

## **New Study Confirms Soy Protein Lowers Cholesterol**

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New research published in the *Journal of Nutrition*, by David Jenkins, MD, PhD and colleagues from the University of Toronto, shows that soy protein significantly lowers LDL-cholesterol, the type of cholesterol known to raise risk of heart disease. While previous research has found similar results, in recent years challenges to the cholesterol-lowering effect of soy protein have been raised. In fact, in October 2017, the U.S. Food and Drug Administration (FDA) announced its intention to revoke the existing health claim for soy protein and coronary heart disease, which was approved in 1999, citing inconsistent data.

The research by Jenkins is a meta-analysis of previously published data, the same data upon which the FDA based its decision. Of the 46 studies identified by the FDA, 41 studies involving 3,228 participants were suitable for inclusion in the analysis for the evaluation of LDL-cholesterol and 43 studies involving 3,290 participants were suitable for the evaluation of total cholesterol. Soy protein lowered LDL-cholesterol 3.2%. Although modest, over time, each 1% reduction in LDL-cholesterol is thought to reduce the risk of heart disease by 1 to 2%.

Other research by Jenkins has shown that because soyfoods are low in saturated fat and high in polyunsaturated fat, when they replace common sources of protein in Western diets, which tend to be high in saturated fat, estimates are that LDL-cholesterol will be lowered about 4% as a result of the favorable change in the fatty acid content of the diet. Thus, soyfoods have the potential to lower LDL-cholesterol by as much as 7% through two different mechanisms. Furthermore, Jenkins has shown that when soy protein is combined with other dietary approaches to lowering cholesterol, LDL-cholesterol can be reduced by as much as 30%.

The FDA found that only 19 of 46 studies (41%) showed that soy protein lowered LDL-cholesterol in a statistically significant way. In its opinion, that wasn't enough to justify the existing unqualified claim. An unqualified claim indicates there is significant scientific agreement. However, many of the cholesterol-lowering studies were small in size, making it difficult to see a statistically significant effect even when cholesterol is reduced. In fact, Jenkins and colleagues also found that less than half of the studies found a statistically significant reduction. But about 75% of the studies showed a reduction. Meta-analyses are conducted in part because they can combine the results of many small studies so that the findings overall can be integrated.

Since the U.S. soy protein health claim was approved, similar claims have been approved in more than 10 other countries. They include Japan, South Africa, the Philippines, South Korea, Turkey, Malaysia, India, Brazil, Chile, Columbia, Ecuador and Peru.

The most recent country to do so was Canada, which approved a claim in 2015. Similar to the review by the FDA, Health Canada found that only about one-third of studies showed a statistically significant reduction in LDL-cholesterol. However, because they also noted that about 80% of the studies reviewed showed a reduction, the claim was deemed warranted. When the data were statistically analyzed by Health Canada, soy protein was found to lower LDL-cholesterol about 4%.

Whatever the FDA decides about the unqualified health claim, the evidence clearly shows that soyfoods can make an important contribution to heart-healthy diets.