

# The Need for a Minimum Healthy Fat Intake



## Canola Oil: A Golden Opportunity for the Nation's Health August 12, 2004

### **EXECUTIVE SUMMARY**

Congress enacted protection for consumers as part of the Nutrition Labeling and Education Act of 1990 (NLEA) that required the U.S. Food and Drug Administration (FDA) to mandate disclosures by manufacturers about the nutritional value of purchased foods. The mandatory disclosures include specific statements about the amount of each essential or well-established nutrient in each serving size of an offered product in a Nutrition Facts part of the label. Thus, there is mandatory disclosure of the exact amount and percentage in relationship to a daily diet of each healthy or required nutrient with the solitary exception of *cis*-polyunsaturated fat.<sup>a</sup> Alternatively, if the food product does not contain a required nutrient, there must be a specific disclosure of that absence. The required information on a food label also includes mandatory disclosures about the presence, in a purchased food, of substances generally viewed as unhealthy when consumed in excess amounts, such as saturated fat, cholesterol, sodium, and recently, *trans*-unsaturated fat. In sum, the consumer reading the Nutrition Facts panel is entitled to know the amount per serving and percent Daily Value of each essential or beneficial nutrient and also each potentially unhealthy substance in a food product.

However, in implementing this mandate, FDA made one omission. There is no required disclosure about healthy or essential fatty acids in the Nutrition Facts panel. All current declarations about the amount or percentage of minimum daily needs of *cis*-unsaturated fat are voluntary. Thus, the consumer is deprived of important nutritional information mandated by the NLEA: the amount of healthy *cis*-unsaturated fat and the percentage of this fat as a part of known daily needs or, as with other essential nutrients, a specific declaration that the product is not a significant source of this essential nutrient. *Cis*-polyunsaturated fatty acids (PUFAs) are essential nutrients for all humans. This omission is striking and should be corrected. We suspect that at the time of the initial promulgation of the regulations, a contingent within the nutrition community contended that the healthiest fat consumption was the lowest possible and mistakenly applied this thinking to all fats, including essential fats, possibly based on the generally high fat consumption in the American diet. We now know this to be

<sup>a</sup> See Section I for chemical classification and terminology applicable to fats.

untrue. First, as recognized by worldwide health authorities and the medical community, healthy fats are an essential and necessary part of the human diet. Maintenance of good health is not possible without the consumption of a diet containing a minimum of the essential fats linoleic acid (LA) and alpha-linolenic acid (ALA). Second, growing evidence also suggests that healthy fat consumption is necessary to reduce obesity or, consequently, that healthy fat consumption may displace unhealthy fat consumption. Recent studies have shown that weight loss diets with substantial amounts of essential *cis*-unsaturated fats and proteins, but reduced levels of carbohydrates, and without imposed caloric restriction, are at least equally effective as intensive caloric restriction in inducing weight loss. These studies suggest that the low fat, high carbohydrate diets implicit in the current nutrition label may not induce satiety without calorie counting and, thus, could contribute to obesity. Third, healthy *cis*-unsaturated fats, whether poly- or monounsaturated, are not associated with risk for heart disease, stroke, cancer, or other medical condition. Indeed, healthy *cis*-unsaturated fats, especially omega-3 fatty acids, may reduce the incidence of acute and chronic heart disease. The declaration and acknowledgement of the necessity of essential fatty acids as a mandatory minimum component in the diet should be a prime consideration in the upcoming revision of federal nutrition guidance and regulations. Fourth, restrictions on the use of health claims for products composed of healthy unsaturated fats, based solely on their unsaturated fatty acid content, should be revised or clarified to reflect the absence of any risk from appropriate necessary amounts of unsaturated fat in the diet.<sup>b</sup> Finally, the absence of recognition of the need for healthy fats in the diet in the Nutrition Facts panel and under other U.S. guidance and regulations should be corrected. The absence of any recommendation about necessary minimum unsaturated fat consumption by FDA stands apart from the recommendations of major international and national public health nutritional guidance, including the National Institutes of Health.

The Nutrition Facts panel is further flawed because the regulations require the manufacturer to misleadingly inform consumers that there is no lower limit of healthy fat content in the diet below which the consumer should not go. In contrast to every other healthy and required nutrient, the consumer is advised that any level of fat consumption below 65 grams in a 2,000- calorie diet is satisfactory. This is simply not true since there is an essential need for certain unsaturated fats in the diet. In contrast, minimum recommendations are set for all other essential nutrients: protein, carbohydrates, dietary fiber, vitamins, and minerals.

The omission of a required declaration for *cis*-unsaturated fats contrasts with other areas of voluntary federal nutrition regulations. For instance, FDA has promulgated a health claim that acknowledges that a diet low in saturated fat and cholesterol may reduce the risk of heart disease. Such a diet, given the essential dietary need for *cis*-unsaturated fats, must of course preferentially include these fats. It must also authorize manufacturers of healthy fats or oils that are sold as meal preparation ingredients to label their product with a statement that when consumed as part of a daily diet, the product may reduce the risk of heart disease and stroke.<sup>c</sup> Nutrition content claims are permitted that

<sup>b</sup> See, e.g., 21 C.F.R. §§ 101.73, 101.75 and discussion, *infra*, section V.

