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**Health Claim  
for High Oleic  
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# HEALTH CLAIM FOR HIGH OLEIC OILS UNDER CONSIDERATION BY FDA

By Mark Messina, PhD, MS

Clinical evidence clearly indicates that replacing saturated fat with unsaturated fat (either polyunsaturated fat or monounsaturated fat) lowers circulating cholesterol levels and therefore should reduce risk of cardiovascular disease (CVD); a supposition that is supported by observational data. Not surprisingly, both commodity soybean oil, which is rich in polyunsaturated fat, and high oleic soybean oil (HOSO), which is rich in monounsaturated fat, have been shown to lower circulating cholesterol levels—which is recognized by the U.S. Food and Drug Administration (FDA) as a surrogate endpoint for CVD and therefore capable of substantiating health claims.

The relationship between dietary fat intake and CVD has been investigated for more than 50 years beginning in earnest with the Seven Countries Study.<sup>1</sup> CVD is the leading global cause of mortality, accounting for over 17 million deaths per year. Given past recommendations, the

American Heart Association recently strongly concluded that “lowering intake of saturated fat and replacing it with unsaturated fats, especially polyunsaturated fats, will lower the incidence of CVD.”<sup>2</sup> (See related article on Page 5.) Consistent with this recommendation is the FDA’s recent authorization of a strong qualified health claim for commodity (conventional) soybean oil, based on its ability to lower blood cholesterol levels. Language supporting this claim is much stronger than the language supporting the qualified claims for corn oil, olive oil and canola oil.

Commodity soybean oil, which dominates the edible oil market, is comprised of 50–55% linoleic acid, the essential omega-6 polyunsaturated fat, and about 20–25% monounsaturated fat (oleic acid).<sup>3</sup> It also provides substantial amounts of the essential omega-3 fatty acid, alpha-linolenic acid.

Commodity soybean oil plays a huge role in the U.S. food supply accounting for approximately 7% of U.S. caloric intake.<sup>4</sup> However, in response to demand from the food industry, two different HOSOs have recently been developed. These HOSOs are comprised of >70% oleic acid. A petition seeking a health claim for oils high in oleic acid (at least 10 grams per serving) is currently being evaluated by the FDA.

Surveys indicate that consumers rate olive oil, which is rich in oleic acid, as the healthiest of oils even though, as noted, language supporting the qualified health claim for this oil is weaker than the claim for soybean oil. Furthermore, U.S. prospective epidemiologic data show that the replacement of saturated fat with polyunsaturated fat reduces risk of coronary heart disease (CHD) more than replacement with monounsaturated fat.<sup>5</sup> More specifically, analysis of 84,628 women from the Nurses’ Health Study and 42,908 men from the Health Professionals Follow-up Study, found that replacing 5% of energy from saturated fat with 5% of energy from polyunsaturated fat reduced risk of developing CHD by 25% whereas replacement with monounsaturated fat lowered risk by only 15%.

Despite this evidence, the favorable consumer perception of olive oil is understandable considering the extensive amount of attention given to the health benefits associated with the Mediterranean diet over the past decade or so. Although monounsaturated fat is derived from multiple sources (e.g., HOSO, canola) olive oil is unique in that it contains compounds independent of its fatty acids (e.g., polyphenols) that potentially reduce CHD risk.<sup>6</sup>

Regardless of the source, substantial human data indicate that replacing saturated fat in the diet with oleic acid is

## FDA Language for Qualified Claims

**Soybean oil:** Supportive but not conclusive scientific evidence suggests that eating about 1½ tablespoons (20.5 grams) daily of soybean oil, which contains unsaturated fat, may reduce the risk of coronary heart disease

**Corn oil:** Very limited and preliminary scientific evidence

**Olive oil:** Limited and not conclusive evidence

**Canola oil:** Limited and not conclusive scientific evidence suggests

Source: U.S. Food and Drug Administration

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**Table 1.** Lipid concentrations (mmol/l) at the end of each of the three experimental diets\*

	Western		High oleic rapeseed		Rapeseed/Flaxseed	
	Mean	SEM	Mean	SEM	Mean	SEM
Total cholesterol	5.65 <sup>a</sup>	0.16	5.27 <sup>b</sup>	0.14	5.12 <sup>c</sup>	0.13
LDL-cholesterol	3.53 <sup>a</sup>	0.14	3.10 <sup>b</sup>	0.12	3.08 <sup>b</sup>	0.12

Source: Reference.<sup>7</sup> Mean values within a row with unlike superscript letters significantly different between treatment groups ( $P < 0.05$ ).

