

# SoyConnection

Health & Nutrition News About Soy

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## Soy Health Claims

**New Soybean Oil Claim  
Based on Strong Evidence**

**Soy Protein Claim  
Under FDA Review**



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# NEW SOYBEAN OIL HEALTH CLAIM BASED ON SOLID BODY OF EVIDENCE

*Editor's Note: The new soybean oil health claim was allowed in response to a petition submitted by Bunge Limited and is available on the FDA website. A letter of enforcement discretion from the FDA authorizing the new claim is also available on that site.*

By Guy Johnson, PhD

The U.S. Food and Drug Administration (FDA) vouched for the heart-health benefits of soybean oil in 2017 by acknowledging that there is sufficient “supportive scientific evidence” to authorize a new Qualified Health Claim (QHC) for soybean oil and certain foods made from it. Exact wording of the new claim reads:

*“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. To achieve this possible benefit, soybean oil is to replace saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of soybean oil.”*

## Foods eligible for the new claim

Soybean oil, including soybean oil that is sold as “vegetable oil,” is eligible to make the claim. The claim also applies to soybean oil-containing dressings for salads, margarines and other spreads as well as other products, as long as they contain at least five grams of soybean oil per Reference Amount Customarily Consumed (RACC) and meet certain other restrictions for saturated fat, cholesterol, sodium and minimum nutrient content.

The rationale for allowing eligible soybean oil-containing foods to make the claim if they contain five grams per RACC is to give consumers the flexibility to incorporate the minimum effective amount of soybean oil (about 1½ tablespoons or 20.5 grams per day) into a typical eating pattern of three meals per day, plus a snack.

## Scientific basis

The petition to the FDA cited 160 publications including controlled intervention studies, observational studies, review papers and meta-analyses as evidence that soybean oil has the potential to reduce the risk of coronary heart disease (CHD). This evidence fell into several categories:

Soybean oil has a favorable fatty acid distribution which is low in saturated fatty acids (SFA) (~15%), moderate in monounsaturated (MUFA) (~23%) and high in polyunsaturated (PUFA) (~57%) fatty acids. Approximately 12% of the PUFAs in soybean oil (~7% of total fatty acids) are in the form of omega-3 fatty acids (mostly  $\alpha$ -linolenic acid [ALA]). This fatty acid distribution makes soybean oil unique because it is a PUFA-dominant oil that is a meaningful source of omega-3 fatty acids; but has only about the same SFA content as olive oil.

The high PUFA content of soybean oil may be particularly important. The petition cited evidence from several controlled intervention studies<sup>1-5</sup> that showed including omega-6 PUFAs (primarily from soybean oil) in the diet of human subjects reduced the incidence of CHD in experiments that lasted between two and eight years. These experiments did not meet the rigor that FDA requires for the authorization of health claims, but they are unique in that very few experiments have been conducted among humans that measured the effect of long-term dietary fatty acid modification on the actual incidence of CHD. These experiments are one of the reasons why public health authorities, including the American Heart Association<sup>6</sup> and dietary guidance including the 2015–2020 *Dietary Guidelines for Americans*, have concluded there is somewhat stronger evidence for the cardioprotective effects of dietary PUFA compared to MUFAs.

The petition also presented emerging evidence to suggest that ALA reduces the risk of CHD in its own

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right, and therefore contributes uniquely to the cardioprotective properties of soybean oil. Although firm conclusions could not be drawn,<sup>7</sup> meta-analyses of observational studies were cited that concluded the intake of ALA is inversely associated with the incidence of CHD.<sup>8,9</sup> In addition, a meta-analysis of 14 intervention studies reported beneficial effects of this fatty acid on plasma fibrinogen and fasting blood glucose concentrations.<sup>10</sup>

Soybean oil also contains non-fatty acid components including vitamin E (mostly in the form of  $\gamma$ -tocopherol) and plant sterols<sup>11</sup> that may also contribute to its cardioprotective properties.

