Consultation Document on Generic Health Claims

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I Introduction

In 1998, following extensive dialogue and consultation with stakeholders, Health Canada published a final policy recommendation that structure/function and risk reduction claims be permitted for foods. As a first step in implementing this policy, a project was begun in 1999 to evaluate ten generic health claims that were authorized in the United States under the standards of evidence in the *Nutrition Labeling and Education Act* (1990) (NLEA).

Health Canada developed a discussion paper on the U.S. health claims to provide a background for a consultation workshop held in July, 1999 and for stakeholders to consider while developing written comments (Fall, 1999). The discussion paper, workshop report and summary of the stakeholder comments are available on the Food Program website: http:/www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/

Health Canada has initiated a process to review the science supporting the 10 generic health claims. The process involved having Canadian experts prepare reports updating the science related to the health claims in the time since the U. S. Food and Drug Administration (FDA) finalized its review (i.e., 1993 for most claims). These reports were subsequently peer reviewed. For the claims on which agreement among the reviewers was apparent, scientific summary reports were prepared based on the experts' reviews and other relevant information. The executive summaries of these reports are attached in Appendices A to D. The scientific summary reports are available on request.Comments on these scientific summary reports are welcome. The review process for the remaining claims is set out in Appendix E.

This document presents proposals for elements and conditions for the use of five of the generic health claims. This document also contains responses to comments from stakeholders concerning claim format issues, claim credibility issues, consumer education and periodic review of the science (see Section VI: *Other Issues*).

The elements of the claims proposed in this document are based on, and supported by conclusions drawn from an extensive and thorough review of the scientific literature. The claims differ in length and complexity mainly due to the quality of the evidence behind them. In diseases or health conditions where there is strong consistent evidence for a range of risk factors for the disease, these risk factors were considered an essential part of the claim (e.g. sodium and hypertension, calcium and osteoporosis). In diseases where the evidence is descriptive (epidemiological) and the markers or endpoints of the disease were less specific, the claim reflects the more general nature of the evidence (e.g. fruits and vegetables and cancer). Comments from stakeholders and Health Canada policies on nutrition guidance were also considered when developing the proposed claim elements and conditions.

As a results of the above considerations, Health Canada developed wording that was regarded as truthful and not misleading in its scientific content. A number of stakeholders suggested that any proposed wording be focus-tested to ensure that it is clear and understandable to consumers, and that they interpret the meaning as intended. Health Canada is in the process of implementing this recommendation, and will be testing the English and French claim wording with consumers (see Section IX: *Next Steps*).

II Claims proposed in this document

All of the U.S. health claims were reviewed. Broad scientific agreement was apparent for five of the claims (see Appendices A to D).

Rather than delay the process until the science was completely updated for the remaining claims, it was decided to move forward with the ones on which there was scientific agreement. This group includes:

- Sodium and Hypertension,
- Calcium and Osteoporosis,
- Saturated and *Trans* Fat and Cholesterol and Coronary Heart Disease,
- Fruits and Vegetables and Cancer, and
- Sugar Alcohols and Dental Caries.

The following claims are being further reviewed and will be resolved by the end of the year (see Appendix E). These claims pertain to:

- Folate and Neural Tube Defects,
- Fibre-Containing Grain Products, Fruits and Vegetables and Cancer,
- Fruits, Vegetables and Grain Products that Contain Fibre, Particularly Soluble Fibre and Risk of Coronary Heart Disease.

The claim pertaining to Dietary Fat and Cancer will not be put forward for adoption based on the consensus of the external reviewers that current evidence does not support the claim.

The claim pertaining to Soluble Fibre from Certain Foods and Risk of Coronary Heart Disease is based on studies using specific sources of fibre. The Policy Paper, *Nutraceuticals/Functional Foods and Health Claims on Foods*, accepted two types of risk reduction claims: generic and product-specific. The efficacy of fibres may be influenced by processing and the food matrix. More work is required to determine the direction this claim should take.

Please see Section VII for submitting your comments.

III General Requirements for Claims

Rather than follow the U.S. approach of setting general requirements for the nutrient composition of foods bearing health claims (qualifying and disqualifying amounts of nutrients), it is proposed that foods bearing health claims should fall into one of the four food groups of *Canada's Food Guide to Healthy Eating* and be consistent with *Nutrition Recommendations for Canadians* and its subsequent update on *Dietary Fat and Children*. It is also proposed that claims not be permitted for foods that fall into the "Other Foods" category of *Canada's Food Guide to Healthy Eating*. These are foods and beverages that are not part of any food group and include foods that are mostly fats and oils; foods that are mostly sugar; high fat and/or high salt snack foods; beverages such as water, tea, coffee, alcohol, and soft drinks; and herbs, spices, and condiments. It is proposed that the

claim relating saturated and trans fat to coronary heart disease be permitted for fats and oils which meet the conditions for the claim. In addition, where exclusions or more stringent requirements are needed for specific claims, these are embodied in the conditions for the claim.

Health claims are not appropriate on the labels of foods intended for infants and children under the age of 2 years.

Nutrition Labelling Requirements

The core list of nutrients for nutrition labelling as well as any nutrient which is mentioned in the claim or is part of a condition for the food bearing the claim, except for alcohol, must be declared. The list of nutrients presented in Section IV is the currently proposed core list for nutrition labelling.

