

# SOY

# & HEALTH



**Overwhelming  
Evidence Shows  
That Soy  
Reduces Heart  
Disease Risk  
and Improves  
Heart Health**

## Soy and Heart Health

Heart disease has been the leading cause of death in the United States since 1918. According to the American Heart Association<sup>1</sup>, 60,800,000 Americans have one or more types of cardiovascular disease (CVD) and 949,619 lives were lost in 1998 due to this devastating illness. This is almost twice as many as the number of lives lost to cancer (541,532). CVD claims a life every 33 seconds – 10,500 more lives per year than the next six leading causes of death combined.

The good news is that the major forms of CVD – coronary heart disease, hypertensive disease, rheumatic fever/rheumatic heart disease and stroke – are largely preventable because the primary risk factors for these diseases are modifiable. The primary risk factors are smoking, high blood pressure and elevated serum cholesterol. Physical inactivity, being overweight or obese, uncontrolled blood glucose levels and poor dietary habits are secondary risk factors. In particular, a heart healthy diet is critically important for both prevention and treatment of CVD, especially with regard to the management of blood cholesterol. A third report from the National Cholesterol Education Program (NCEP) updates the existing recommendations for clinical management of high blood cholesterol<sup>2</sup> and provides the following new guidelines for low density lipoprotein (LDL) "bad" cholesterol, total cholesterol and high density lipoprotein (HDL) "good" cholesterol:

### LDL cholesterol (mg/dL)

< 100	Optimal
100-129	Near or above optimal
130-159	Borderline high
160-189	High
≥ 190	Very high

### HDL cholesterol (mg/dL)

< 40	Low
≥ 60	High

### Total cholesterol (mg/dL)

< 200	Desirable
200-239	Borderline high
≥ 240	High

NCEP recommends a multifaceted lifestyle approach to decrease the risk of heart disease, which includes reducing intakes of saturated fat to no more than seven percent of total calories and cholesterol to 300 mg/day maximum. Soyfoods are an excellent choice for a heart healthy diet. Because cholesterol is found only in animal foods, soybeans contain no cholesterol. Soybeans also provide very high quality protein, equivalent to animal sources of protein such as meat and milk.<sup>3,4</sup> Additionally, soybeans are low in saturated fat. In fact, approximately 85 percent of the fat in soybeans is unsaturated. Most importantly, however, dozens of human clinical trials have demonstrated that soy consumption can lower both total and LDL cholesterol.<sup>5</sup>

### Author

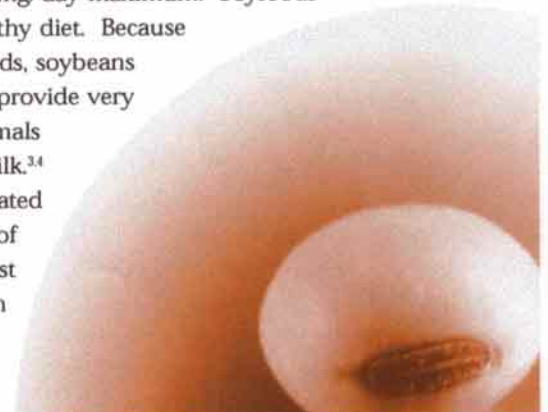
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The cholesterol-lowering effect of soy was initially recognized over 90 years ago. Public health professionals did not take particular note of this health benefit of soy, however, until the mid-1990s when a meta-analysis of 38 clinical studies involving more than 700 subjects demonstrated that, in comparison to control diets, substitution of soy protein resulted in significant reductions in total cholesterol (9.3 percent), LDL-cholesterol (12.9 percent), and triglycerides (10.5 percent), with a small but insignificant increase (2.4 percent) in HDL-cholesterol.<sup>6</sup>

Because of soy's effectiveness in lowering the major blood lipids associated with an increased risk of heart disease, on October 26, 1999, the U.S. Food and Drug Administration (FDA) approved a health claim for the relationship between the consumption of soy protein and reduced risk of CHD.<sup>7</sup> Health claims were made possible by the Nutrition Labeling and Education Act of 1990 (NLEA) and allow statements on food labels that characterize the relationship of any food or food component to a disease or health-related condition.<sup>8</sup> The following health claim may now be utilized on qualified soy products:

*Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides [amount] g of soy protein.*

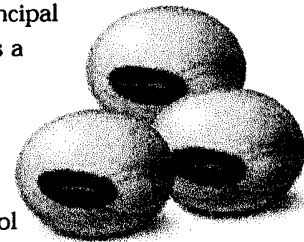
In order to bear the health claim, products must be a low saturated fat and low cholesterol food and must contain a minimum of 6.25 g of soy protein per serving. This per serving level was determined by dividing the daily qualifying level (25 g) by four to represent the four daily eating occasions (breakfast, lunch, dinner and snack). In addition to the FDA-approved health claim for soy, the American Heart Association recently issued a statement for healthcare professionals which recommended including soy protein foods in a diet low in saturated fat and cholesterol to promote heart health<sup>9</sup>. Significantly, FDA made an exception for the high fat limit for the health claim and allows health claims for tofu and other full fat whole soybean foods.

