

The Soyfoods Association of North America
Washington, DC 20036
(202) 659-3520 | press@soyfoods.org



Body of literature indicates soy supports heart health
Science shows soy protein improves circulating cholesterol

WASHINGTON, September 1, 2017 – The Soyfoods Association of North America is relieved that the FDA’s review of the soy protein health claim is nearing completion, but we are concerned that FDA is apparently proposing to modify the claim from unqualified to qualified. Both unqualified and qualified health claims characterize a relationship between a substance (i.e., a specific food component) and a disease (i.e., heart disease) or health-related condition (i.e., high blood pressure) and are supported by scientific evidence. However, unqualified health claims suggest substantial scientific agreement, whereas qualified health claims indicate a lower level of scientific consensus.

Numerous scientific studies published before and since the soy protein health claim was approved in 1999 consistently show that soy protein lowers LDL-cholesterol and that the totality of the evidence supports continued approval of an unqualified claim. FDA’s decision is inconsistent with 12 other countries that have authorized health claims on soy protein and heart disease, including Health Canada’s most recent approval of such a claim in 2015.¹

FDA’s proposal is expected to be issued in October 2017 and will be followed by a comment period before it goes into effect. If it goes into effect, food products that have used the claim in the past can still reference the association of soy protein consumption and reduced cardiovascular disease risk, but they will need to modify the wording to reflect qualified claim requirements.

Representing manufacturers of high-quality, highly nutritious soyfoods, the Soyfoods Association of North America will be engaged with FDA during this comment period. We will advocate for continuation of an unqualified claim, based on the totality of the evidence demonstrating that soy protein lowers LDL-cholesterol.

History and Background

More clinical studies have been conducted to assess the cholesterol-lowering effects of soy protein than any other cholesterol-lowering food ingredient. The research was so well supported that in 1999, the Food and Drug Administration (FDA) approved the following health claim for soy protein:

¹ Japan (1996), South Africa (2002), The Philippines (2004), Brazil (2005), Indonesia (2005), Korea (2005), Turkey (2006), Malaysia (2006), Chile (2006), Colombia (2008), India (2013) and Canada (2015)

“25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease.”

In the time following FDA’s original approval of the soy protein coronary heart disease health claim, new scientific evidence further substantiated the association between soy protein and a reduction in total and LDL cholesterol, though sometimes to varying degrees. Poor study design and control, starting cholesterol levels of subjects and dietary protocols are all factors that influence study findings, and sometimes produce inconsistent findings.

Since FDA first approved the soy protein and cardiovascular disease health claim, twelve other countries have reviewed the science and approved similar claims, including Health Canada as recent as 2015.

To date, FDA has approved only 11 unqualified health claims, or claims with substantial scientific agreement, of which the soy protein and cardiovascular disease risk reduction relationship was one of them. Soy protein remains the only protein source with an approved claim, qualified or unqualified.

The Challenges of Research Demonstrating Diet and Disease Relationships

Scientifically establishing a direct connection between a specific food and a disease is extremely difficult, considering that foods are not medicines. The availability of effective cholesterol-lowering medications and extensive cholesterol-lowering education have dampened the magnitude of cholesterol reductions possible by a food ingredient, such as soy protein.

However, studies continue to confirm the significant scientific consensus that formed the basis for the 1999 FDA Health Claim on Soy Protein and Coronary Heart Disease. Soyfoods are one of the few foods proven to lower cholesterol and should be an important part of an overall heart healthy diet and lifestyle.

Heart Disease and Diet in Context

Heart disease remains the leading cause of death globally for both men and women. Consuming soy protein as part of a diet low in cholesterol and saturated fat, has been found to reduce the risk of heart disease and have a favorable impact on blood lipids, lowering LDL-cholesterol, total cholesterol, and triglycerides, without lowering cardio-protective HDL-cholesterol.²

Over the past two decades, American consumers have received significant information about the role of diet in reducing the risk of heart disease. Health claims on food

² Anderson JW, et al. Soy Protein Effects on Serum Lipoproteins: A Quality Assessment and Meta-Analysis of Randomized, Controlled Studies. *J Am Coll Nutr.* Apr 2011;30(2):79-91.

packages is just one source of such information. There is general consensus that a healthy diet, low in saturated fat and cholesterol and higher in lean protein sources, such as soy protein, can help to lower blood cholesterol and the risk of coronary heart disease. Science also supports that consumption of soluble fiber, plant sterols and stanols may have an effect as well.

Soyfoods are often low in saturated fat, are cholesterol-free, and contain high-quality protein, essential fatty acids, dietary fiber, and numerous other nutrients. As part of a healthy diet, soyfoods can replace less healthy foods that are high in saturated fat and cholesterol, thus enhancing their impact on cholesterol lowering. Incorporating plant-based soyfoods into the diet may also improve blood pressure and other coronary heart disease risk factors.

Finally, the American Heart Association reports that soyfoods should be considered beneficial because of their high content of polyunsaturated fats, fiber, vitamins, minerals and low content of saturated fat and no cholesterol.³

For media inquiries please contact the Page Schmid at press@soyfoods.org.

About Soyfoods Association of North America

The Soyfoods Association of North America is a non-profit trade association that has been promoting consumption of soy-based foods and beverage since 1978. The Soyfoods Association is committed to encouraging sustainability, integrity and growth in the soyfoods industry by promoting the benefits and consumption of soy-based foods and ingredients in diets. More information is available at www.soyfoods.org.

###

³ Circulation. 2006;113(1): 1-12.