By far the most important area of evidence supporting the cardioprotective properties of soybean oil from a regulatory perspective was its ability to lower the concentration of total cholesterol (TC) and low-density lipoprotein cholesterol (LDL-C) when used as a replacement for dietary saturated fat without adversely affecting high-density lipoprotein cholesterol (HDL-C) or triglycerides (TG). The petitioner submitted 10 publications<sup>12–21</sup> that described 14 dietary interventions in which soybean oil was substituted for a diet higher in saturated fat. All but one of these studies<sup>14</sup> (which included two interventions) were classified as high or medium quality according to criteria published by FDA in its 2009 document entitled, “Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims—Final.” Nine of the 12 interventions from the high and medium quality studies reported that a soybean oil-containing diet resulted in significantly lower concentrations of both TC and LDL-C compared to a higher saturated fat control diet.

However, FDA’s rigorous review of these studies disqualified four of them due to what it deemed inappropriate statistical analysis,<sup>12</sup> inadequate control group,<sup>14</sup> insufficient fatty acid intake data,<sup>15</sup> and data derived from a subset of a previously published study.<sup>18</sup> Therefore, the final evaluation of the proposed claim was based on eight interventions described in the six remaining publications.<sup>13,16,17,19–21</sup> Six of the eight comparisons in these studies reported that soybean oil statistically significantly lowered both TC and LDL-C compared to a control diet higher in saturated fatty acids.

The petitioner also submitted a large Costa Rican case-control study to substantiate the proposed claim.<sup>22</sup> This study reported that palm oil users were more likely

to have a myocardial infarction (MI) than users of soybean oil (adjusted odds ratio = 1.33; 95% confidence interval: 1.08–1.63) based on 2,111 case-control pairs (mean age = 58 years) who were survivors of a first acute MI.

The FDA considered all of this evidence and decided to authorize claim language that is stronger than any of the other oils that currently have a QHC. This decision was prompted by the consistency of results from the controlled intervention studies as well as alignment with the available observational data.

Specifically, FDA agreed with the qualifying language proposed by the petitioner—“Supportive, but not conclusive scientific evidence suggests . . .” This phrase is less restrictive than the qualifying language already stipulated for olive oil and canola oils (i.e., “Limited and not conclusive scientific evidence suggests . . .”) and much less restrictive than that for corn oil (i.e., “Very limited and preliminary scientific evidence suggests . . .”).

### Qualified vs. unqualified health claims

The perception by some that QHCs should not be taken seriously because they are based on less scientific evidence than unqualified health claims is an oversimplification. The regulatory standard for an unqualified claim is “Significant Scientific Agreement” (SSA) among experts qualified by scientific training and experience to evaluate such claims

(21 CFR §101.14[c]). The FDA requires a high degree of consistency among a large number of high quality studies conducted among many participants before it agrees that the SSA standard has been met. In fact, only five such claims have been approved since the enactment of the Nutrition Labeling and Education Act of 1990: Folic acid and neural tube defects; noncariogenic sweeteners and dental caries; soluble fiber and risk of CHD; plant sterol/stanol esters and risk of CHD; and soy protein and risk of CHD. The latter claim is currently being re-evaluated by the FDA as discussed in another article in this issue.

On the other hand, 23 QHCs have been authorized based on varying degrees of scientific evidence. The scientific veracity of these claims can be determined from the qualifying language that has been stipulated. For example, claims with less restrictive language



such as that for nuts and reduced risk of CHD—“Scientific evidence suggests but does not prove . . .” or for omega-3 fatty acids and reduced risk of CHD—“Supportive but not conclusive research shows . . .” are based on a considerable amount of science (as is the new claim for soybean oil.) However, QHCs with severe qualifying language are based on considerably less scientific evidence. Examples of such claims include, “FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain,” or “Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.” Health professionals have an opportunity to use qualifying language to help consumers understand the relevance of such claims.

## Conclusions

The new QHC for soybean oil is among the strongest of such claims approved by the FDA to date. This outcome reflects the strength of the scientific evidence attesting to the cardioprotective protective properties of this commonly used oil, and is consistent with recommendations in the 2015–2020 *Dietary Guidelines for Americans* and those from other public health authorities. The availability of this claim allows soybean oil and certain soybean oil-containing foods to use

heart-shaped vignettes in labeling and promotional materials, and offers incentives for the food industry and other stakeholders to educate consumers about the benefits of this heart-healthy oil. 🍷

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# SOY PROTEIN HEALTH CLAIM: WHERE DOES THE EVIDENCE STAND?