Risk Reduction

In developing the conditions for the claims and the elements considered essential for each claim, consideration was given to the recent deliberations of the Codex Committee on Food Labelling (CCFL) on health claims. The CCF proposed that claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition must consist of two parts:

1) Information on an accepted diet-health relationship; followed by
2) Information on the composition of the product relevant to the relationship.

The CCF included the following paragraph in the section on reduction of disease risk claims to define risk reduction and distinguish it from prevention:

Risk reduction means significantly altering a major risk factor(s) for a disease or health-related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of risk reduction claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

IV Proposed Claim Elements and Conditions for Claims

Sodium and Hypertension

Claim Elements

"Moderation in intake of sodium may reduce the risk of high blood pressure, a condition also associated with overweight, excessive alcohol consumption, inadequate intake of dietary potassium, and inactivity. (Naming the food) is [low in sodium/sodium free]."

Conditions for Food

The food contains not more than

- 140 mg sodium; and
- 2 grams of saturated and *trans* fats combined

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; and

- 15% of energy from saturated and trans fat combined; and
- 0.5% alcohol.

Prepackaged meals and main dish entrees contain not more than

- 140 mg sodium per 100 g;
- 2 g saturated and trans fat combined per 100 g; and
- 15% of energy from saturated and trans fat combined.

The label carries a declaration of the energy value and the contents of protein, fat, saturated fat, *trans* fat, carbohydrate, fibre, sodium, potassium, calcium and iron.

**Standardized amounts of foods based on average intake at single eating occasions established as basis for nutrient content claims.*

Calcium and Osteoporosis

Claim Elements

"**A healthy diet with adequate calcium and regular exercise help to achieve strong bones in children and adolescents and may reduce the risk of osteoporosis in older adults. Adequate intake of Vitamin D is also necessary. (Naming the food) is a [good/high/excellent] source of calcium."**

Conditions for Food

The food contains not less than

- 200 mg of calcium

per reference amount and per serving of stated size.

The phosphorus content (excluding that provided by phytate) must be less than the calcium content.

Prepackaged meals and main dish entrees contain not less than 300 mg calcium per labelled serving.

The label carries a declaration of the energy value and the contents of protein, fat, saturated fat, *trans* fat, carbohydrate, fibre, sodium, calcium, iron, vitamin D and total phosphorus.

Saturated and *Trans* Fat and Coronary Heart Disease

Claim Elements

"**A diet low in saturated and *trans* fats may reduce the risk of heart disease**. **(Naming the food) is [low in / free of] saturated and *trans* fat."**

Conditions for Food

The food contains not more than

- 2 g saturated and *trans* fats combined;
- 100 mg cholesterol; and
- 480 mg 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;

- 15% of energy from saturated and *trans* fats combined; and
- 0.5% alcohol.

Prepackaged meals and main dish entrees contain not more than

- 140 mg sodium per 100g;
- 2 g saturated and trans fat combined per 100 g; and
- 15% of energy from saturated and trans fat combined.

The label carries a declaration of the energy value and the contents of protein, fat, saturated fat, *trans* fat, cholesterol, carbohydrate, fibre, sodium, calcium and iron.

Fruits and Vegetables and Cancer

Claim Elements

"**A diet rich in a variety of fruits and vegetables may help reduce the risk of some types of cancer**"

Conditions for Food

The food must be a fresh, frozen, dried or canned fruit or vegetable or its juice or combination thereof, with or without seasonings, salt, food additives, or sweetening ingredients permitted by the standards in Division 11 of the Food and Drug Regulations, and excluding white potatoes, yams, cassava, plantain, banana and corn.

The food contains not more than

- 0.5% alcohol.

The label carries a declaration of the energy value and the contents of protein, fat, saturated fat, *trans* fat, carbohydrate, fibre, sodium, calcium and iron.

Sugar Alcohols and Dental Caries

Claim Elements

"Won't Cause Cavities", or
"Does not promote tooth decay", or
"Does not promote dental caries", or
"Non-cariogenic".
"Tooth Friendly" may be used in conjunction with one of the preceding claims.

Conditions for Food

The food is a chewing gum, confectionery, or breath freshening product sweetened by one or more of the following: xylitol, sorbitol, sorbitol syrup, mannitol, maltitol, maltitol syrup, isomalt, lactitol, hydrogenated starch hydrolysates, acesulfame K, aspartame, or sucralose.

The food contains not more than 0.25 per cent starches, dextrins, mono-glycerides, di-glycerides and oligosaccharides, combined.

V. Discussion of Proposed Claim Elements and Conditions for Specific Health Claims

Sodium and Hypertension

Claim Elements

"**Moderation** refers to a level of intake that is neither excessive nor severely restricted. The latter may be harmful under some circumstances (see Appendix A).

The phrase "**high blood pressure**" is proposed rather than "hypertension," as the term is more familiar to consumers.

Listing in the claim the major risk factors associated with hypertension (**overweight, excessive alcohol consumption, inadequate intake of dietary potassium,** and **inactivity**) is appropriate since the control of these risk factors will have a larger impact on reducing hypertension than a moderate reduction of sodium intake alone (see Appendix A). It would be misleading to omit these factors when sodium reduction by itself has a smaller effect.

The phrase "**inadequate intake of dietary potassium**" should not be shortened to "inadequate dietary potassium," which suggests that the food supply is low in potassium, which is not true. People are not consuming enough potassium-rich foods (i.e., fruits and vegetables), hence the proposed wording.

