- "Iron is a factor in red blood cell formation. Split peas are a good source of iron."

Nutrient function claims can also be used for other nutrients found in pulses 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 pulses as an ingredient, such as chili, 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 <u>Table</u> 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 pulses:

"Our chili with beans contains 72% more iron than our chili without beans."

#### **Comparative Claims for Fibre Content**

To make a comparative claim for fibre, as indicated in the CFIA Guide (item (d) of <u>Table 7-13</u>), 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 pulses:

• "Our chili with beans contains 7 grams more fibre per cup than our chili without beans."

#### **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 pulses. <sup>5</sup> According to the CFIA Guide (<u>Table 8-1</u>), pulses could meet the criteria for the following disease risk reduction claims:

- "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."
- "A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease. [Naming the food] is high in potassium and low in sodium."

For a product that meets the conditions as set out in the CFIA Guide (<u>Table 8-1</u>), the above disease risk reduction claims could be applied to pulses, or a product that contains pulses, without pre-market approval.

#### References

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<sup>&</sup>lt;sup>5</sup> See <a href="https://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php">www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/assess-evalu/index-eng.php</a> for a list of accepted claims.

# Appendix A: References Included in the Literature Review after Filtering

From a literature search that identified 5,774 articles on the relationship between the consumption of pulses and CVD, the following is a list of the 12 references included in the literature review after filtering.

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- Mackay S, Ball MJ. Do beans and oat bran add to the effectiveness of a low-fat diet? Eur J Clin Nutr. 1992 Sep;46(9):641-8.
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- Oosthuizen W, Scholtz CS, Vorster HH, Jerling JC, Vermaak WJ. Extruded dry beans and serum lipoprotein and plasma haemostatic factors in hyperlipidaemic men. Eur J Clin Nutr. 2000 May;54(5):373-9.
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- Winham DM, Hutchins AM, Johnston CS. Pinto bean consumption reduces biomarkers for heart disease risk. J Am Coll Nutr. 2007 Jun;26(3):243-9.

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Cat. No. A72-105/1-2011E-PDF ISBN 978-1-100-19241-3 AAFC No. 11598E

Aussi offert en français sous le titre : Examen des bienfaits pour la santé des légumineuses à grains

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