By Mark Messina, PhD, MS

Meta-analyses of the clinical data consistently show that soy protein lowers circulating LDL-cholesterol (LDL-C) levels.<sup>1-10</sup> The most recent meta-analysis demonstrating this finding to be the case was published in 2015.<sup>6</sup> The first one was published in 1995.<sup>11</sup> Four years later, after conducting its own analysis of the literature, the U.S. Food and Drug Administration (FDA) authorized a health claim for soy protein and reduced risk of coronary heart disease. Since 1999, similar claims have been approved in 11 other countries;<sup>12</sup> the most recent country to do so was Canada in 2015.<sup>13</sup>



Nevertheless, in December of 2007, the FDA indicated its intention to reevaluate evidence in support of the soy protein health claim. On October 31, 2017 the FDA announced that it is proposing to revoke the existing heart health claim. The current claim is an “unqualified” claim which indicates that the very rigorous significant scientific agreement standard has been met in support of the hypocholesterolemic effects of soy protein. The FDA announcement suggested that a qualified claim could be approved if the existing claim is revoked. Not surprisingly, a qualified claim requires less support than an unqualified one. A total of 23 qualified claims exist whereas there are only 12 unqualified claims and only five of those have been approved since the enactment of the Nutrition Labeling and Education Act of 1990.

It isn't precisely clear why the FDA undertook its review of the soy protein health claim, although a 2006 science advisory from the American Heart Association (AHA) questioning the hypocholesterolemic effects of soy protein may have been a factor.<sup>14</sup> The AHA found that soy protein lowered LDL-C only by about three percent. However, the AHA didn't actually conduct a meta-analysis of the data. When such an analysis was done four years later, Jenkins et al.<sup>1</sup> found that soy protein lowered LDL-C by 4.3% using the same 22 studies the AHA used for its estimate. This magnitude of reduction is similar to that of soluble fiber, which has an *unqualified* health claim. The 4.3% reduction noted by Jenkins et al.<sup>1</sup> is much lower than the initial estimates reported by Anderson et al. in 1995,<sup>11</sup> but it has been known for some time

that the hypocholesterolemic effect of soy protein is more modest than initially thought.<sup>15</sup>

In the October announcement, the FDA cited inconsistency of the data as the reason to propose revoking the existing soy protein health claim. Some inconsistency is not at all unexpected as there is probably no nutrition area that has been rigorously investigated where clinical studies have produced entirely consistent findings. This fact is true even for the effects of sodium on blood pressure<sup>16,17</sup> and calcium on bone mineral density.<sup>18,19</sup> Nevertheless, reducing the intake of sodium is routinely recommended by health professionals as a means of reducing the risk of heart disease and increasing calcium intake as a means of preventing osteoporosis.

The FDA found that only 19 of 46 studies showed soy protein statistically significantly lowered LDL-C. However, in nine of those 46 studies, the amount of soy protein ingested by study participants was <25 g/day—the threshold intake established by the FDA for the cholesterol reduction claim. Therefore, the results of these studies are of questionable relevance. Furthermore, a reasonable argument can be made that the binary approach (i.e., an individual study was judged to be either supportive or not supportive) adopted by the FDA that lacked a statistical analysis of the data, isn't the optimal approach for evaluating the evidence. Before making a final decision about the claim, the FDA will consider any comments submitted during the 75-day comment period.

Regardless of what the FDA decides, from a practical perspective, adding soyfoods to the diet as a means of reducing coronary heart disease (CHD) risk makes sense. To markedly reduce cholesterol levels and CHD risk requires adopting a comprehensive dietary approach. At the very least, soybeans provide high quality protein<sup>20</sup> that considerable evidence suggests lowers cholesterol as well as heart-healthy fat.<sup>21</sup> It is not surprising that soy has been a key component of comprehensive dietary approaches that have led to dramatic reductions in cholesterol.<sup>22-27</sup> 🍲

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