Although the FDA-approved health claim for soy is based on its protein content, a number of other physiologically-active components may contribute to its cholesterol-lowering effect, including amino acids, saponins, phytic acid, trypsin inhibitors, fiber, globulins (storage proteins found in soy) and isoflavones.<sup>10</sup> Isoflavones are a major class of estrogens from plants with a chemical structure very similar to that of estradiol, the principal circulating estrogen in our bodies.<sup>11</sup> Whether isoflavones are the principal physiologically-active component responsible for the lipid lowering effect of soy is a subject of considerable controversy.<sup>12</sup>

Although a study by Crouse et al.<sup>13</sup> found that 25 grams per day of isolated soy protein containing increasing levels of isoflavones (4, 27, 37, or 62 mg) reduced cholesterol in those persons consuming 37 or 62 mg/day isoflavones, the results were modest, with the highest level of isoflavones (62 mg) lowering total cholesterol and LDL cholesterol levels by only four percent and six percent respectively, and this effect was restricted to a subset of participants with an average LDL cholesterol concentration greater than 166 mg/dL. These data support the hypothesis that isoflavones must be present *along with soy* to result in cholesterol lowering. Furthermore, several recent clinical trials have shown isoflavone supplements to be ineffective in lowering cholesterol.<sup>14-18</sup> Thus, in the final ruling for the soy health claim<sup>7</sup>, the FDA stated that they were "not persuaded that the isoflavone component of soy protein was a relevant factor to the diet-disease relationship...." While still under investigation, it is possible that isoflavones must be present in conjunction with the protein for soy to have a significant effect on blood lipids.

In addition to the ability of soyfoods to lower both total and LDL cholesterol, soy may have additional heart health benefits, including reducing the oxidation of LDL cholesterol and decreasing arterial compliance (i.e., increased stiffness) of the arteries. These physiological effects of soy may eventually prove to be as beneficial to heart health as the effects on blood lipids.

The oxidation of LDL cholesterol is now recognized as a key event in the pathogenesis of atherosclerosis.<sup>19</sup> Individuals with cardiovascular disease have elevated levels of oxidized LDL or have an increased susceptibility of in vitro LDL oxidation. Several recent studies have shown a beneficial effect of soy product consumption on the



reduction of LDL oxidation in human subjects. In a study by Wiseman et al.<sup>20</sup>, 56 mg isoflavones significantly increased LDL oxidation lag time by eight percent in a study in 24 subjects consuming 15 g textured soy protein/day (contained in one soy burger) for 17 days. No significant effect on LDL lag time was noted when low isoflavone (1.9 mg) burgers were consumed, suggesting that isoflavones were responsible for the antioxidant action.

Two recent studies by Jenkins et al. also demonstrate that consumption of soyfoods can reduce LDL oxidation. In the first study<sup>21</sup>, 20 hyperlipidemic men and postmenopausal women consumed  $12 \pm 2$  g soy protein per day from a self-selected menu of soy-based foods as part of an NCEP step 2 diet. After eight weeks, LDL oxidation was significantly reduced by  $8.5 \pm 3.3$  percent. The test diet also significantly elevated HDL cholesterol  $6.4 \pm 2.4$  percent. In a second study by this research group, in which 25 hyperlipidemic men and women consumed a soy-based breakfast cereal containing 36 grams per day of soy protein and 168 mg/day isoflavones for three weeks<sup>22</sup>, oxidized LDL was significantly reduced by  $9.2 \pm 4.3$  percent. These studies suggest that the consumption of soyfoods can increase the resistance of LDL to oxidation, which, in turn, may benefit heart health.

Decreased arterial compliance, a measure of "stiffness" of the arteries, is also thought to contribute to cardiovascular disease.<sup>23</sup> Because isoflavones are plant-derived estrogen-like compounds that have been shown to enhance brachial artery flow-mediated dilation<sup>24</sup>, it is not surprising that soy isoflavones would increase arterial compliance. Studies have shown that isoflavones derived from either red clover<sup>16</sup> or from soybeans<sup>15</sup> can significantly improve arterial compliance by more than 20 percent even though they failed to lower blood lipids.

## **Conclusion**

Overwhelming evidence has shown that soy consumption reduces the major blood lipids associated with cardiovascular disease risk. Soy and its associated isoflavones may also have other heart health benefits, including the ability to reduce the oxidation of LDL cholesterol and promote vascular relaxation, physiological effects which are emerging as an important risk factors for heart disease. Scientific researchers and health professionals agree that the public should be encouraged to incorporate a variety of soy products into a heart healthy diet and lifestyle plan.

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