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Summary of Health Canada's Assessment of a Health Claim about the Replacement of Saturated Fat with Mono- and Polyunsaturated Fat and Blood Cholesterol Lowering

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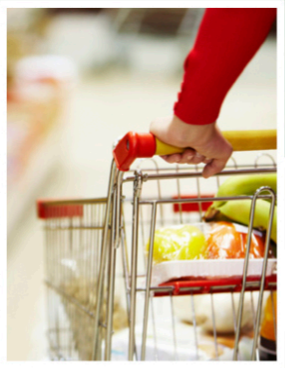
Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch



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Background

In January 2009, Health Canada's Food Directorate received a submission from industry requesting approval for the use of a disease risk reduction claim on vegetable oils and on foods containing vegetable oils. This claim would stipulate a linkage between the replacement of saturated fatty acids with unsaturated fatty acids and a reduced risk of heart disease by lowering blood cholesterol levels. The information below is a summary of the review that was conducted based on Health Canada's *Interim Guidance Document, Preparing a Submission for Foods with Health Claims* (IGD).

Health Canada has recently reconsidered the classification of food products with disease risk reduction claims or therapeutic claims in light of clarified principles for the classification of foods at the Food-Natural Health Product interface. The current position of Health Canada is that when food products are marketed for a disease risk reduction or therapeutic benefit which comes as a result of the food's normal use as part of the diet, these products may be classified and regulated as foods. In other words, the use of a disease risk reduction claim or a therapeutic claim would not be sufficient in itself to classify the product as a natural health product.

Scientific Evidence Supporting the Claim

In 2002, the Institute of Medicine (IOM) released the 'Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids' which included evidence from both observational and clinical studies. The report brief indicated that "monounsaturated and polyunsaturated fatty acids reduce blood cholesterol concentration and help lower the risk of heart disease when they replace saturated fatty acids in the diet". Health Canada decided to accept, as the evidence base, an update of the literature from the time of the 2002 IOM report. The petitioner provided an updated literature review (2000-12-01 to 2008-02-01) to confirm that the findings of the IOM report are still current. The petitioner's literature review was further updated by Health Canada and 17 relevant clinical studies[1] (23 relevant trial arms) were identified.

The studies included normocholesterolemic and hypercholesterolemic men and women free of chronic diseases and ranging from 10 to 75 years old. Treatment duration ranged from 2.5 weeks to almost 13 weeks, and the quantity of saturated fat that was replaced with unsaturated fat ranged from about 2% to 20% of energy.

The direction of effect (without taking statistical significance into account) was highly consistent towards a reduction for total cholesterol (100%) and LDL-cholesterol (96%) when unsaturated fats replaced part of the saturated fats in the diet. In addition, a high proportion (82% and 83% respectively) of trial arms showed a statistically significant reduction in total and LDL-cholesterol levels when a portion of the saturated fats in the diet was replaced with unsaturated

[1] References are listed at the end of this document.

fats. The magnitude of the cholesterol-lowering effect in the relevant studies was variable. LDL-cholesterol reduction ranged from approximately 0.4% to 2.8% for every gram of fat that was replaced.

Whether monounsaturated, polyunsaturated or combinations of monounsaturated and polyunsaturated fats were used to replace saturated fats did not seem to impact on the beneficial effect observed on blood cholesterol. A statistically significant reduction in LDL-cholesterol was observed for 6 out of 7 trial arms (86%) using mainly monounsaturated fatty acids to replace saturated fatty acids, for 8 out of 11 trial arms (73%) using mainly polyunsaturated fatty acids and for all 5 trial arms using monounsaturated and polyunsaturated fatty acids almost equally to replace saturated fatty acids.

