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Soy Protein and the Heart Health Claim

The FDA's recent proposal to revoke its heart health claim for soy protein marks the first time the agency has moved to revoke a claim since it started approving such statements.

By Lauren R. Hartman, Product Development Editor

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For years, manufacturers of soy protein foods have been allowed to claim their products help reduce the risk of heart disease. But that came into question on Oct. 30, 2017, when the FDA proposed to revoke the claim, saying that the science doesn't appear to back it up.

Soy protein is easy to include as an added ingredient in processed foods for its clean, bland flavor and smooth texture. It provides amino acids and phytochemicals needed to help lower dietary cholesterol and has been shown to have a favorable impact. Yet some animal studies indicate soy isoflavones might increase the recurrence of breast cancer by promoting the growth of estrogen-sensitive cells.



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In early January, the FDA stated it was completing its evaluation of the scientific evidence between soy protein and coronary heart disease and was developing the final proposal – although the agency did extend the public comment period to March 19, in response to requests. According to industry figures FDA cited, the claim that soy protein can reduce heart disease appears on about 200-300 products in the U.S., including popular brands of soy milk.

While admitting there is some evidence soy protein can have a heart benefit, "the totality of current scientific evidence calls into question the certainty of the relationship," says Susan Mayne, director of the FDA's Center for Food Safety and Applied Nutrition. "Our review of that evidence has led us to conclude the relationship between soy protein and heart disease does not meet the rigorous standard for an FDA-authorized health claim."

Issued in 1999, the claim said soy protein included in a low saturated fat and low cholesterol diet may reduce the risk of coronary heart disease by lowering blood cholesterol levels. Soybean use soon rose, reports the USDA, in products like soy milk, tofu, edamame products and soybean oil.

According to the Hartman Group, heart health is the top health feature U.S. consumers look for when grocery shopping. In addition, 55 percent of consumers are trying to avoid or reduce saturated fat in their diet, and nearly 40 percent are trying to incorporate healthier fats such as polyunsaturated and monounsaturated fats.

No scientific consensus

If the agency does rescind the soy-heart health claim, food and beverage companies would be allowed to use a less rigorous qualified health claim, as long as they have sufficient evidence to support a link between eating soy protein and a reduced risk of heart disease. A "lower scientific standard of evidence" than the authorized health claim would let producers use language that explains that the evidence on the link is limited.

To use the qualified health claim on a product, manufacturers are asked to petition the FDA about the phrasing they want to use. There are no specific phrases that meet the FDA's criteria for a qualified health claim. Rather, they will be determined on a case-by-case basis, and the agency will decide what language is in line with available evidence.

The qualified claim for soy doesn't mean the FDA wants people to stop consuming soy, elaborated Douglas Balantine, director of the Office of Nutrition and Food Labeling. "The Dietary Guidelines clearly continue to advise the use of plant-based foods like soy as a replacement for foods higher in saturated fat, [and that is] one technique that would reduce the risk of heart disease."

Only a dozen such health claims to date have received the FDA's blessing. One example is the effect of calcium and vitamin D in lowering the risk of osteoporosis.

Costs associated with relabeling the 200-300 products currently making the health claim are estimated at between \$370,000 and \$860,000 upfront, according to a federal filing.

The American Heart Assn. (www.heart.org), which submitted a comment letter with the agency in 2007 to get soy's authorized claim revoked, says its position hasn't changed since then.

"We are on board with the FDA's proposal to revoke the soy protein and coronary heart disease health claim," says the AHA's Retha Sherrod, director of media advocacy. "Back in 2007, we urged them to take this action. One of the key reasons this is necessary is because we concur with the FDA's stance that the scientific evidence no longer supports a significant scientific agreement level health claim."

Though it frequently reviews the evidence that certain foods fight heart disease, the AHA found there wasn't enough evidence that soy lowers cholesterol so much that it reduces heart disease risk. "In the comment letter we are currently drafting on this proposal, we are asking the FDA to make it clear to the public why this claim is being

rescinded," Sherrod continues. "We don't want to unintentionally discourage consumers from using plant protein such as soy to replace animal protein that contains saturated fat."