SEM = standard error of mean

cardioprotective. The petition submitted to the FDA seeking a health claim for high oleic oils suggested the following language be used for the claim:

“Daily consumption of edible oil with at least 10 grams of oleic acid per serving (one tablespoon) reduces the risk of coronary heart disease. To achieve this benefit, oleic acid containing oils with at least 10 grams of oleic acid per serving should replace a similar amount of saturated fat and not increase the total number of calories you eat in a day.”

The petition for the health claim is based on the hypocholesterolemic effect of oleic acid. Two clinical trials were cited as the primary support for the cholesterol-lowering effect and a third trial was considered important, but carried less weight.

In the first trial cited (a randomized, controlled, single-blind, crossover clinical study), 36 hypercholesterolemic adult men and women consumed a typical Western diet containing either high oleic rapeseed (canola) oil (73.7% oleic acid) or a flaxseed/high oleic canola oil blend.<sup>7</sup> The diets derived 50% of their energy from carbohydrates, 15% from protein, and 35% from fats. Only the fat, and thus the fatty acid composition, was modulated between the control and intervention groups. Diets were consumed for 28 days followed by a 4–8 week washout period. Diets were prepared in the metabolic kitchen at the Richardson Centre Clinical Nutrition Research Unit at the University of Manitoba, where study participants consumed breakfast daily and were supplied cold-packed takeout lunches and dinners for consumption outside of the research unit.

As seen in Table 1, total and LDL-cholesterol values were significantly lower in the rapeseed-containing diets. Reduction in cholesterol in the blend diet occurred, despite containing similar amounts of monounsaturated fat as in the Western diet; the former was much lower in saturated fat (7.5% vs 28.6%) and much higher in alpha linolenic acid (32.4% vs 0.8%).

The second study cited in the petition examined the effect of dietary fat saturation on cholesterol levels in 21 normolipidemic women (13 premenopausal and 8 postmenopausal) during three consecutive diet periods.<sup>8</sup> During the first 4 weeks, participants consumed a diet high in saturated fat rich in palm oil and butter [19% saturated fatty acids (S), 14% monounsaturated fatty acids (M), and 3.5% polyunsaturated fatty acids (P)], followed by 6 weeks of a monounsaturated diet rich in olive oil (11% S, 22% M, and 3.6% P), and 6 weeks of a polyunsaturated diet rich in sunflower oil (10.7% S, 12.5% M, and 12.8% P). Approximately 36% of the calories on each of the diets was derived from fat. As can be seen from Table 2, compared with the diet rich in saturated fatty acids, both diets rich in unsaturated fatty acids lowered total and low-density lipoprotein cholesterol. Although not shown in Table 1, high-density lipoprotein cholesterol and apolipoprotein A-I were higher during the monounsaturated-rich period than in the polyunsaturated-rich (10.5% and 12.7% respectively,  $P < 0.001$ ) and the saturated-rich periods (5.3% and 7.9% respectively,  $P < 0.05$ ).

As noted above, a third trial was also cited in the petition but, because of some design weaknesses, was not relied upon as heavily to support the health claim.<sup>9</sup> In this randomized, single-blind study, changes in serum lipid levels were assessed in 16 men consuming diets that provided 39% of calories as fat from either safflower oil or canola oil-based diets for 8 weeks after initially being stabilized for 3 weeks on a typical American (baseline) diet. Compared with baseline, LDL-cholesterol decreased from 3.78 to 3.03 mmol/l in response to the high polyunsaturated fat diet and from 3.64 to 3.21 mmol/l in response to the diet high in monounsaturated fat. The decreases were statistically significant in both cases. The high polyunsaturated diet contained 7% saturated fat, 9% monounsaturated fat, and 22% polyunsaturated fat, whereas the high monounsaturated fat diet contained 7% saturated, 22% monounsaturated and 11% polyunsaturated.