<sup>c</sup> The regulation clearly permits a health claim for the reduced risk of heart disease for prepared foods comprised of healthy fats based on the fact that they use an alternative to saturated and *trans* fats. While the regulation is not clear on its face that the same health claim would necessarily apply to the ingredients themselves, for those making their own baked goods or salad dressings, a common sense application recognizes that oil is never customarily consumed alone and thus, the health claim is available to pure canola oil. See, *infra*, Section VII.

tout the benefits of *cis*-unsaturated fat, an increase in *cis*-unsaturated fat relative to other comparable oils, or the relative absence of saturated fat relative to other oils. The agency has recently promulgated new regulations for *trans*-unsaturated fats that would similarly permit manufacturers of *cis*-unsaturated oils to make comparative nutritional content statements relative to these unhealthy fats. Additionally, as newer research has shown the potential benefits of omega-3 unsaturated fat, the agency has recently permitted statements about this healthy fat. The agency has permitted the touting of potential cardiovascular benefits of consuming oils containing omega-3 fatty acids. Finally, agency action or inaction in response to submitted claims related to structural or functional activities for dietary supplements also permit touting omega-3 fatty acid nutrient content. These permissible claims provide further support for the need to amend mandatory labeling requirements to require disclosure of *cis*-unsaturated fatty acid content in amount per serving and percent Daily Value. In addition, the FDA should clarify the applicability of health claims to healthful fats and oils.

The U.S. Canola Association believes that the time has come for mandatory recognition of the need for healthy fats in the diet and clarification of any voluntary labeling conditions that might restrict consumer information about the healthfulness of dietary unsaturated fatty acids. Canola oil itself serves as a prototype of an ideal healthy oil with its commercial availability, high content of *cis*-PUFAs (ALA and LA), its almost negligible content of saturated fat (7%), especially in contrast to all other commercial oils, and its relatively high content of the omega-3 unsaturated fat ALA (11%). Canola oil is also a good source of vitamins E and K. Among commercially useful oils, canola is nutritionally the best. However, all healthy oils should be recognized by a required disclosure of quality. The declaration of the need for healthy fats on food labels should be mandatory.

## I. ESSENTIAL FATTY ACIDS AND FAT NOMENCLATURE

Chemically, fats are long chains of carbon atoms with an acid moiety at one end and a methyl group or carbon with three hydrogens at the other. Each carbon atom is permissibly bound to four other atoms in a tetrahedral format so that a carbon in the middle of a chain of carbons has two free bonding sites. If the binding sites are each occupied by a hydrogen, the fat is described as fully saturated. If there is only one hydrogen, the other bond attaches to an adjacent carbon forming a double bond. Since tetrahedrons are right or left handed, the second bond can either deform or kink the chain of carbons (*cis* conformation) or straighten the chain (*trans* conformation). *Trans* conformations are preferentially induced when a saturated fat is chemically dehydrogenated. *Cis* conformations are more typical for naturally occurring or enzymatically induced dehydrogenation. A carbon chain can have one, two, or more double bonds within the chain. One double bond is identified as a monounsaturated fat. More than one double bond would be polyunsaturated. Most naturally occurring vegetable origin carbon chains are 16 or 18 carbons long. Twenty- and 22-carbon chains are mostly derived from fish or animals. Finally, the location of the first double bond from the end or methyl group is important. If the first double bond occurs three carbons in, the fat is termed an omega-3 unsaturated fatty acid; if at the sixth, it would be an omega-6. Table 1 illustrates the foregoing nomenclature and provides the common names applied to the respective fats.

Twenty and 22-two carbon *cis*-polyunsaturated oils (EPA, DHA) are essential building blocks for

**Table 1. Fatty Acid Classification**

Carbons (#)	Double Bonds (#)	Location of 1 <sup>st</sup> Double Bond	Common Name	Category	Primary Dietary Sources
16	0	Not applicable	Palmitic	Saturated	Palm oil, animal fat
	1	Not applicable	Palmitoleic	Monounsaturated	Animal fat
18	0	Not applicable	Stearic	Saturated	Animal fat
	1	Omega-9	Oleic	Monounsaturated	Canola, olive oils
		Omega-3	Alpha-Linolenic (ALA)	Polyunsaturated	Canola, flaxseed oils
	2 or more	Omega-6	Linoleic (LA)	Polyunsaturated	Canola, safflower, sunflower, corn, soybean, cottonseed, and other plant oils
		0	Not applicable	Eicosanoic	Saturated
20	2 or more	Omega-3	Eicosapentaenoic (EPA)	Polyunsaturated	Fatty fish, fish oil
		Omega-6	Arachidonic (AA)	Polyunsaturated	Liver
22	2 or more	Omega-3	Docosahexaenoic (DHA)	Polyunsaturated	Fatty fish, fish oil
		Omega-6	Docosapentaenoic (DPA)	Polyunsaturated	Fatty fish, fish oil