Conditions for food

Sodium. A food bearing this health claim must meet the Canadian definition for "low in sodium"or "sodium free". A moderate intake of sodium cannot be achieved without consuming a number of low sodium foods.

Saturated and *trans* **fats.** Hypertension is a risk factor for a number of diseases, including heart disease. Saturated and *trans* fats are dietary factors that must be controlled in reducing the risk of, and in the management of, coronary heart disease and therefore foods bearing this claim should be low in saturated and trans fat.

Alcohol. The requirement to limit the alcohol content of foods bearing this claim is proposed because excessive alcohol consumption is a risk factor for high blood pressure, and this claim would not be appropriate on foods containing alcohol.

Calcium and Osteoporosis

Claim Elements

The phrase "**a healthy diet**" is considered necessary in this health claim since a healthy diet would provide all the nutrients essential for proper bone formation (e.g. protein, minerals, vitamins). Including the phrase also removes the possibility that some consumers might conclude from the claim that calcium in a less than healthy diet will enhance bone growth or reduce the risk of osteoporosis.

The phrase, " **with adequate calcium**" is proposed for inclusion in this health claim

since calcium promotes bone formation in childhood and has been shown to increase bone density and decrease fracture incidence in post menopausal women and in men.

"**Regular exercise**" appears to be a significant determinant of bone health in young adults. In addition, calcium alone will not prevent bone loss in the absence of weight bearing exercise (see Appendix B). The documented link between exercise and bone health supports the proposal to include the phrase "regular exercise" in this health claim.

The phrase "**help to achieve strong bones in children and adolescents**" is important since peak bone mass is the major factor in the risk of developing osteoporosis later in life (see Appendix B). It is therefore appropriate to include this phrase in the proposed health claim to encourage consumption of high calcium foods by children and adolescents, whose bones are still growing.

"Osteoporosis" is the name of the disease in this claim. Stakeholder comments indicated that the term is well understood by consumers. It is also important to include the phrase "**in older adults**" since osteoporosis is seen mainly in the "over 50" population, and adequate calcium intake in older adults, as noted above, increases bone density and decreases fracture incidence.

The proposal to include the phrase "**adequate intake of Vitamin D is also necessary**" in this health claim recognizes the fact that adequate vitamin D is important for bone health in all segments of the population. An especially at-risk group is the elderly, particularly those with limited exposure to sunlight.

Conditions for Food

Calcium. It is proposed that a food bearing this health claim contain not less than 200 mg of calcium per reference amount and per serving of stated size. This level satisfies the current requirements for the "good / high source of calcium" nutrient content claim. The level was chosen to provide approximately 15% of the Adequate Intake recommended for children and adolescents (1300 mg) and older adults (over 50 years) (1200 mg) in the DRI report.[1]

It is proposed that a prepackaged meal or entree bearing this health claim contain not less than 300 mg of calcium per reference amount and per serving of stated size. This would provide 25% of the Adequate Intake recommended for older adults aged over 50 years (1200 mg).

Phosphorus. A large part of the phosphorus in the body is present in bone, associated with calcium in a one-to-one ratio. According to many researchers, a high phosphorus diet will lower the level of calcium in the blood, which then releases parathyroid hormone that removes calcium from bone in order to increase serum calcium. It is appropriate that the calcium-phosphorus ratio in foods bearing this claim not negatively

[1] Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food & Nutrition Board, Institute of Medicine (1997). Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D & Fluoride.

affect bone density, especially in children, by the mechanism mentioned above. (The phosphorus in high phytate foods is less available so should be excluded from the calculation of phosphorus content).

No fat restriction. Health Canada does not recommend restricting the fat intake of children during linear growth (bone growth). *Nutrition Recommendations Update...Dietary Fat and Children* recommends that from the age of two until the end of linear growth, there should be a transition from the high fat diet of infancy to a diet which includes no more than 30% of energy as fat and no more than 10% of energy as saturated fat.

Saturated and *Trans* Fat and Coronary Heart Disease

Claim Elements

A review of the scientific literature strongly indicates that the primary effect of dietary fat on coronary heart disease or plasma lipid risk factors for coronary heart disease is related to saturated and *trans* fats. Some studies suggest that *trans* fats may be a greater risk factor than saturated fats for coronary heart disease (see Appendix C). It is appropriate that this proposed coronary heart disease health claim include both these nutrients of concern: "**saturated and *trans* fats**".

"**Heart disease**" is the name of the disease mentioned in this claim. Stakeholder comments indicated that the term is well understood by consumers.

Conditions for Food

Saturated and trans fats. It is proposed that a food bearing this claim must meet the definition for "'low in" or "free of" saturated and *trans* fats".

Cholesterol. Evidence indicates that dietary cholesterol is not a major factor for coronary heart disease in the general population. This is a departure from earlier dietary guidance. However, the scientific literature continues to provide evidence that some individuals are "high responders" to dietary cholesterol. Therefore, a proposed requirement for a food bearing this claim is that it contain "not more than 100 mg cholesterol per 100 g". This is consistent with the amount of cholesterol allowed in a serving of meat, fish or poultry on Step I and II diets frequently prescribed for people at risk of cardiovascular disease. People on these diets should be allowed to eat foods bearing this claim. And, as noted above, a health claim pertaining to risk reduction of a particular disease cannot be inconsistent with scientifically recognized diet therapy for that condition. Dietary cholesterol restriction continues to be part of diets for management of coronary heart disease.