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**Table 2.** Lipid concentrations (mmol/l) at the end of each of the three experimental diets\*

	Baseline	Saturated	Monounsaturated	Polyunsaturated
Total cholesterol	4.94 ± 0.83	5.27 ± 0.85	4.80 ± 0.85 <sup>a</sup>	4.73 ± 0.83 <sup>a</sup>
LDL-cholesterol	2.92 ± 0.62	3.44 ± 0.70	2.80 ± 0.62 <sup>a</sup>	2.95 ± 0.65 <sup>a</sup>

Source: Reference.<sup>8</sup> <sup>a</sup>Significantly different from saturated fat diet

The soybean plant is a remarkably healthful plant. Soy protein, soy oil and other nutritive components have long been admired for the health benefits they provide. In fact, because of its favorable fatty acid profile, the Food and Drug Administration (FDA) recognizes soybean oil as beneficial in supporting a heart healthy diet.<sup>1</sup> However, a new kind of soybean oil is available in limited quantities that has nutritional properties similar to olive oil and functionality features that cooks will appreciate.

The new trans-fat-free product is called high oleic soybean oil. It is a newly cultivated oil with a special blend of fatty acids that enhance both health benefits and cooking capabilities. As a liquid oil, high oleic soybean oil contains zero trans fats, lower saturated fats, and more monounsaturated fatty acids (MUFAs) compared to conventional soybean oil.

MUFAs have been studied extensively for health benefits. In fact, a 2014 review of a number of studies concluded that greater consumption of oleic acid resulted in an overall reduction of risk of all-cause and cardiovascular mortality.<sup>2</sup> Other research has shown that when replacing dietary saturated fats, oleic acid consumption helps to reduce LDL-cholesterol, lower blood pressure, support healthy blood sugar levels and may have anti-inflammatory properties.<sup>3,4</sup>

Because of its unique components, high oleic soybean oil can easily be used in cooking healthy foods under high heat temperatures.<sup>5</sup> This new oil has a high smoke-point (450° F), meaning that it is stable under conditions of high temperatures. Healthful fats like olive oil are not able to function as well under high temperatures. Additionally, because of its neutral flavor, high oleic soybean oil complements a wide-variety of flavors and seasonings without difficulty.

High oleic soybean oil is not yet available in your favorite grocery store, but hopefully will be soon. On a larger scale, the new oil is being tested and used by restaurants and in major food operations and has received favorable reviews from chefs across America.

If you are unable to purchase high oleic soybean oil right now, conventional soybean oil (i.e., vegetable oil) is widely available. As a trusted plant-based oil, soybean oil supports heart health, provides essen-

tial omega-3 fats, and builds flavor support to many cuisine favorites. Once available, high oleic soybean oil will add one more healthful option to your pantry. 🌱



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# AHA, DIETARY GUIDELINES ADVISE REDUCING CVD RISK WITH UNSATURATED DIETARY FATS

By Christine Werner, PhD, RD, PA-C

A recently published presidential advisory from the American Heart Association (AHA) concludes that replacing saturated fat and refined carbohydrates with unsaturated fats reduces low-density lipoprotein cholesterol (LDL-C) and risk of cardiovascular disease (CVD) in both men and women.<sup>1</sup>

No single dietary fat contains 100% of any given fatty acid; rather, they contain a varied concentration of many fatty acids. Sources of predominantly saturated fat include animal products such as dairy, butter, lard and tallow, as well as plant sources like palm and coconut oil. Rich sources of unsaturated fats composed of polyunsaturated fats (PUFA) and monounsaturated fats (MUFA) include vegetable oils such as soybean, canola, corn, safflower and sunflower oils. Soybean oil is a particularly rich source of dietary unsaturated fat because it has a high percentage of PUFA and is the most widely consumed vegetable oil in the American diet.<sup>2</sup> Additional dietary sources of PUFA and MUFA include avocados and tree nuts like almonds, pistachios, pecans, hazelnuts and cashews.