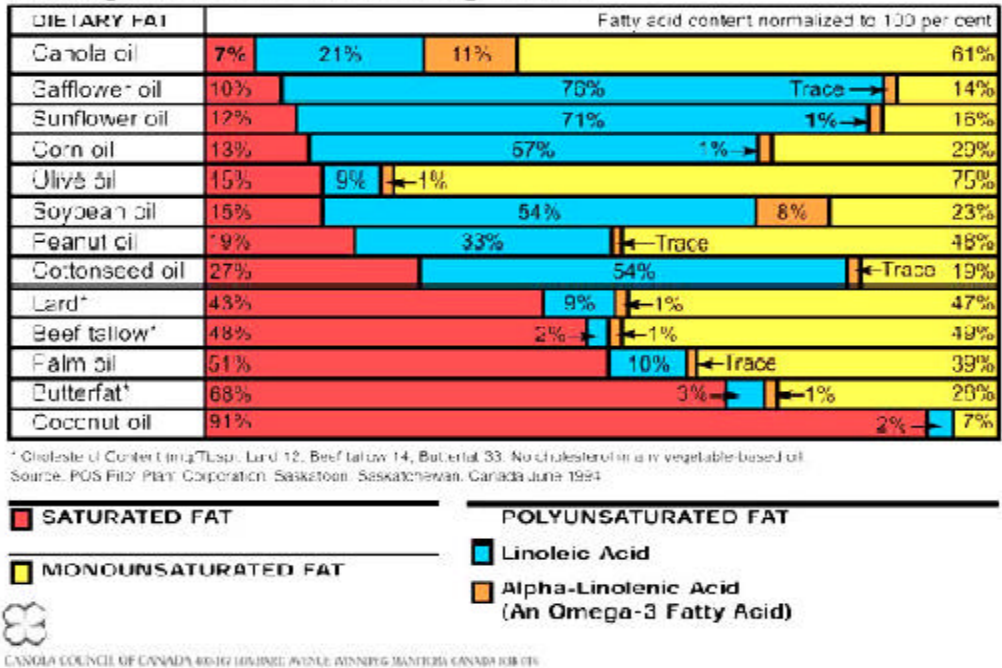
many parts of the human body (cell membranes, muscle) and for many messenger substances (prostaglandins, leukotrienes, thromboxanes) that control blood flow in normal and inflammatory states. The human body is incapable of producing these and other omega-3 and omega-6 fatty acids, so they must be consumed. However, the human liver contains enzymes that can elongate ALA and LA into longer chains, such as EPA and DHA, while leaving the location and number of double bonds unchanged relative to the methyl end. The human body is incapable, however, of producing the original double bonds at the omega-3 and omega-6 position. Thus, ALA and LA have been identified as essential fatty acids because, while ALA and LA can be turned into any greater length omega-3 or omega-6, the longer chain omega-6 and omega-3 cannot be easily shortened for use in manufacturing cell membranes.

## II. CANOLA OIL

Canola oil represents one of the most healthful oils available. Canola's nutrient content profile, as compared to other common commercial oils, is presented in Figure 1. Canola oil is high in *cis*-PUFAs (32%), including ALA (11%) and LA (21%). Canola oil contains the most omega-3 fatty acids of any vegetable oil with its ALA content. Canola oil also contains vitamin E with one tablespoon having 2.39 mg of alpha tocopherol or 15% of the recommended dietary allowance. It is low in saturated fat and *trans*-unsaturated fatty acids (6-7%). It is high in *cis*-monounsaturated fat (61%). The dietary intake of an oil like canola oil with its healthy and essential fats, especially ALA and LA, should be a necessary component of any recommended diet that will reduce the risk of cardiovascular disease, heart attack, and stroke. Canola oil also has important commercial benefits since it is relatively resistant to breakdown when heated, has a negligible taste (as compared to other healthy oils such as fish oil), has a high smoke point, and remains fluid at refrigeration temperatures. Canola oil, as any oil with a comparable healthful profile, has the characteristics of an oil that should be recommended by public health authorities for use in baking, stir-frying, deep-frying, and in salad dressings, either primarily or as a replacement for *trans*-unsaturated and saturated fats.

**Figure 1. Fatty Acid Comparison of Food Oils**

**Comparison of Dietary Fats**



**III. RECOMMENDED HEALTHY FAT INTAKE BY PUBLIC HEALTH AUTHORITIES**

International consensus has been reached, with the glaring absence of FDA and the U.S. Department of Health and Human Services (DHHS), on the need to advise consumers about the need for consumption of healthy fat. The World Health Organization recommends that PUFAs represent 6% to 10% of the daily diet.<sup>1</sup> An international workshop on fatty acids composed of nutrition experts recommended that ALA and LA, two components of canola oil, be consumed at no less than 6.5 grams/day for a person having a 2,000 kcal diet.<sup>2</sup> In contrast, the U.S. FDA has no recommendation for minimum PUFA consumption and, contradictorily, recommends that all fats, including saturated fats, be consumed at any amount less than 65 grams/day for a person having a 2,000 kcal diet with no set minimum.<sup>3</sup> The absence of a minimum healthy unsaturated fat intake in the Nutrition Facts panel is confusing, misleading, and wrong.