Total cholesterol and LDL-cholesterol were the endpoints measured in the reviewed studies. These are recognized risk factors or biomarkers for heart disease. There is evidence that the replacement of saturated fats with polyunsaturated fats results in a reduction of the risk of coronary heart disease[2,3]; however, monounsaturated fat intake was not associated with coronary heart disease risk in a pooled analysis of 11 cohort studies conducted by Jakobsen *et al*.[2]

Health Canada's Conclusions

Health Canada has concluded that the results of the updated literature review are consistent with the results of the 2002 IOM report on the replacement of saturated fat with unsaturated fat and blood cholesterol lowering, in other words, scientific evidence exists in support of the therapeutic claim linking the replacement of saturated fat with unsaturated fat to a reduction of blood cholesterol. The claim is relevant and generally applicable to the Canadian population given that a high proportion of the population (approximately 44%)[4] is hyperlipidemic. Based on the scientific evidence available, feedback from the petitioner and consideration of decisions made in other jurisdictions, it is Health Canada's opinion that the therapeutic claim statements set out below are substantiated in relation to vegetable oils and foods containing vegetable oils when specific conditions for the food carrying the claim are met.

[2] Jakobsen *et al*. 2009. Major types of dietary fat and risk of coronary heart disease: a pooled analysis of 11 cohort studies. Am. J. Clin. Nutr. 89:1425-32.
[3] Mozaffarian *et al*. 2010. Effects on Coronary Heart Disease of Increasing Polyunsaturated Fat in Place of Saturated Fat: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. PLoS Med. 7(3):e1000252.
[4] MacLean *et al.* 1999. Plasma lipids and lipoprotein reference values and the prevalence of dyslipoproteinemia in Canadian adults. Can. J. Cardiol. 15(4):434-444.

Health Claim

The following statements may be made in the labelling and advertising[5] of food products meeting the qualifying criteria.

Primary statement[6]:

> **"Replacing saturated fats with polyunsaturated and monounsaturated fats (from vegetable oils) helps lower/reduce cholesterol. [Statement that the food is reduced or lower in saturated fat as defined in items 20 and 21, respectively, in the table following section B.01.513 of the *Food and Drug Regulations*][7] (and is a source of omega-3/omega-6 polyunsaturated fat)"**

For example[8]:

If the food is a vegetable oil:

> **"Replacing saturated fats with polyunsaturated and monounsaturated fats from vegetable oils helps lower cholesterol. 2 teaspoons (10 mL) of this blend of corn and canola oil contains 84% less saturated fat than 2 teaspoons (10 g) of butter"**

If the food is made with a vegetable oil or a blend of vegetable oils:

> **"Replacing saturated fats with polyunsaturated and monounsaturated fats from vegetable oils helps lower cholesterol. This blueberry muffin (55 g) is made with canola oil, contains 25% less saturated fat than our regular blueberry muffin (60 g) and is a source of omega-3 polyunsaturated fat"**

The following additional statement could be used in letters up to the same size and prominence as those of the primary statement:

> **"High cholesterol is a risk factor for heart disease"**

Conditions for Foods to Carry the Claim

The following qualifying criteria apply to all food products carrying the above-mentioned health claim.

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[5] The information in this document complements the guidance on using health claims on food labels and in advertising in the Guide to Food Labelling and Advertising available on the Canadian Food Inspection website. It is the responsibility of all manufacturers and importers to ensure that their products comply with all relevant Canadian legislation.

[6] ( ) = optional; [ ] = mandatory; / = or

[7] If the food is made with vegetable oil(s), the name of the food should include the name(s) of the vegetable oil(s) containing >80% polyunsaturated and monounsaturated fat that it is (primarily) made with.

[8] Foods and values used in examples are for illustration purposes only. They do not necessarily reflect acceptable health claims.

Conditions specific to the health claim

(a) The food does not meet the conditions for "low in fat" (Item 12 in the table following section B.01.513 of the *Food and Drug Regulations*);
(b) The food is a vegetable oil containing >80% polyunsaturated and monounsaturated fat or a food product containing >80% of total fat as polyunsaturated and monounsaturated fat from a vegetable source. For the purpose of this claim, polyunsaturated and monounsaturated fats are as defined in section B.01.001 of the *Food and Drug Regulations*, but excluding long chain omega-3 polyunsaturated fatty acids such as omega-3 polyunsaturated fatty acids found in fish oils (eicosapentaenoic acid or EPA, and docosahexaenoic acid or DHA);
(c) The food meets the conditions for "reduced in saturated fatty acids" or "lower in saturated fatty acids" (Items 20 and 21, respectively, in the table following section B.01.513 of the *Food and Drug Regulations*);
(d) The composition of the food does not promote higher fat or energy intake than the composition of the similar reference food or reference food of the same food group[9];
(e) The similar reference food or reference food of the same food group does not contain >80% of total fat as polyunsaturated and monounsaturated fat from a vegetable source.