Sodium. The basis for proposing to limit the sodium content to 480 mg per reference amount and per serving of stated size is that hypertension is a risk factor for heart disease (see Appendix A). Moderation in sodium intake may reduce the risk of hypertension and should therefore be limited in foods bearing this claim. This amount represents 10-20%

of a moderate sodium intake (2-4 g/d).

Alcohol. The requirement to limit the alcohol content of foods bearing this claim is proposed because excessive alcohol consumption is a risk factor for hypertension, a risk factor for heart disease, and this claim would not be appropriate on foods containing alcohol.

Fruits and Vegetables and Cancer

Claim Elements

The proposed wording for this health claim contains the phrase "... a diet rich in a **variety** of fruits and vegetables ..." The scientific literature remains consistently and strongly supportive that increases in fruit and vegetable consumption may decrease the relative risk of a number of cancers (see Appendix D). There is not enough evidence to support a relationship between any one food component and reduced cancer risk Because of the wide range of nutrients and phytochemicals contained in different plant families, a variety of fruits and vegetables is recommended.

The proposed wording for this health claim contains the phrase "... **may help** ... reduce the risk of ..." Including the phrase "...**may help** ..." removes the possibility that some consumers might conclude from the claim that diet is the only factor in reducing the risk of some types of cancer.

The disease is referred to in this claim as "**some types of cancer.**" The data supporting this claim, which are epidemiological in nature, provide evidence that higher intakes of fruits and vegetables reduce the risk of some, but not all, types of cancer (see Appendix D).

Conditions for Food

Nature of the food. It is proposed that a food bearing this health claim be a fresh, frozen, dried or canned fruit or vegetable, or a fruit or vegetable juice. It would not be appropriate to permit the use of the claim for foods where the fruit or vegetable is not the primary ingredient.

Other ingredients. Prepared fresh, frozen, dried or canned fruits or vegetables or their juices commonly contain other ingredients in small quantities. Therefore it is proposed that the fruits or vegetables may contain seasonings, permitted food additives, salt, or sweetening ingredients, within the limits set out in the Standards.

Excluded foods. It is proposed to prohibit the use of this health claim on white potatoes, yams, cassava, plantain, bananas and corn. Although these foods are nutritious, for the purpose of this health claim, there is insufficient evidence for the claim to be extended to these foods (see Appendix D; World Cancer Research Fund and the American Institute for Cancer Research, 1997).

Alcohol. *Canada's Food Guide to Healthy Eating* suggests limiting alcohol

consumption. It is therefore proposed that a food bearing this health claim contain no more than 0.5% alcohol.

Sugar Alcohol and Dental Caries

Claim Elements

Currently, "**Won't cause cavities"** and **"Does not promote tooth decay"** are acceptable claims for sugarless chewing gum in Canada. It is expected that these claims will continue to be used on small packages of products such as sugarless chewing gum, breath mints and the like. Stakeholders expressed a desire for this claim to be short enough for small packages. Accordingly, the following choices of wording are proposed: **Won't Cause Cavities, Does not promote tooth decay, Does not promote dental caries, Non-cariogenic.** It is proposed that the term **"Tooth Friendly"** may only be used in conjunction with one of the preceding claims.

Conditions for Food

Nature of the food. The food is to be a chewing gum, confectionary or breath freshening product.

Non-cariogenic sweeteners. It is proposed that only sweeteners listed (one or more of: xylitol, sorbitol, sorbitol syrup, mannitol, maltitol, maltitol syrup, isomalt, lactitol, hydrogenated starch hydrolysates) and that have been determined to be non-cariogenic may be used to sweeten products bearing one of these claims.

Minor non-nutritive sweeteners. Chewing gum or confectionary products sweetened with the ingredients listed may also contain, as minor constituents, one or more of the non-nutritive, low-calorie sweeteners: acesulfame-potassium (K), aspartame and sucralose.

Carbohydrates. It is also proposed to require that a product bearing this claim contain not more than 0.25 per cent starches, dextrins, mono-glycerides, di-glycerides and oligosaccharides, combined.

This requirement would remove the need for manufacturers to assess the effect of the food on plaque pH by means of the "indwelling plaque pH test." The test is technically demanding and not widely available worldwide.

VI. Other Issues

Claim format issues

Number of claims on one package. The manufacturer of a food product may use more than one health claim, provided the product qualifies for more than one.

Split claims. A split claim is "a concise statement on the front with additional information on the side or back panel." Health claims are complex. If the consumer does not read the whole claim, they would not get a true picture of the relationship of the risk factor for the disease. Accordingly, it is proposed that split claims not be permitted for these claims.

Claims in advertising. When a health claim appears in an advertisement, it is proposed that the entire health claim be presented. Any information required to be given in relation to a health claim shall be given on the label, where the claim is made on the label, or in the advertisement or on the label, where the claim is made in an advertisement.

Standardization of format. All elements of the claim statement must be of the same type face and size, grouped together, and given equal prominence. Other decisions concerning the "look" of the claim are the responsibility of the manufacturer.

Fortification. The claim for calcium and osteoporosis may be made for foods containing added calcium if the food is permitted to contain added calcium as a mineral nutrient at the level required for the claim (Table to Section D.03.002).