International health authorities follow more generally accepted recommendations. The National Heart Foundation of Australia recommends that healthy persons consume a minimum of 2 grams/day of plant oils containing ALA with specific mention of canola oil as such an oil.<sup>4</sup> Health and Welfare of Canada recommends that adults consume at least 1.6 grams/day of unsaturated fatty acids containing ALA or other omega-3 fatty acids.<sup>5</sup> The Nordic Council of Ministers recommends that healthful fats compose a minimum of 3.5% of the diet.<sup>6</sup> The British Nutrition Foundation sets a minimum dietary allowance for healthful fats at 1.2% including 1.25 gram/day of PUFAs.<sup>7</sup> Similar recommendations are made by the Health Council of the Netherlands.<sup>8</sup>

Public health organizations in the United States, including other governmental components within DHHS other than FDA, also support daily minimum necessary intake recommendations related to

unsaturated fat content in the diet. The Institute of Medicine recommends that ALA and LA be consumed at no less than 1.6 gram/day and 14 grams/day, respectively, for men and 1.1 grams/day and 11 grams/day for women and that PUFAs in total should represent approximately 11% of total energy intake or 24 grams/day for a 2,000 kcal diet.<sup>9</sup> The National Heart Lung and Blood Institute Cholesterol Education Program supports the American Heart Association (AHA) recommendations for higher dietary intakes of polyunsaturated fatty acids.<sup>10</sup> The AHA itself recommends a minimum consumption of 1-4 grams/day of PUFAs.<sup>11, 12</sup>

With these minimum intake recommendations for a healthful diet and reduced risk of coronary artery disease, it is unconscionable to have no mandatory labeling for *cis*-unsaturated fatty acid content and no required statement of minimum needs. Instead, U.S. consumers are mistakenly advised on the label that there is no lower limit fat consumption below which one should not go. The “no fat is a good diet” message on the U.S. nutrition label is not good health advice.

Finally, while public health authorities recommend consumption of more LA than ALA, ALA is harder to get in the diet since omega-3 PUFAs are found in fewer food sources. This fact makes canola oil’s rich content of ALA particularly important to health-conscious consumers.

#### **IV. CONSUMER INFORMATION ABOUT DIET AND HEALTH**

Current U.S. nutrition labeling requirements, as embodied in the mandatory Nutrition Facts panel and related regulations, mandate disclosures with regard to almost all essential nutrients with the exception of *cis*-unsaturated fats. These regulations require that the specific amount per serving and percent Daily Value of each essential nutrient be declared or a statement that the food item is devoid of the nutrient. The principle for essential nutrients is to provide consumers with exact information on the impact of a food item on their daily needs for all essential nutrients and potential harmful ingredients. There is no parallel requirement for essential unsaturated fat in the diet. It is the only essential nutrient for which such a declaration is not required.

For vitamins and minerals, the requirement for complete disclosure in terms of recommended daily intake is provided at 21 C.F.R. § 101.9(c)(8)(iv). If the food item is devoid of a particular vitamin or mineral, the label must bear the warning that the product is either “not a significant source” of the nutrient or that it “contains less than 2% of the Daily Value” of the nutrient. *See* 21 C.F.R. § 101.9(c)(8)(iii).

For protein, a minimum daily need of 50 grams is set at 21 C.F.R. § 101.9(c)(7)(iii). There is a corresponding requirement to declare the amount per serving for every labeled food item in grams and as a percent of 50 grams unless the food item contains less than 1 gram. In that case, there is a requirement to declare that the product “contains less than 1 gram” or to state the content as zero or, finally, provide a warning that the food is “not a significant source of protein.” *See* 21 C.F.R. § 101.9(c)(7)(i). There are similar requirements for fiber at 21 C.F.R. § 101.9(c)(6)(i); for sugar at C.F.R. § 101.9(c)(6)(ii); for cholesterol at C.F.R. § 101.9(c)(3); for calories from fat at C.F.R. § 101.9(c)(1)(ii); and, finally, for saturated fat at C.F.R. § 101.9(c)(2)(i). From Jan. 1, 2006, labeling of the content of *trans* unsaturated fat is also required.

These regulations are, therefore, at odds with both international and national public health recommendations due to lack of PUFA content disclosure and minimum intake recommendations. Arguably, the regulations are even internally inconsistent because of the permissible touting of the health benefits of food products that contain PUFAs.

## V. FDA SYSTEM FOR MAKING FOOD HEALTH CLAIMS

FDA and the Federal Trade Commission (FTC) share authority to regulate the health information that marketers may or must communicate about foods on their labels and in advertising. FDA regulates the claims that may appear on food labels and labeling. The FTC has authority over the information disseminated in advertising. In most instances, a food product claim will satisfy FTC requirements if it meets applicable FDA requirements. The mandatory components of the nutrition declaration have been reviewed in Part IV. These requirements lack any mandatory information for consumers about the amount or percent Daily Value for essential fatty acids (*i.e.*, ALA and LA) in foods they consume.

FDA provides for four general categories of voluntary claims that may appear on food labels and labeling: health claims, nutrient content claims, dietary guidance, and structure/function claims.