For consistency with nutrient content claims in the table following B.01.513

(f) The food meets the conditions for "source of omega-3 polyunsaturated fatty acids" (Item 25 in the table following section B.01.513 of the Food and Drug Regulations) if the statement "source of omega-3 polyunsaturated fat" is used.
(g) The food meets the conditions for "source of omega-6 polyunsaturated fatty acids" (Item 26 in the table following section B.01.513 of the Food and Drug Regulations) if the statement "source of omega-6 polyunsaturated fat" is used.

For consistency with previously approved health claims about heart disease or cholesterol lowering and to create an acceptable food profile for foods carrying a health claim about heart disease or cholesterol lowering

(h) The food contains 2 g or less of saturated fatty acids and *trans* fatty acids combined[10]
    (i) per reference amount and serving of stated size, or
    (ii) per 100 g, if the food is a prepackaged meal;
(i) The food contains 100 mg or less of cholesterol per 100 g of food;

[9] An increase of less than 25% of fat or energy (to a maximum of 40 calories) would be tolerated
    (i) per reference amount of the food, than the reference amount of the similar reference food or reference food of the same food group; or
    (ii) per 100 g, than 100 g of the similar reference food or reference food of the same food group, if the food is a prepackaged meal.

[10] Condition (h) is similar to the "low in saturated fatty acids" condition in Item 19 of the table following section B.01.513 of the *Food and Drug Regulations*, except that the condition that "the food provides 15% or less energy from the sum of saturated fatty acids and trans fatty acids" is not included because it has been replaced by condition (b) which is more specific to this claim.

(j) The food contains
  (i) 480 mg or less of sodium per reference amount and per serving of stated size, and per 50 g if the reference amount is 30 g or 30 mL or less, or
  (ii) 960 mg or less of sodium per serving of stated size, if the food is a prepackaged meal;

To create an acceptable food profile for foods carrying a health claim about heart disease or cholesterol lowering

(k) The food contains less than 0.2 g of *trans* fatty acids[11]
  (i) per reference amount and serving of stated size, or
  (ii) per serving of stated size, if the food is a prepackaged meal;

For consistency with previously approved health claims and to promote overall better food choices by creating an acceptable food profile

(l) The food, other than a vegetable oil, contains at least 10% weighted recommended nutrient intake (WRNI) of a vitamin or mineral nutrient
  (i) per reference amount and per serving of stated size, or
  (ii) per serving of stated size, if the food is a prepackaged meal;
(m) The food contains 0.5% or less alcohol;

Conditions for the Label and Advertisement

1) If the statement or claim is made on the label of or in the advertisement for a prepackaged product, by or on the direction of the manufacturer of the product, the Nutrition Facts table shall include the amount of monounsaturated and polyunsaturated fats, as well as omega-3 and omega-6 polyunsaturated fatty acids in accordance with subsection B.01.402(2)
2) If the statement or claim is made on the label of or in the advertisement for a food that is not a prepackaged product, or in the advertisement for a prepackaged product that is not made or placed by or on the direction of the manufacturer of the product, the label or advertisement shall include the amount of monounsaturated and polyunsaturated fats, as well as omega-3 and omega-6 polyunsaturated fatty acids per serving of stated size, in accordance with section B.01.602 if applicable.

Health Canada will propose regulatory amendments to consolidate the conditions for the use of the above stated health claims and to confirm that foods which are subject of such claims are not governed by the provisions of the *Food and Drugs Act* with respect to drugs, nor do they contravene subsections 3(1) and (2) of the Act.

[11] Condition (k) is similar to the "free of trans fatty acids" condition in Item 22 of the table following section B.01.513 of the *Food and Drug Regulations*, except that the condition that the food meet the conditions for "low in saturated fatty acids" is not included for the reasons mentioned above (see previous footnote).

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