Health claims and fresh fruits and vegetables. It is proposed that banners displaying the fruits and vegetables and cancer health claim be permitted in close proximity to mixed displays of fruits or vegetables, provided the excluded foods mentioned in the "Conditions for food" for the claim form a minor part of the display. Where there is a wide variety of products, such as in the produce section of a food store, it is proposed that nutrition labelling not be required. For single products, nutrition labelling would be required.

Pre-approvals. Manufacturers need only ensure the food product meets the food requirements for health claims set out in this document. It is not necessary to have the product pre-approved before labelling with a health claim.

Claim credibility issues

Endorsement of claims by Health Canada. A statement on a food or in advertising using Health Canada's name will not be permitted.

Endorsement of claims by third party organizations. Stakeholders should refer to Canada's *Guide to Food Labelling and Advertising*, section VII.3, for information on policies concerning third party endorsements, logos and seals of approval.

Educating consumers and review of scientific evidence

Educating consumers. A number of stakeholders commented that an education campaign should be implemented for consumers. Health Canada is committed to an education program to support the use of food labels in making informed food choices for healthy eating.

Review of evidence. Stakeholders noted that the science behind the health claims should be reviewed periodically. Health Canada also recognizes the need for periodic reviews.

VII. How to Comment

Your comments on the elements and conditions proposed in Section IV, issues in Section VI, or any discussion contained in this document are welcome and may be sent to the project leader in one of the following ways:

i) by mail: Melodie Wynne
Generic Health Claims Project
Bureau of Nutritional Sciences
Food Directorate
Banting Research Bldg., 3rd Floor
Tunney's Pasture, Address Locator (A.L.) 2203A
Ottawa, ON K1A 0L2

ii) by fax: (613) 941-6636

iii) by e-mail: melodie_wynne@hc-sc.gc.ca

Please be sure to complete the Respondent Profile on the next page.

VIII Respondent Profile:

Respondent Name:

Organization:

Address:

If this comment represents more than one respondent, briefly describe the process you used to arrive at your response.

Circle area represented:

Health / Education / Media
Industry (please specify)
Public
Academia
Other (please specify)

Other Comments:

Thank you!

IX Next Steps

- An important next step is to verify that the claims are clear and understandable to a range of Canadian consumers and that consumers interpret them as intended. Health Canada is in the process of focus-group testing the English and French claim element wording with consumers. Where the intent of the proposed language is not clear, the consumer focus groups will suggest alternate wording.

- Your comments, due by **September 8, 2000**, together with the results of the consumer focus group testing, will be considered in the development of the health claim wording that goes forward to Canada Gazette I.

X. Appendices

Appendix A.

Health Canada Scientific Summary on the U. S. Health Claim for Sodium and Hypertension

Executive Summary

Since the US. Health Claim on sodium and hypertension was accepted in 1993, considerable research has been completed clarifying those who respond to changing sodium intakes with changes in blood pressure, factors affecting this response, quantifying short term and long term blood pressure changes in response to dietary sodium restriction in normotensive and hypertensive populations, and clarifying the role of other risk factors for hypertension. Risks associated with low sodium intakes as well as excessive intakes have also been identified.

Hypertension is a risk factor for stroke, coronary artery disease, peripheral vascular disease, congestive heart failure and renal failure and as such is considered a major public health problem. Hypertension affects approximately 22% of Canadian adults, the incidence increasing with age such that by age group 55 to 64 years, 46% of that population has hypertension. An additional 26% of adults have diastolic pressure in the high normal range. Risk factors for hypertension include overweight and obesity, alcohol in excess of 2 drinks per day, physical inactivity, adult onset diabetes, poor nutrition, including excessive sodium intakes at least in certain segments of the population, and inadequate intakes of other dietary components particularly potassium and possibly calcium.

The fundamental question addressed by this report is whether lowering sodium intake in a whole population will reduce risk of hypertension. Four meta analyses of randomized controlled trials have been conducted since 1993, and consistently show a small, statistically significant reduction in systolic blood pressure (about 1.2 mm Hg) in normotensive individuals for a large (100 mmol or about 6 g salt) reduction in sodium intake over the short term. Over the longer term of 3 years, although some reduction in population sodium intake is achievable (25-50 mmol/d), the effect on blood pressure is very small (1 mm Hg systolic) compared to usual care, and not significant as a main effect.

In hypertensive individuals, from the same 4 meta analyses, a consistent and more robust effect of sodium reduction on blood pressure was seen in the short term.

Biological differences in blood pressure response to sodium have been identified recently, such that a sub-group of both the normotensive and hypertensive population show a marked blood pressure rise with relatively high sodium intake. Sodium sensitivity is a reproducible phenomenon, but is also influenced by nutritional status, particularly potassium and calcium intakes, by age and by overweight/obesity. Prevalence estimates of sodium sensitivity are 15-35 % of the normotensive population and 29-50 % of the hypertensive population.

Potential risks of sodium reductions have recently been suggested from three prospective cohort

studies and one meta analysis. The inverse association of all-cause mortality with sodium intakes, suggests that sodium restriction may be harmful under some circumstances, but these observations need further study.

Although expert views and interpretations of this data are not consistent, there is substantial evidence that reducing sodium intake in at risk populations has a minimal effect on population mean blood pressure at current levels of intake, (4.1 g sodium or about 10 g salt/d in the 3 year study above). Based on recent estimates of sodium intake, over 25% of Canadian men age 18 to 49 consume excessive sodium (over 10g salt/d), as do 10% of men over 50. Given that between 15 and 35% of the Canadian population may be salt sensitive, and that 22% of the population has hypertension, a prudent population-based strategy to reduce risk of hypertension is to avoid excessive sodium intakes.