### A. HEALTH CLAIMS

Health claims describe a relationship between a food (food component or dietary supplement ingredient) and a human disease or health condition. In general, any statement that a product is intended to act in a certain manner with regard to a disease automatically classifies the product as a drug under the Federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. § 321(g). However, as a part of the NLEA, Congress exempted from drug classification foods with authorized health claims if limited to a declaration that they may “reduce the risk” of a disease or health-related condition. A health claim has three essential components: (1) a subject or food substance (whether a food, food component, or dietary ingredient); (2) a verb or statement of relationship, as in “reduce the risk of”; and, (3) an object or disease or health-related condition. Under this law and subsequent court interpretations, there are now three ways by which FDA may oversee voluntary health claims that may be used on a food label or labeling:

- The 1990 NLEA expressly enables FDA to issue regulations, under notice-and-comment rule-making authorizing health claims for foods and dietary supplements after FDA’s detailed review of scientific evidence submitted in a health claim petition;<sup>13</sup>
- The 1997 FDA Modernization Act provides that individuals may make health claims for their products if they are based on an authoritative statement by a scientific body. Two types of common statements about health and food are not subject to an FDA review process. FDA deems statements addressing dietary patterns or general categories of foods (e.g., fruits and vegetables) and health to be *dietary guidance* rather than health claims. Dietary guidance statements used on food labels must be

truthful and not misleading, but unlike the three categories of health claims discussed above, do not require submission or notification to FDA.

The second category of claims outside the FDA submission and authorization process is a claim about the effect of the food on the normal function or structure of the human body or so-called “structure/function” claims.<sup>e</sup> These claims are statements that a specific substance maintains normal healthy structures or functions of the body (e.g., “calcium builds strong bones”). Structure/function claims may not explicitly or implicitly link the substance to a disease or health-related condition or to disease prevention or cure. For foods, as opposed to dietary supplements, the agency suggests in non-binding guidance that the structure/function claim should be based upon a nutritive element within the food (e.g., ALA or vitamin E content). Stated differently, a structure/function claim is one that relates a component of the food to a normal metabolic activity of the human body, such as a statement that sugar provides fuel for cellular activity.

## C. NUTRIENT CONTENT CLAIMS

### a. General

The NLEA also permits use of authorized “nutrient content claims,” which characterize the level of a nutrient in a food. A nutrient content claim must be made in accordance with FDA’s authorizing regulations. Nutrient content claims can describe the level of a nutrient or dietary substance in the food quantitatively or by using terms relative to an absolute such as *free*, *high*, *low*, or *a good source*. Nutrient content claims may also compare the level of a nutrient in a food to that of another comparable reference food, using terms such as *more*, *reduced*, and *less*.

An accurate quantitative statement (e.g., 200 mg of sodium) that does not “characterize” the nutrient level may be used to describe the amount of a nutrient in a food. However, a statement such as “only 200 mg of sodium” characterizes the level of sodium as being low, so it would need to conform to the FDA definition for “low.” Alternatively, such a claim may carry a disclosure statement that it does not comply with the definition. Similarly, any statement relative to a comparable food must meet FDA requirements set forth for comparative nutrient content claims that define the reference food to which such comparisons must be made.

### b. Implicit or Explicit Health Claims

According to FDA, any representation that a nutrient voluntarily declared as present in a food is healthy or at a healthy level or an ~~isolated~~ label statement about healthfulness must meet minimum requirements for content of total fat, saturated fat, cholesterol and sodium,

<sup>d</sup> A “qualification” is an ancillary statement that expresses the level of doubt or scientific uncertainty in the purported relationship of the food to the reduction in disease risk.

<sup>e</sup> These claims derive from the statutory definition of drug, which exempts as foods any item that may bear claims relative to their effect the structure or function of the human body. 21 U.S.C. § 321(g)(1)(C).



under the assumption that too much of these components cannot be in a healthy food. [This regulation does not, on its face, deal with a food item that is sold as an ingredient for use in home preparation.] There must also be a minimum quantity for a single serving in excess of 1 tablespoon or 30 grams. The food must contain 10% of the Daily Value of vitamins A and C, calcium, iron, protein, and fiber. Finally, these amounts cannot arise from fortification of the food. These rules that set a minimum healthful standard in terms of risk from heart disease for use of a -nutrient content claim that implies healthfulness -are collectively identified colloquially as the “jelly bean rule” as they would preclude a jelly bean packed with vitamins from making claims about the benefits of the added vitamins. *See* 21 C.F.R. § 101.65(d)(2). Of course, this requirement would seemingly preclude a truthful declaration that a healthful oil containing necessary and essential PUFAs and without significant saturated fat is healthful, unless, most likely, the label acknowledges that the pure oil is intended as a food preparation ingredient, such as use in another finished food as would be the customary method of consumption of oil in a salad dressing or as cooking. This lack of clarity is at odds with national and international public health recommendations, which call for minimum needed unsaturated fat or PUFA intake. A statement about PUFAs being healthy and needed in the diet is truthful and non-misleading as well as essential information for consumers.

