

## **Summary of Research Supporting a Qualified Health Claim for Canola Oil**

The U.S. Canola Association (USCA) filed a petition for a qualified health claim (QHC) for canola oil and reduced risk of coronary heart disease on Jan. 9, 2006 with the U.S. Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition. The petition was authorized by the agency on Oct. 6, 2006. Manufacturers of canola oil and qualified canola oil-containing products can now use the following QHC on their labels and advertising materials:

*Limited and not conclusive scientific evidence suggests that eating about 1½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of canola oil.*

In order to receive FDA authorization, the USCA's petition showed that 1) the totality of credible scientific information to date supports the above QHC; 2) there was strong regulatory precedent for it, including the QHC the agency authorized for olive oil; 3) the canola oil QHC met the criteria FDA uses to authorize such petitions; and 4) it falls in line with public recommendations from governmental and professional organizations.

### **Scientific Basis**

The weight of the available scientific evidence shows that canola oil has favorable effects on blood fats by lowering total and/or LDL ("bad") cholesterol when substituted for dietary saturated fat. The 21 studies discussed in the USCA's petition compared canola oil-containing diets with those higher in saturated fat and were given FDA quality ratings and levels of support for the QHC. Seven of the nine highest quality studies provided strong support for the claim and 11 of 12 lower quality studies provided suggestive support.

Only three studies failed to show that canola oil lowers total and/or LDL cholesterol when substituted for saturated fat. Two of these studies fed subjects relatively small amounts of canola oil, so that differences between the control and experimental diets with respect to saturated and unsaturated fats may not have been sufficient to elicit a significant response. The third study used subjects who were not representative of the general population.

In conclusion, the published intervention studies provide consistent, credible evidence that unsaturated fat from canola oil lowers total and/or LDL cholesterol in healthy human subjects compared to diets higher in saturated fats. In addition, these studies show that dietary unsaturated fat from canola oil are as good as or better in this regard than diets containing olive oil.

### **Diet Modeling**

Substitution of canola oil for fats commonly used in the United States would increase compliance with dietary recommendations, according to a modeling study that was conducted for the USCA's QHC petition. This statistical study, conducted in October 2005, examined the effect of substituting canola oil for selected vegetable oils and canola oil-based margarine for other margarines and butter in the diet of adult Americans.

Food recall data from the 1999-2002 National Health and Nutrition Examination Survey (NHANES) were used to calculate the effect of substituting canola oil for corn, cottonseed, safflower, soybean and vegetable oils described as "not further specified" and of canola oil-based margarine for other margarines and butter in the diet at 25%, 50% and 100% replacement levels. The study was based on NHANES data from nearly 9,000 adults over 20 years of age.

Results showed that saturated fat intake would decrease by 4.7% and 9.4% with 50% and 100% substitution, respectively. Complete substitution would increase monounsaturated fatty acid (MUFA) and alpha-linolenic acid (ALA, an omega-3) intakes by 27.6% and 73.0%, respectively. Intakes of energy, total fat and cholesterol would not change significantly.

The amount of trans fat reduced by the replacement of canola oil for other sources of fat in the diet could not be determined because the USDA database has incomplete information on trans fat. In addition, reformulation by food makers in anticipation of mandatory trans fat labeling that occurred in January 2006 made it difficult to assign trans fat levels to various food products. The modeling did not replace hydrogenated fats with canola oil. It only replaced soybean and other oils if they were used as oils, not as shortenings in cakes, cookies, pies, etc.

Overall findings were that canola oil, when consumed in place of other sources of fat in the diet, including butter, margarine and other vegetable oils, would significantly reduce saturated fat intake and increase intake of MUFAs and ALA for consumers eating average and higher amounts of total fat. This change would increase compliance with dietary recommendations (i.e., Dietary Guidelines for Americans 2005 and Institute of Medicine, Dietary Reference Intakes) for saturated fat, MUFAs and ALA among U.S. adults. Such dietary changes have the potential to positively impact public health.