The Dietary Guidelines for Americans recommend consumption of less than 10% of calories from saturated fats.<sup>3</sup> While research tends to support this recommendation, at least one study found that replacing saturated fat with an equal number of calories from carbohydrates failed to show CVD risk reduction unless the carbohydrates were in the form of whole grains.<sup>4</sup>

The AHA presidential advisory included a meta-analysis of 4 randomized clinical trials (RCTs) that evaluated the effects of replacing saturated fat with PUFA on cardiovascular events rather than just risk factors such as blood lipids.<sup>1</sup> Results from the meta-analysis revealed a 29% reduction in CVD events when saturated fat was replaced with polyunsaturated fat for at least two years.<sup>1</sup> Of note, 3 of the 4 RCTs described their primary source of PUFA as soybean oil, while the fourth trial lacked information on dietary fat sources.

Additional meta-analyses and systematic reviews evaluating the data of select RCTs specifically investigating the replacement of saturated fat with PUFA on CVD risk reveal an overall significant CVD risk reduction of 19%<sup>5</sup> and 27%,<sup>6</sup> respectively.

While all commonly used vegetable oils on the market today contain varying degrees of saturated, MUFA and PUFA, there is somewhat more evidence to support the replacement of saturated fat with PUFA, com-

pared to MUFA-predominant oils.<sup>2,7</sup> This conclusion is due to the fact that long-term RCTs have shown that replacement of saturated fat with PUFA sources decreases the clinical incidence of CVD while no such studies have been conducted with MUFA sources. The available data for MUFA-predominant oils are based on CVD risk factors rather than clinical endpoints.

Both linoleic (omega-6) and alpha-linolenic acid (omega-3) are essential fatty acids. Alpha-linolenic acid occurs naturally in soybean and canola oil, although soybean oil is the main source of this fatty acid in the American diet because of its widespread use.<sup>8</sup> Physiologically, the essential fatty acids help regulate the immune system and blood pressure and are involved in brain development.

Oleic acid is an omega-9 MUFA found abundantly in various animal fats and vegetable oils. Because oils high in PUFA are susceptible to oxidation and therefore have a reduced shelf and fry life, high oleic vegetable oils were introduced in the market in 2011.<sup>8</sup> Clinical trials have shown that replacement of saturated fat with high oleic oils including soybean and canola oils favorably alters blood lipids. In a systematic review analyzing clinical trials that replaced saturated fat with high oleic soybean oil for at least three weeks, total cholesterol decreased by 8%, LDL cholesterol by 10.9%, and apolipoprotein by 7.9%.<sup>9</sup>

While recent marketing efforts have promoted the intake of coconut oil to improve HDL cholesterol status, coconut oil is approximately 82% saturated fat, which would be expected to raise LDL cholesterol and could outweigh any CVD risk reduction benefit. The AHA and the Dietary Guidelines do not recommend the intake of coconut oil as part of a heart healthy diet.<sup>13</sup>

In summary, there is consistent clinical evidence that lowering saturated fat intake and replacing this ener-

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## Conclusions

If the FDA approves the pending petition for a health claim for oils high in oleic acid, HOSO will qualify for a health claim. The claim will help to increase public awareness that oil produced from the soybean can meet the demand for foods high in polyunsaturated fat and monounsaturated fat. It bears emphasizing that the benefits of unsaturated fat are not necessarily limited to lowering LDL-cholesterol levels, but may also include reducing insulin resistance<sup>10</sup> and visceral fat,<sup>11</sup> and enhancing endothelial function<sup>12</sup> and cholesterol efflux capacity.<sup>13</sup> Thus, there are multiple reasons for replacing dietary saturated fat with unsaturated fat. 🍷

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gy source with PUFA and/or MUFA lowers the risk of CVD. Vegetable oils and vegetable blend oils generally contain fewer than 4 grams of saturated fat per tablespoon.<sup>2,7</sup> 🍷

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