## **VI. NUTRIENT CONTENT CLAIMS**

### **A. SPECIFIC CLAIMS OR STATEMENTS ALREADY AUTHORIZED FOR USE IN LABELING ABOUT BENEFICIAL NUTRIENTS IN CANOLA OIL INCLUDE:**

#### **i. Unsaturated fat content**

An accurate, quantitative statement about PUFAs or unsaturated fat content may be made, for example, “contains 4 g of PUFAs per serving” or “8 g of monounsaturated fat per tablespoon.” Additionally, truthful dietary guidance or claims related to the absolute content of essential fatty acids can also be made, such as the quantity of ALA or LA per tablespoon along with a characterization that these PUFAs are essential fatty acids. Further, in the context of the permissible comparative claims related to saturated fat or cholesterol, described below, a truthful comparison to other fats or oils used for similar purposes could be made that would provide the absolute quantity of unsaturated fats in each.

#### **ii. Omega-3 unsaturated fat content**

FDA has authorized both absolute and relative (i.e., comparative) claims that could highlight the ALA content of canola oil:

“High”-type absolute claims may be used:

- “High in ALA omega-3”; “Rich in ALA omega-3”; “Excellent source of ALA omega-3”
- “High”-type claims characterize canola oil containing 320 mg or more of ALA (i.e., 20% the 1.6 g Daily Value) per 1 tablespoon reference amount customarily consumed (RACC).

- “High”-type claims about ALA content must be accompanied by a statement helping consumers to understand the significance of the claim in the context of a total daily diet, for example: “Contains 1.3 g of ALA per serving, which is 81% of the Daily Value for ALA (1.6 g).”

“More”-type relative claims may be used to compare the ALA content of canola oil to competitive oils:

- “More ALA omega-3”; “Fortified with ALA omega-3”; “Enriched with ALA omega-3”; “Added ALA omega-3”; “Extra ALA omega-3”; “Plus ALA omega-3”
- “More”-type claims characterize canola oil containing at least 160mg (i.e., 10% of 1.6 g) more ALA per 1 tablespoon RACC than an appropriate reference food (e.g., olive oil).
- A statement such as the following must accompany “more” -type claims about ALA content: “74% more of the Daily Value for ALA per serving than olive oil. This product contains 1,302 mg ALA omega-3 per serving, which is 81% of the Daily Value for ALA omega-3 (1,600 mg). Olive oil contains 107 mg ALA omega-3 per serving.”

The parenthetical “(an omega-3),” could be substituted for “omega-3” in each of the absolute and relative claims. Also, the term “omega-3 ALA” alternatively could be used to name the nutrient. As noted previously, the truthful statement that ALA is an essential dietary component can also be made in the context of these claims as such a statement is dietary guidance.

#### **i. Vitamin E**

Canola oil products that contain at least 3 International Units (IUs) per 1 tablespoon serving (i.e., 10% of the 30 IU Daily Value), qualify for a “good source”-type claim: “Good source of vitamin E”; “Contains vitamin E”; “Provides vitamin E.” 21 C.F.R. §§101.9(c)(8)(iv), 101.54(c) (1).

#### **ii. Vitamin K**

A single tablespoon serving of canola oil contains 20 mcg of Vitamin K and thus qualifies for being “high” (20% or more of the Daily Value of 80 mcg) or a “good source” (10-19% of the Daily Value) definition. Similarly, comparative claims against other oils used for the same purpose with less vitamin K can be made (e.g., olive oil).

### **B. SPECIFIC STATEMENTS OR CLAIMS AUTHORIZED FOR USE IN LABELING ABOUT NUTRIENTS ABSENT OR LOW IN CANOLA OIL:**

#### **i. Saturated fat content**

FDA has authorized both absolute and relative (i.e., comparative) claims to highlight the low saturated fat content of canola oil. “Low”-type absolute claims may be used:

- “Low in saturated fat”; “Low saturated fat”; Low source of saturated fat”; “A little saturated fat”
- “Low”-type claims characterize canola oil containing 1g or less of saturated fatty acids per 1 tablespoon RACC and not more than 15% of calories from saturated fatty acids. 21 C.F.R. §101.62(c)(2)(i). Eligibility of canola oil for these claims is based on our understanding that canola oil contains about 0.8g of saturated fat per 1 tablespoon RACC, providing about 6% (7.2 calories) of the 120 calories per RACC.
- Claims should be expressed, for example, as “canola oil, a low saturated fat food,” to signify that the claim is not unique to a brand. 21 C.F.R. §101.62(c)(2)(ii).

“Less”-type relative claims may be used to compare the saturated fat content of canola oil to competitive oils:

- “Less saturated fat”; “Lower saturated fat”; “Lower in saturated fat.”
- “Less”-type claims characterize canola oil containing at least 25% less saturated fat per 1 tablespoon RACC than an appropriate reference food (e.g., olive oil).
- A statement such as the following must accompany “less” -type claims about saturated fat content: “Contains 55% less saturated fat per serving than olive oil.” Also, quantitative information comparing the level of saturated fat in canola oil per serving with that of the reference food must accompany the claim or appear on the Nutrition Facts panel of the label, for example: “This product contains about 1 g of saturated fat per serving, as compared to about 2 g in olive oil.”

