



## ENSA statement on the proposal of the US FDA to revoke the soy protein health claim

**Brussels, 31 October 2017** – The US Food and Drug Administration (FDA) announced its proposal for a rule to revoke the authorized health claim regarding the relationship between soy protein and reduction of risk of coronary heart disease. The FDA also stated that it will allow a qualified health claim as long as there is sufficient evidence to support it. Qualified health claims are approved and supported by scientific evidence, however they do not meet the significant scientific agreement standard that is required for authorized health claims, which is different to the European context.

A qualified US health claim would continue to support and would not detract from the health claim recently approved by [Health Canada](#) regarding the relationship between soy protein and reduction in blood cholesterol.

Indeed, meta-analyses published over the last years consistently demonstrate the hypocholesterolemic effect of soy protein and confirm the scientific basis for a qualified health claim.<sup>1 2 3 4 5</sup>

Moreover, soy foods also have a beneficial fatty acid composition, are low in saturated fat and contain polyunsaturated fat, which makes them fit in a healthy and balanced diet.<sup>6</sup>

In July 2017, the FDA approved also a [qualified health claim](#) for soybean oil and reduction of risk of coronary heart disease.

The American Heart Association (AHA) recently published a review regarding dietary fats and cardiovascular diseases.<sup>7</sup>

In its conclusions, AHA strongly agrees that reducing the consumption of saturated fats and replacing them with unsaturated fats, especially polyunsaturated fats, lowers the incidence of cardiovascular diseases. The replacement of saturated with unsaturated fats lowers LDL-cholesterol, a cause of atherosclerosis. The AHA recommends to make this shift as part of an overall healthy diet.

In countries, such as Canada and the USA, mechanisms are in place to communicate more effectively to consumers the health benefits of foods, such as the support that soy protein can provide towards maintaining healthy cholesterol levels.

For this reason, ENSA and EUVEPRO believe it is important for the US FDA to value the existing scientific evidence by approving a qualified health claim.

At the same time, ENSA and EUVEPRO regret that in Europe, the EFSA approach to evaluating health claim applications still fails to accommodate grades of scientific evidence that are applicable to real foods and that the EU regulatory framework does not envisage the adoption of qualified health claims.

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<sup>1</sup> Tokede OA, Onabanjo TA, Yansane A, Gaziano JM, Djousse L. Soya products and serum lipids: a meta-analysis of randomised controlled trials. *Br J Nutr* 2015;114:831-43.



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- <sup>2</sup> Yang B, Chen Y, Xu T et al. Systematic review and meta-analysis of soy products consumption in patients with type 2 diabetes mellitus. *Asia Pac J Clin Nutr* 2011;20:593-602.
- <sup>3</sup> Harland JJ, Haffner TA. Systematic review, meta-analysis and regression of randomised controlled trials reporting an association between an intake of circa 25g soya protein per day and blood cholesterol. *Atherosclerosis* 2008;200:13-27.
- <sup>4</sup> Reynolds K, Chin A, Lees KA, Nguyen A, Bujnowski D, He J. A meta-analysis of the effect of soy supplementation on serum lipids. *Am J Cardiol* 2006;98:633-40.
- <sup>5</sup> Anderson JW, Bush HM. Soy protein effects on serum lipoproteins: a quality assessment and meta-analysis of randomized, controlled studies. *J Am Coll Nutr* 2011;30:79-91.
- <sup>6</sup> Jenkins DJ, Mirrahimi A, Srichaikul K et al. Soy Protein Reduces Serum Cholesterol by Both Intrinsic and Food Displacement Mechanisms. *J Nutr* 2010;140:2302S-11S.
- <sup>7</sup> Sacks FM, Lichtenstein AH, Wu JHY et al. Dietary Fats and Cardiovascular Disease: A Presidential Advisory From the American Heart Association. *Circulation* 2017;CIR.

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