Thus a prudent claim is **"moderation in intake of sodium may reduce the risk of high blood pressure, a condition associated with many factors including overweight, excessive alcohol consumption, inadequate intake of dietary potassium, and inactivity".**

Other interventions such as weight reduction are effective in both the short and long term. A well-substantiated claim for the Canadian population is: **Attaining and maintaining a healthy body mass index will reduce the risk of hypertension, a condition associated with many factors.**

Appendix B.

Health Canada Scientific Summary on the U. S. Health Claim Regarding Calcium and Osteoporosis

Executive Summary

The objective of this summary is to review the scientific literature on the relationship between calcium intake and osteoporosis that has been published since the health claim was adopted by the U.S. Food and Drug Administration in 1993. For this health claim, two Canadian scientists recognized as experts in this field were contracted by Health Canada to independently evaluate the scientific literature. Studies identified in the Dietary Reference Intakes (DRI) report relating to the role of calcium in osteoporosis, in bone mineral density or bone mineral content and in fracture rates as well as studies published subsequent to the DRI Report were reviewed and included in the present summary report.

Osteoporosis is a disease characterized by low bone mass and micro architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk. Peak bone mass is the major factor determining the risk of developing osteoporosis and by about age 20, the human skeleton has reached 90-95% of its peak bone mass, with the final 5-10% of bone mineral added during the next 10 years. People who have achieved a greater peak bone mass are less susceptible to osteoporosis. An estimated 1.4 million Canadians are believed to have osteoporosis, one in four women and one in eight men over 50 years of age. One Canadian survey has estimated the 1993 total health care costs (hospitalization, patient care, drug therapy) attributable to osteoporosis at $465 million and when long term facility care and chronic hospital care were included, the total reached $1.3 billion annually.

No national data on the calcium intakes of Canadians are available, although data from the Nova Scotia and Quebec Provincial surveys have reported relatively recent data for calcium intakes (data were obtained from surveys conducted in 1990). Mean calcium intake data for these provinces ranged from about 770 to 1160 and 574 to 788 mg/d (depending on age) for males and females respectively, with intakes declining with increasing age.

Controlled clinical trials of calcium supplementation have been conducted for almost every age group (children and older) and for the most part support the calcium and osteoporosis health claim.

In children, clinical trials have shown a modest but positive effect of calcium supplementation, particularly in those children with intakes <1000 mg/d, on bone mineral accretion. Similar benefits have been seen with calcium intakes >1000 mg/d. In general, supplementation resulted in 1 to 5% greater gains in bone mineral density or bone mineral content compared to controls. However the long term benefits of such an increase and whether the increase is sustained, remain unclear at the present time.

Data concerning the role of calcium in bone health in young adults is particularly lacking compared to other age groups. No recent clinical trials in this age group were found and

observational studies, although suggestive of a benefit, were not consistent. A small but significant correlation between calcium intake and bone mass was found in a meta analysis of 24 observational studies. Physical activity appears to be a significant determinant of bone health in this age group.

The studies reviewed in the DRI report and those conducted since the DRI report show several consistent effects regarding the role of calcium in bone loss in post menopausal women. Early post menopausal women are less responsive to calcium supplementation than late post menopausal women; where effects were seen, they tend to be in cortical bone, with spine less responsive to calcium. Late menopausal women with low calcium intakes tend to gain more BMD from calcium supplementation than do women with higher usual intakes of calcium. Observational studies in post menopausal women and one study which included men generally indicated a positive effect of calcium on bone density. Several studies also suggested that higher intakes of calcium earlier in life were related to reduced incidence of fractures or increased BMD in post menopausal women.

Many studies conducted in the elderly have shown a benefit of supplements or higher intakes of calcium on the clinically important outcome - fracture rate. Almost half of the trials in the elderly found decreased fracture incidence, in addition to changes in BMD. More studies in this age group than in any other have included male subjects and benefits appeared to apply equally to men. In the elderly, most studies have provided a supplement of vitamin D along with calcium. Given that vitamin D deficiency is most prevalent among the elderly, particularly among institutionalized or house bound individuals, it appears important that they have adequate vitamin D in order to utilize calcium or to benefit from additional calcium.

Based on this evidence, several elements are required for this health claim: 1) The reference to a healthy diet to provide all the nutrients necessary for proper bone formation (protein, minerals, vitamins, and essential fatty acids) should be included. 2) Calcium alone will not prevent bone loss in the absence of weight bearing exercise and several of the recent studies and the recent meta analysis by Kelley (1998) affirm maintaining the link with exercise in this claim. 3) There is sufficient evidence that calcium at or near levels recently recommended by the 1997 DRI Panel provides additional bone mass in children and adolescents and reduces bone loss in older adults. Since the DRI Panel has named its recommendations as Adequate Intake, the term “adequate calcium” would be preferable to “enough calcium”. 4) There is evidence that adequate calcium during childhood can promote more bone formation and that during later adult life, particularly during late post menopause and in the elderly, calcium can protect against bone loss and fractures. Therefore, the claim should not be restricted to teens and young adults. 5) Reference to any specific ethnic group is not justified for Canada: it is likely that all ethnic groups have some risk and there is little information on calcium intakes and effects on bone parameters in groups such as First Nations, East Indians and many others. 6) As indicated by the DRI Panel and results in the elderly, there is no evidence of a specific gender effect in need for calcium (although there are fewer studies conducted in men than in women). Therefore, gender need not be specified. 7) The term “osteoporosis” is in common usage due to publicity by groups such as the Osteoporosis Society of Canada and use of this term should not impede the understanding of this claim. 8) Vitamin D is important, particularly in older adults and in children, in enabling them to adequately use calcium and should be part of this health claim.