#### **i. Cholesterol content**

“Free”-type claims may be used if accompanied by a total fat disclosure statement:

- “Cholesterol free”; “Free of cholesterol”; “Zero cholesterol”; “Without cholesterol”; “No cholesterol”; “Trivial source of cholesterol”; “Negligible source of cholesterol”; “Dietarily insignificant source of cholesterol.”
- “Free”-type claims characterize canola oil containing less than 2 mg of cholesterol and no more than 2 g of saturated fatty acids per 1 tablespoon RACC/serving. 21 C.F.R. §101.62(d)(1)(ii)(A)-(C).

- Claims should be expressed, for example, as “Canola oil, a cholesterol free food,” to signify that the claim is not unique to a brand. 21 C.F.R. §101.62(d)(1)(ii)(E).
- Claims should be accompanied by a total fat disclosure, for example: “Canola oil, a cholesterol free food, contains 14 g of fat per serving.”

**i. Sodium content**

“Free”-type claims may be used:

- “Sodium free”; “Free of sodium”; “Zero sodium”; “Without sodium”; “No sodium”; “Trivial source of sodium”; “Negligible source of sodium”; “Dietarily insignificant source of sodium.”
- “Free”-type claims characterize canola oil containing less than 5 mg of sodium per 1 tablespoon RACC/ serving. 21 C.F.R. §101.61(b)(1)(i).
- Claims should be expressed, for example, as “Canola oil, a sodium free food,” to signify that the claim is not unique to a brand. 21 C.F.R. §101.61(b)(1)(iii).

**VII. HEALTH CLAIMS**

**A. LOW SATURATED FAT AND CHOLESTEROL AND HEART DISEASE**

Canola oil is likely to be eligible for the FDA-authorized health claim related to a diet low in saturated fat and cholesterol provided its labeling makes clear that the oil is intended to be used as a food ingredient for use in home food preparation. If consumed alone as a beverage, canola oil would be precluded from making a health claim because of general limitations placed on the use of health claims. The general health regulations contain a rule similar to the “jelly bean rule” for nutrient content claims, which also precludes use of health claims on items solely composed of fat, even when such fat is healthy and necessary and the intention is to use the fat in home food preparation of healthful foods.<sup>f</sup>

**i. FDA’s regulations provide certain general barriers to health claim eligibility**

- Disqualifying total fat level: FDA regulations generally disqualify foods containing more than 13 g of total fat per RACC (or per 50 g for small RACC (e.g., RACC less than 2 tablespoons) foods). 21 C.F.R. §§ 101.14(a)(4), (e)(3). Since canola oil content is limited to fat, at 1 tablespoon RACC/serving, canola oil would exceed this disqualifying level for total fat unless the consumer is informed that the oil is intended for use only as a food ingredient in which the oil would be diluted by at least 500% (*i.e.*, the final canola oil content would be less than 20% of the finished food).

- The “jelly bean rule” generally prohibits health claims for a food unless it contains 10% or more of the Daily Value for vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC prior to any nutrient addition. 21 C.F.R. § 101.14(e)(6). Since canola oil is not a significant source of and does not contain any of these nutrients, the consumer would be required to understand that the finished food to which canola oil is added as an ingredient contains these nutrients (i.e., the claim would have to establish a context of a quantity and type of grain or salad components to which a reference amount of canola oil is applied).

But for these barriers, canola oil would be eligible for an authorized health claim about sodium and hypertension. *See generally* 21 C.F.R. § 101.74.

**ii. Specific authorized health claim about dietary saturated fat and cholesterol and risk of coronary heart disease.** FDA regulations provide for a health claim about low intake of saturated fat and cholesterol and risk of coronary heart disease (CHD). *See generally* 21 C.F.R. §101.75. However, the same restrictions relative to total fat content in the final product would have to be made clear in phrasing the claim.

## **B. CONTEXTUAL HEALTH CLAIMS**

While there may be dispute as to whether pure canola oil is eligible to bear any authorized health claim in labeling, as discussed above, the time is appropriate for FDA to amend the relevant regulations to clarify that healthful oils, such as canola, must be permitted to bear health claims regardless of “total fat” content, i.e., only saturated and *trans*-unsaturated fat content is relevant to the “disqualifying” health issues. For example, regulations authorizing health claims for soy protein and CHD as well as plant sterol/stanol esters and CHD require that eligible foods be “low saturated fat” and “low cholesterol,” but not always “low fat.” 21 CFR §§101.82(c)(2)(iii)(B), 101.83(c)(2)(iii)(B). In some situations, FDA has required a fat disclosure statement, rather than imposing -a “low fat” or other total fat disqualifying level. E.g., 21 CFR §101.83(c)(2)(iii)(C) (plant sterol/stanol esters and CHD - spreads and salad dressings); Qualified Health Claims: Letter of Enforcement Discretion - Walnuts and Coronary Heart Disease (Docket No 02P-0292); Qualified Health Claims: Letter of Enforcement Discretion - Nuts and Coronary Heart Disease (Docket No 02P-0505).

