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Summary of Health Canada's Assessment of a Health Claim about Vegetables and Fruit and Heart Disease

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Bureau of Nutritional Sciences
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Health Products and Food Branch



Canada 

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Background

In 1993, a health claim about vegetables and fruit and heart disease was accepted by the U.S. Food and Drug Administration.¹ In 2006, Health Canada posted its [Position Paper on Five U.S. Health Claims for Use in Canada](#) (Position Paper) for online consultation. This paper included a proposal for a claim about vegetables and fruit and the risk of heart disease in Canada. Stakeholders from all sectors generally supported the decision to accept the claim. Certain stakeholders questioned the eligibility of juices to use the claim, citing a lack of evidence for heart disease risk reduction.

On June 13 2015, Health Canada published proposed regulatory amendments in *Canada Gazette*, Part I.² Although there was general support among stakeholders for the proposed regulations allowing a new health claim for vegetables and fruit and the reduced risk of heart disease, some questioned why certain foods were excluded from eligibility to carry the claim. In response to these comments, Health Canada has made some adjustments to the conditions for foods to carry the claim.

Scientific Evidence Supporting the Claim

The Position Paper proposal was based on the U.S. Food and Drug Administration decision and an assessment of the scientific evidence published since the U.S. claim was accepted through to the year 2000. Four of 8 controlled trials selected for inclusion reported positive effects on blood lipids. Two of the four positive trials included participants with elevated lipids and/or blood pressure. Ten of 13 prospective cohort studies selected for inclusion supported an effect of vegetables and fruit on coronary heart disease (CHD) risk reduction. In the largest and best-controlled study, CHD mortality reductions ranged from 15 to 37%, with a 20% reduction in risk reported for individuals consuming more than 8 servings per day compared with those consuming less than 3 servings per day (Joshipura et al, 2001).

In 2011, Health Canada assessed 3 systematic reviews published since 2000 to ensure that the scientific evidence still supported the claim. Dauchet et al (2006) found that the risk of CHD was decreased by 4% [RR (95% CI): 0.96 (0.93–0.99), P=0.0027] for each additional portion per day of vegetables and fruit. He et al (2007) found that risk of CHD was decreased by 17% [0.83 (0.77-0.89), P<0.0001] for individuals with more than 5 servings per day compared with those who had less than 3 servings per day. Mente et al (2009) concluded that there is strong evidence for a causal association between vegetables and CHD risk reduction and moderate evidence for a causal association between fruits and CHD risk reduction.

Legumes and potatoes (and other starchy roots and tubers such as yams, cassava and plantain) were generally not included in the estimate of vegetables and fruit intake. In addition, potatoes

¹Food and Drug Administration, Department of Health and Human Services. Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease. 58 FR 2578 (Jan. 6, 1993).

²Government of Canada. Canada Gazette Part I. [Accessed on: 2015 Jun 2]. Available from: <http://www.gazette.gc.ca/archives/part1-archives-partiel-eng.html>.

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are commonly consumed in large amounts relative to other vegetables and they were not associated with CHD risk reduction when looked at separately (Joshi et al, 2001).

Condiments, preserves and powders made with vegetables or fruit were also generally not included as vegetables and fruits. Likewise, coconut, cashew, almond, pistachio, walnut and pecan, which botanically are fruits or seeds of fruits, would not have been included in the estimate of fruit intake.

Corn is no longer in the list of foods ineligible to carry the claim. Although it is botanically a grain, it is often considered a vegetable, including in [Canada's Food Guide](#). In addition, corn was included in the vegetable intake estimate of some important studies (including the Nurses' Health Study and the Health Professionals Follow-up Study) and there was no mention of corn being specifically excluded in other studies.³

Health Canada also assessed the evidence to see whether there was support for juice and CHD risk reduction. Three of the 8 controlled trials specifically tested the effects of fruit juice on CHD biomarkers. Two of the 3 reported no effect; the third found that 4 weeks of 6 servings per day of orange juice, but not at lower servings per day (i.e., 2 or 4), improved high-density lipoprotein (HDL) cholesterol levels as well as the ratio of HDL to low-density lipoprotein (LDL) cholesterol in individuals with hypercholesterolemia (Kurowska et al, 2000). This amount of juice is not consistent with the pattern for healthy eating recommended in [Canada's Food Guide](#).