Regarding the "qualified" health claim, Sherrod says, "If the FDA moves in that direction, we would be interested in reviewing the claim language to make sure consumers can understand the disclaimer or qualifying statement. We hope once the agency reviews the scientific evidence, as well as the comments, it will move forward and revoke the coronary heart disease health claim for soy."

Many public comments submitted to the Federal Register support the agency's proposed revocation. "There are many people who have borderline thyroid function for various reasons, and consuming soy products can make their situation worse," wrote one individual. "Soy appears to have thyroid-toxic effects, is also a goitrogen, and a common allergen," wrote another. Others remarked on the "pervasive" and "risky" use of soy in food products, including in infant formulas and animal feed.

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Soon after the FDA's proposal to revoke the claim was announced, the Soy Nutrition Institute (thesoynutritioninstitute.com) and the American Soybean Assn. (soygrowers.com) countered, pointing out that soy protein lowers blood cholesterol levels, based on years of scientific evidence and the conclusions of the FDA and health agencies in Canada and 11 other countries.

"In a time when heart disease is the No. 1 cause of death both in the United States and the world, we can't afford to discourage people from taking steps to improve their diets with heart-healthy ingredients," said Ron Moore, president of the American Soybean Assn. and an Illinois farmer. "There is still evidence that shows eating soy protein can help reduce the risk of heart disease, and while we are of course disappointed that FDA is looking at moving the health claim for these products from 'unqualified' to 'qualified,' it's important for consumers to remember that soy protein can be an important part of a heart-healthy diet."

The Soyfoods Assn. of North America (SANA, www.soyfoods.org) is concerned the FDA's proposal to modify the claim from unqualified to qualified will suggest a lower level of scientific consensus. "Numerous scientific studies published before and since the soy protein health claim was approved in 1999 consistently show soy protein lowers LDL-cholesterol, and the totality of the evidence supports continued approval of an unqualified claim," says executive director John Cox.

"Since the FDA first approved the soy protein and cardiovascular disease health claim, 12 other countries have reviewed the science and approved similar claims, including Health Canada as recently as 2015," he says. SANA advocated for the continuation of an unqualified claim. SANA and other organizations requested an extension of the comments period by 60 days, to give parties more time to comment on this important issue.

And the Soy Nutrition Institute (thesoynutritioninstitute.com), of which the United Soybean Board is a member, indicated that changing the claim to a qualified one would be confusing.

"It means that while the FDA believes the scientific evidence still supports consumption of soy protein as a way to lower blood cholesterol levels, it recognizes some inconsistencies in the results of recent clinical trials," the institute noted. "No adverse effects were observed in these studies. Such inconsistency is not at all unexpected, as there is no nutrition research area where clinical studies have produced entirely consistent findings."

"No one is saying soy is bad," argued Steve Nissen, a cardiologist at the Cleveland Clinic. "Can soy be part of a healthy diet? Of course it can. Just don't expect any magical benefits."

Soybean oil qualifies

Soybean oil will still be able to carry a qualified claim as being heart-healthy. Soy oil marketers, like those offering canola and olive oil, can label their products stating 1.5 tablespoons of soybean oil a day may reduce the risk of coronary heart disease when it replaces saturated fat and does not increase calories. The move follows a review in August of a petition filed by soybean oil producer Bunge Ltd. (www.bunge.com), which included a summary of human clinical studies from top nutrition researchers demonstrating the heart-health potential of soybean oil.

Seapoint Farms, which produces edamame snacks, dry-roasted seed, fruit and edamame mixes, frozen edamame and edamame pastas that are currently labeled with the heart-healthy logo, says a diet high in plant-based protein may improve heart health. "By swapping 10 percent of the calories from carbohydrates to lean protein, you may experience a 21 percent reduction in the risk of heart disease," the company says.

Lean protein can contribute to weight loss, the company adds. Shifting caloric intake to lean protein, such as its edamame products, has benefits. "It's also rich in iron and calcium and is low-calorie and gluten-free, making it a good fit for nearly anyone's diet," it says.

So for tofu, soy milk, edamame and other soy-containing products deemed healthy, they are; it's just that scientists disagree whether the protein they contain guards the heart as much as first thought. Still, the wording on soy product packaging will likely have to be changed.



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