Children in Canada likely receive adequate vitamin D through fortification of milk and margarine and through sunlight exposure, however, for older adults who require 10 µg/d (age 51-70) to 15 µg/d (age >70), which are double and triple, respectively, the recommended intakes for younger age groups, dietary sources are vital. This statement may prevent over focussing on calcium at the expense of other nutrients, particularly vitamin D. Foods bearing a health claim for calcium must contain at least 200 mg calcium per reference amount and per serving of stated size.

Based on a review of the evidence related to the various claim elements, the following health claim is proposed for Canada:

> **A healthy diet with adequate calcium and regular exercise may help to achieve strong bones in children and adolescents and may reduce the risk of osteoporosis in older adults. An adequate intake of vitamin D is also necessary.**

The following compositional criteria are proposed for foods bearing this claim: the food must provide at least 200 mg calcium per serving of stated size and the phosphorus content (excluding that provided by phytate) must be less than the calcium content.

Appendix C.

Health Canada Scientific Summary on the U. S. Health Claim Regarding Dietary Fat, Saturated Fat, Cholesterol, *Trans* Fatty Acids and Coronary Heart Disease

Executive Summary

This report is a critical review and evaluation of the scientific literature from 1993-2000 inclusive on the relationship of the dietary level of total fat, saturated fat, cholesterol and *trans* fat on coronary heart disease (CHD), or plasma lipid risk factors for CHD. The cumulative evidence from these reports strongly indicates that the primary effect of dietary fat is related to saturated and *trans* fatty acids. Recent metabolic studies show that unless there is a concomitant reduction in saturated fat, a reduction in total fat will not lower plasma cholesterol or lipoprotein levels. A reduction in total fat does not have a beneficial effect on CHD, or CHD risk factors independent of its effect on lowering saturated fat.

The effectiveness of lowering dietary saturated fat in reducing plasma cholesterol, especially low-density lipoprotein (LDL)- cholesterol, the major risk factor for CHD, is well established. This position continued to be supported by the scientific findings over the past seven years and by meta-analyses of metabolic studies reported over the last 30 years. A reduction in saturated fat by replacement with either *cis* mono- or poly-unsaturated fatty acids, or a combination of both (i.e., modifying fat quality) rather than by increasing carbohydrate, produces more favourable effects. This judgement is based on the role of low plasma levels of high-density lipoprotein (HDL)-cholesterol and high plasma levels of triglyceride (TG) as risk factors for CHD and clinical trials showing a reduction of dietary fat along with an increase in carbohydrates decrease cardioprotective HDL-cholesterol and increase atherogenic TG.

Consumption of diets with higher levels of *trans* fatty acids results in increased plasma levels of LDL-cholesterol. In addition, *trans* fatty acids, in contrast to saturated fatty acids, lower plasma levels of HDL-cholesterol and raise the blood level of atherogenic lipoprotein (a), which suggests that *trans* fatty acids may be a greater risk factor for CHD than dietary saturated fatty acids.

Evidence has also accumulated over the period of 1993-1999 that indicates dietary cholesterol is not a major factor influencing plasma cholesterol and lipoprotein levels in the general population. It appears that the earlier predictions of the effect of each 100 mg of dietary cholesterol on plasma total cholesterol were too high; namely 1.75 mmol/L for each 100 mg/day dietary cholesterol. All the meta-analyses and carefully controlled studies reported since 1993 estimate that a decrease of 100 mg dietary cholesterol results in decrease of plasma cholesterol of 0.05 mmol/L. On a population basis this change is relatively insignificant considering that it represents approximately 1% of the average population plasma cholesterol concentration. Even though the magnitude of the effect of dietary cholesterol is very small for the general population, scientific literature continues to provide evidence that some individuals may be high responders to dietary cholesterol. However, the effect appears to be primarily on plasma total cholesterol; the effect of dietary cholesterol on plasma LDL varies among reports.

In conclusion, there is appreciable scientific support for the benefits of reducing the intakes of dietary saturated and *trans* fats in lowering the risk of CHD. The position is weaker for the benefits of reducing total fat and cholesterol. Guidelines for the prevention of CHD should therefore focus primarily on reducing the dietary intakes of saturated and *trans* fats. It is proposed that a health claim which states that **diets low in saturated and *trans* fats "may" or "might" reduce the risk of heart disease** is the most appropriate claim that may be made on the label or in the labelling of foods

Appendix D.

