



Brussels, March 2018  
Dockets Management Staff  
U.S. Food & Drug Administration  
Docket No. FDA-2017-N-0763

**Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease (CHD)**

**Re: Proposed Rule, Soy Protein and Coronary Heart Disease**

The European Natural Soy and Plant-based food Manufacturers Association (ENSA) and the European Vegetable Protein Association (EUVEPRO), as key stakeholder associations in soyfoods and in soy protein products, call for the continued approval of a “Soy Protein and Coronary Heart Disease” authorized health claim in the United States. Our members are internationally operating companies, ranging from large corporations to small and medium sized businesses. We consider that FDA guidance is very important in a global context, and its decisions have repercussions on other parts of the world.

On December 21, 2007, the FDA published a notice ([72 FR 72738](#)) of intent to reevaluate the scientific evidence for health claims, including the authorized health claim for soy protein and reduction in the risk of Coronary Heart Disease (§ 101.82).

Similar reviews have taken place in other countries e.g. in 2015 Health Canada reviewed the scientific data and approved a health claim.

The FDA stated that from their review there is some scientific evidence of a link between soy protein consumption and cholesterol reduction, but this does not meet the significant scientific agreement standard for an authorized health claim. The FDA therefore proposes to revoke the authorized health claim and potentially issue a statement regarding the use of a qualified health claim.

Scientifically establishing a direct connection between a specific food and a disease is extremely difficult, considering that foods are not medicines. While soy protein may not reduce blood cholesterol levels as significantly as certain medications (e.g. statins), the totality of the scientific evidence <sup>1-6</sup> continues to support the consensus that is the basis for the FDA Health Claim on Soy Protein and Coronary Heart Disease risk reduction.

The benefits of lowering LDL-cholesterol (by 3- 6%)<sup>4,6</sup> and total cholesterol without lowering HDL cholesterol, present a clinically relevant dietary intervention that can be a part of a healthy diet. This is relevant from a population perspective since each 1% reduction in LDL cholesterol results in a reduction of 1-3% in CHD- related adverse events <sup>9</sup>.

There are other food components from plant sources that are recognized for decreasing risk factors (LDL- cholesterol reduction) associated with coronary heart disease. Unsurprisingly, similar inconsistencies can be found in the data evaluating the cholesterol-reducing potential of other food components such as oat and barley  $\beta$ -glucan or psyllium<sup>7, 8,10</sup>. Note also that these claims are based on far fewer studies than exist for soy and that the observed magnitude of potential effect is similar to soy. Comparatively, soy protein indeed appears to be as effective as  $\beta$ -glucan or psyllium in lowering cholesterol to an extent that has clinical relevance.

The FDA proposes that a benefit in changing this rule would be better information for consumers and it would stimulate consumption of other products that do retain an authorized health claim. Heart disease still remains the leading cause of death globally for both men and women. In light of the scientific evidence and clinical relevance described above, discouraging consumption of soyfoods would potentially cause confusion among consumers, by denying important information about the health benefits of soy.

EUVEPRO and ENSA therefore call on the FDA to maintain the authorized health claim that describes the connection between soy protein and the reduction of risk of coronary heart disease, which is confirmed by the totality of published scientific evidence.

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<p><b>ENSA Secretariat</b>  <b>Vinciane Patelou</b>  Tel:+ 32 2 213 13 16  Email: <a href="mailto:secretariat@ensa-eu.org">secretariat@ensa-eu.org</a>  Website: <a href="http://www.ensa-eu.org">www.ensa-eu.org</a></p>	<p><b>EUVEPRO Secretariat</b>  <b>Susanne Meyer</b>  Tel : +32 2 761 16 50  Email: <a href="mailto:euvepro@kellencompany.com">euvepro@kellencompany.com</a>  Website: <a href="http://www.euvepro.eu">www.euvepro.eu</a></p>
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## References

1. 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.
2. Jenkins, D.J., et al., Soy protein reduces serum cholesterol by both intrinsic and food displacement mechanisms. *J Nutr*, 2010. 140(12): p. 2302S-2311S.
3. Zhan, S. and S.C. Ho, *Meta-analysis of the effects of soy protein containing isoflavones on the lipid profile.* *Am J Clin Nutr*, 2005. 81(2): p. 397-408.
4. Harland, J.I. and T.A. Haffner, *Systematic review, meta-analysis and regression of randomised controlled trials reporting an association between an intake of circa 25 g soya protein per day and blood cholesterol.* *Atherosclerosis*, 2008. 200(1): p. 13-27.
5. Benkhedda, K., et al., *Food Risk Analysis Communication. Issued By Health Canada's Food Directorate. Health Canada's Proposal to Accept a Health Claim about Soy Products and Cholesterol Lowering.* *Int Food Risk Anal J*, 2014. 4:22 | doi: 10.5772/59411.
6. Tokede, O.A., et al., *Soya products and serum lipids: a meta-analysis of randomised controlled trials.* *Br J Nutr*, 2015. 114(6): p. 831-43.
7. Ho HV, Sievenpiper JL, Zurbau A, et al. The effect of oat beta-glucan on LDL-cholesterol, non-HDL-cholesterol and apoB for CVD risk reduction: a systematic review and meta-analysis of randomised-controlled trials. *Br J Nutr.* 2016;116:1369-82.
8. Brown L, Rosner B, Willett WW, Sacks FM. Cholesterol-lowering effects of dietary fiber: a meta-analysis. *Am J Clin Nutr.* 1999;69:30-42.
9. Law, M. R., N. J. Wald, and S. G. Thompson. "By how much and how quickly does reduction in serum cholesterol concentration lower risk of ischaemic heart disease?" *BMJ.* 308.6925 (1994): 367-72.
10. Commission regulation (EU)1048/2012 of 08/11/2012 and 1160/2011 of 14/11/2011

## About ENSA

Established in January 2003, the ENSA represents the interests of natural soy and plant-based food manufacturers in Europe. The term "natural" refers to the production process used by ENSA members to produce food using whole soybeans. Soy food products from ENSA members are produced without any use of GM (genetically modified) material or GM beans.

ENSA is an association of internationally operating companies, ranging from large corporations to small, family-owned businesses with an annual turnover of €0.7 billion. Since its establishment in 2003, ENSA has been raising awareness about the role of soy and a plant-based diet in moving towards more sustainable food production and consumption patterns.

For more information about ENSA, please visit [www.ensa-eu.org](http://www.ensa-eu.org) or contact the ENSA Secretariat.

## About EUVEPRO

EUVEPRO is the European Vegetable Protein Association, representing the interests of manufacturers and distributors of plant protein ingredients for human consumption (food) in the European Union.

Founded in 1977, EUVEPRO has been the recognised voice of the vegetable protein production and commercialisation industry, and is valued as a reliable partner by both the EU institutions and stakeholder associations of related industries. EUVEPRO promotes the recognition in European, national and international legislation, of vegetable protein products as foodstuffs and ingredients in their own right forming part of the normal diet of EU consumers.