<sup>f</sup> We believe that this contextual limitation may overcome the barriers cited in this section because the claim is truthful, non-misleading, scientifically reviewed by FDA and authorized, and because the clinical studies upon which the claim was authorized used test diets with canola and similar profile oils as the source of necessary oils to demonstrate that a diet low in saturated fat and cholesterol results in the reduction in cholesterol that was the agency’s endpoint for validation. However, legal analysts may differ in this conclusion and arrive at the decision that no health claim is authorized for pure canola oil sold for use as an ingredient by the consumer. Currently, FDA is considering withdrawal of the companion “jelly bean rule” based on the same lack of clarity that results in misleading information for consumers about the need and benefit of healthful fats. This lack of clarity should also be removed in the context of health claims.

## VIII. “STRUCTURE/FUNCTION” CLAIMS APPLICABLE TO CANOLA OIL

Since one tablespoon of canola oil contains 15% of the daily value of vitamin E, this permissible serving size (21 C.F.R. § 101.12) does not meet FDA requirements for being “high” in vitamin E but does meet the requirements of having “more” vitamin E or being a “good source” under the regulatory definitions of these terms. 21 C.F.R. §§ 101.54(b), (e). Since canola oil is a good source of vitamin E, the following structure/function claims are likely to be acceptable<sup>g</sup>

- Contains fat soluble antioxidants
- Plays a role in maintaining healthy cell membranes
- Protects against free radicals
- Supports a healthy cardiovascular system
- To support a healthy heart
- Supports healthy immune function
- Nutritional support for free radical defense
- Is essential for healthy teeth, gums, and bones
- Supports healthy lipid oxidation
- Supports healthy blood circulation
- Supports red blood cell health
- Contributes to mental health
- Contributes to prostate health
- Regulates health oxidation reactions in the body
- Provides powerful antioxidant protection

Similarly, unmodified canola oil contains 11% omega-3 fatty acids. Thus, a tablespoon (or reference amount customarily consumed, 21 C.F.R. § 101.12) contains approximately 1.5 grams of ALA – the amount generally recommended by authoritative health organizations as 100% of the daily nutritional requirement, canola oil should be able to make the following statements relative to being high in omega-3 fatty acids:<sup>h</sup>


- Promotes health heart function
- Promotes cardiovascular health
- Supports healthy circulation
- Supports healthy blood lipid levels
- Supports healthy cholesterol levels
- Supports healthy triglyceride levels
- Required by the body to make the substances that ensure that blood flows normally and smoothly through the body without clotting.

## IX. SUMMARY OF PERMISSIBLE CLAIMS APPLICABLE TO CANOLA OIL

<sup>g</sup> A single serving of canola oil should satisfy either a “high” (20% or more of the Daily Value) or “good source” (10-19% of the Daily Value) definition. For vitamin E, the Daily Value is 30 IUs.

<sup>h</sup> A statement that this nutrient is an essential dietary component can also be made as dietary guidance.

Canola oil can make claims about the content of essential fatty acids (LA and ALA) under the provisions relating to dietary guidance, as these nutrients are essential to the diet and a single reference amount of canola oil provides the minimum daily needs. Nutrient content claims can be made for the content of unsaturated fat, vitamin E, and omega-3 fatty acids in canola oil in absolute terms by specifying the amount of such nutrients in the oil per serving. Relative nutrient content claims can specify that canola oil is high in omega-3 fatty acids and a “good source” of or having “more” vitamin E. Canola oil can also make comparative and absolute nutrient content claims related to the absence of cholesterol and sodium and the relatively low or lessened amount of saturated fat. Finally, structure/function claims are available to canola oil based on its content of essential PUFAs, including omega-3 fatty acids, and based on the presence of vitamins E and K.

With regard to health claims, there is currently a lack of clarity as to whether pure canola oil can make authorized health claims for a reduction in risk of heart disease and hypertension by virtue of being low in saturated fat and cholesterol and sodium, respectively. While the body of scientific evidence used to support and validate these health claims used canola or a similar oil as a food ingredient or source of necessary oil in the diet used in the studies that validated the claim, FDA has promulgated general barriers to the use of a health claim on any products that could preclude the use of health claims on healthful oils that are sold as food ingredients for home food preparation. FDA should clarify these regulations. That said, a truthful and non-misleading statement that provides context, by providing information on how a salad or specific baked good can be made with a pure oil that meets the health claim, may be permissible on the label. Given the different legal authority for the FTC, such truthful and non-misleading claims can be made in canola oil advertising. Alternatively, consideration should be given to FDA issuance of an opinion that such a claim for canola oil is a permissible qualified health claim to ensure its legality. 

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14. Examples of health claims based on authoritative statements may also be found at <http://www.cfsan.fda.gov/~dms/flg-6c.html>.
15. A summary of the qualified health claims authorized by FDA may be found at <http://www.cfsan.fda.gov/~dms/qhc-sum.html>.
16. <http://www.cfsan.fda.gov/~dms/flg-6c.html>.

## GLOSSARY

ALA	Alpha-linolenic acid
CFR	Code of Federal Regulations
DHHS	U.S. Department of Health and Human Services
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
LA	Linoleic acid
NLEA	Nutrition Labeling and Education Act
PUFAs	Polyunsaturated fatty acids
RACC	Reference Amount Customarily Consumed
USC	United States Code

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