Health Canada Scientific Summary of the U. S. Health Claim Regarding Fruits, Vegetables and Cancer

Executive Summary

Since the U. S. Health Claim pertaining to low fat diets rich in fruits and vegetables and cancer risk reduction was accepted in 1993, subsequent new evidence continues to support the claim particularly regarding fruits and vegetables. A report by the World Cancer Research Fund and the American Institute for Cancer Research (WCRF/AICR, 1997) concluded that there was convincing evidence to support a protective effect of fruits and vegetables against many types of cancers. This conclusion was based on numerous case-control studies that showed that cancer patients consumed less fruit and vegetables than comparable control cancer-free groups. Fruits in their review excluded high starch plantains and bananas, and vegetables excluded high starch roots and tubers. Since potatoes are consumed in large quantities in most North American diets, the inclusion of potatoes as a vegetable could potentially confound the effect of vegetable intake. The WCRF/AICR, 1997 did not support the inclusion of the caveat "low fat diets" in the health claim, because, although a possible link exists, the evidence was not sufficient to make a definitive judgement. The evidence for a fat /cancer relationship will be examined elsewhere.

Current Canadian intakes of vegetables including juice but excluding potatoes and corn range between 140 (Nova Scotia) and 194 (Québec) g /d for adult men and women combined, and fruit intake including juices range between 164 (Nova Scotia) and 212 (Québec) g/d. Based on defined serving sizes, in the Québec survey, the average fruit and vegetable intake was 4 servings of fruit and vegetables /d. Potential benefits of increased fruit and vegetable consumption can be estimated indicating that relatively small increases in fruit and vegetable consumption may decrease the relative risk of lung and stomach cancers, for example.

A large number of case control studies conducted since 1997 and recent reviews consistently support that diets rich in fruits and vegetables reduce the risk of some types of cancer. Evidence from prospective cohort studies is supportive of the relationship for certain cancers and for certain fruit or vegetable groups, but not all. Given the association of overweight with all-cancer mortality, both energy intake and body mass index (BMI) should be controlled as potential confounders, but most studies control for only one of these factors. However, when one of these have been controlled, usually BMI, the significant independent effects of fruit and vegetable intakes remain. One very recent large randomized controlled trial did not show a significant reduction in colorectal adenomas over a 4 year period in older adults (mean age 61 years) with a history of adenomas consuming a low fat diet high in fibre, fruits and vegetables compared to controls; however, the effect of diet on cancer initiation versus cancer prevention has not yet been established.

Given the consistency of the epidemiological and other research on the cancer risk reduction of fruit and vegetables, a health claim stating that **a diet rich in a variety of fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors** is

warranted. It is highly unlikely that non-dietary factors explain this reduction in risk. Although high starch roots and tubers may also provide valuable nutrients, there is insufficient evidence for the claim to be extended to these foods. There is not enough evidence to support a relationship between any one food component and reduced cancer risk.

Appendix E.

Claims Requiring Further Work

Process to Date:
Each claim has been reviewed by 3 external scientists for validity based on current science, except in the case of folate and neural tube defects (NTDs) in which 2 external reviews have been contracted.

Scientific Summaries will be prepared for each claim which bring together all the evidence and will conclude with a science-based recommendation about the claim. Interested parties will have an opportunity to review the Summaries and any recommendations.

The status of these claims is as follows:

Dietary Fat and Cancer

The three external reviewers state that current evidence does not support the claim. Although early case-control evidence supported a relation between total dietary fat intake and cancer risk, cohort studies did not and most still do not support an association, nor do recent case control studies. Based on the consensus of the external reviewers, this claim will not be put forward for adoption.

Fibre-containing Grain Products, Fruits and Vegetables and Cancer

Preliminary results:

Evidence supports the fruits and vegetables and cancer risk reduction claim. To date, the external reviewers agree that the 'fibre-containing' aspect of the claim is misleading, and two of the three recommend a claim referring to 'a diet rich in whole grain products, fruits and vegetables'. The third considers that the evidence for the fibre aspect of the claim is inconsistent and weak.

Next steps:

Health Canada is reviewing the evidence since 1996 for the whole grain products and cancer risk. Health Canada will prepare a Scientific Summary by the end of September 2000 which will form the basis of a recommendation to support or reject a claim for whole grains and cancer.

Fruits, Vegetables and Grain Products that contain Fibre, particularly Soluble Fibre and the Risk of Coronary Heart Disease

Preliminary results:

The three external reviewers provide evidence that supports the consumption of whole grains, fresh fruits and vegetables and CHD risk reduction. There is not consistent support for a specific reference to soluble fibre.

Next steps:

Health Canada will prepare a Scientific Summary by Fall, 2000, based on the above reviews and the original research papers pertaining to the claim, to reach a final resolution and recommendation on the claim.

Folate and Neural Tube Defects

Preliminary results:

One external review is completed, and a second one is underway. This claim is not consistent with current Health Canada recommendations on the prevention of NTDs. Current advice is that women who may become pregnant need to consume a multi-vitamin and mineral supplement containing 400 µg folic acid. Hence the science review must take into account the relative effectiveness of the interventions.

Next steps:

When the second review is completed, Health Canada will prepare a Scientific Summary based on the above reviews and any other relevant data to resolve the issue and make a recommendation on the claim by Fall, 2000.

Soluble Fibre from Certain Foods (Oats/Psyllium) and Risk of Coronary Heart Disease

Preliminary results:

Two of the three external reviewers state that the evidence does not support the claim, and all agree that the soluble fibre terminology is too non-specific. The Policy Paper, *Nutraceuticals/Functional Foods and Health Claims on Foods* accepted two types of risk reduction claims: generic and product-specific. Evidence linking soluble fibre with a reduced risk of coronary heart disease is based on studies using specific sources of fibre. The efficacy of fibres may be influenced by processing and the food matrix.

Next steps:

More work is required to determine the direction this claim should take.