Juices were included in the estimate of vegetables and fruit intake in several prospective cohort studies, with various results, however, there are concerns with the consumption of juices instead of vegetables and fruit, especially regarding the sugar content of fruit juices. Fruit juices are high in free sugars, which are generally recognized as a nutrient to limit.⁴ Vegetable juices and drinks are no longer in the list of foods ineligible to carry the claim, since their sugars content is much lower than fruit juices.

³Popcorn, which is also a grain, would not be eligible to carry the claim as it is not usually considered a vegetable.

⁴World Health Organization. 2015. Guideline: Sugars intake for adults and children. [Accessed on: 2016 February 15]. Available from: http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/

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Health Canada's Conclusion

Health Canada has concluded that sufficient scientific evidence exists to support a health claim about vegetables and fruit consumption and a reduced risk of heart disease. The claim is relevant and generally applicable to the Canadian population. Heart disease is a major public health concern in Canada. In 2011, heart disease was the second leading cause of death in Canada, accounting for 20% of all deaths.⁵

Health Claim

Section 3 of the *Food and Drugs Act* prohibits the labelling and advertising of products that refer to the treatment, prevention or cure of conditions listed in Schedule A, including arteriosclerosis, to the general public. Since CHD, the most common type of heart disease, is often used as a synonym for arteriosclerosis,⁶ claims about heart disease are prohibited until a regulatory amendment is made that permits qualifying foods to carry a heart disease related claim.

Health Canada published final regulatory amendments in *Canada Gazette*, Part II on December 14, 2016, that allows for the following health claim related to heart disease to be made on qualifying vegetables and fruit sold on the Canadian marketplace:

A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of heart disease.⁷

Conditions for Foods to Carry the Claim

The following are the qualifying criteria for foods to use the health claim:⁷

The food:

- (a) is one of the following vegetables or fruits and may contain only food additives that are subject to section 2 of a marketing authorization, salt, herbs, spices, seasonings, water:
 - (i) a fresh, frozen, canned or dried vegetable,
 - (ii) a fresh, frozen, canned or dried fruit,
 - (iii) a vegetable juice or vegetable drink, or
 - (iv) a combination of the foods set out in any of subparagraphs (i) to (iii);

⁵Statistics Canada. The 10 leading causes of death, 2011. [Accessed on: 2015 May 11]. Available from: <http://www.statcan.gc.ca/pub/82-625-x/2014001/article/11896-eng.htm>.

⁶Health Canada. Guidance Document: Schedule A and Section 3 to the Food and Drugs Act. [Accessed on: 2015 May 11]. Available from: http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/guide-ld/scha_guide_ld-eng.php

⁷The final wording and conditions for claims that are subject to regulatory amendments are provided in the table following section B.01.603 in the [Food and Drug Regulations](#).

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- (b) is not one of or does not contain any of the following:
 - (i) potatoes, yams, cassava, plantain, mature legumes and their juices,
 - (ii) vegetables or fruit used as condiments, garnishes or flavourings, including maraschino cherries, glacé fruit, candied fruit and onion flakes,
 - (iii) jams or jam-type spreads, marmalades, preserves and jellies,
 - (iv) olives,
 - (v) a fruit juice or fruit drink,
 - (vi) powdered vegetables or fruit, or
 - (vii) the seed of a fruit known as a drupe, including almonds, cashews and coconuts;
- (c) contains 0.5% or less alcohol; and
- (d) contains less than 15% of the Daily Value 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.

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