

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to soy protein and reduction of blood cholesterol concentrations pursuant to Article 14 of the Regulation (EC) No 1924/2006¹

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following an application from HarlandHall Ltd. on behalf of the Soya Protein Association (SPA), the European Vegetable Protein Federation (EUVEPRO), and the European Natural Soyfood Manufacturers Association (ENSA) submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver a scientific opinion on soy protein and reduction of blood cholesterol concentrations.

The scope of the application was proposed to fall under a health claim referring to reduction of a disease risk.

The food constituent that is the subject of the health claim is soy protein, i.e. the protein component of the soybean *Glycine max.* Soy protein occurs in whole soy bean products that have undergone minimal processing such as toasting, roasting, boiling or soaking yielding products such as boiled soy bean, soy drink, soy cream, soy cheese, soy yoghurts, tofu, soy meat replacer and edamame. Alternatively, it is present in soy bean extracts such as soy protein isolate (SPI), soy protein concentrate (SPC) or soy protein flour (SPF) or textured soy protein derived from them. The starting material from which these three products derive is hulled, defatted soybean flake, which contains approximately 50 % protein by weight. The products typically contain the following amount of protein: SPF-hulled and defatted 52-54 %; SPC 65-72 %; SPI 90-92 %; textured soya protein 40-90 %; full fat soy flour (SF)-hulled full fat soybean 40 %. In addition to protein, SPI, SPC, SPF and soy foods contain other food constituents which might exert an effect on blood cholesterol (e.g., fat and fatty acids, including polyunsaturated fatty acids, fibre, isoflavones). The applicant has clarified that the protein component of soy is the food constituent which is proposed for the claimed effect. Protein can be measured in soy protein-containing products by established methods. The Panel considers that the food constituent, soy protein, which is the subject of the health claim, is sufficiently characterised.

1 On request from HarlandHall Ltd, Question No EFSA-Q-2009-00672, adopted on 9 July 2010.

2 Panel members: Carlo Virginio Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

3 Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Virginio Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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The claimed effect is “reduces blood cholesterol and may therefore reduce the risk of (coronary) heart disease”. The target population is healthy adults. The Panel considers that lowering LDL-cholesterol is a beneficial physiological effect by reducing the risk of coronary heart disease.

The applicant provided 40 studies in humans, 32 of which were randomised controlled trials and eight were observational studies. The applicant also provided 10 meta-analyses and a review of possible mechanisms by which soy protein might exert the claimed effect.

The Panel notes that most of the studies selected by the applicant were not appropriately designed to test the effect of soy protein *per se*, but were conducted using either soy protein isolate (SPI) or soy foods which contain, in addition to protein, other constituents which have been reported to exert an effect on blood cholesterol in human intervention studies (e.g., fat and fatty acids, including polyunsaturated fatty acids, soy fibre, soy isoflavones). This was the case for a meta-analysis of a subset, comprising 23 studies, of the 32 RCTs submitted by the applicant.

Following a request to provide studies which could show the effect of protein *per se*, the applicant re-assessed the results of the meta-analysis by considering only the studies performed using soy protein isolate and by taking into account study quality (high, medium and low quality). The Panel considers that the design of the studies on SPI rated by the applicant as having medium or low quality does not address the effects of the food constituent that is the subject of the health claim (the protein component of soy alone) on LDL-cholesterol concentrations.

Four intervention studies identified as high quality by the applicant were included in a new meta-analysis which aimed to address the effects of soy protein *per se* on blood cholesterol concentrations.

One randomised double blind controlled parallel study was designed to assess the effects of soy protein isolate with and without isoflavones on blood lipids. There was a statistically significant dose-response relationship between the intake of isoflavones and the decrease in total and LDL-cholesterol concentrations. The Panel notes that, in the context of this study, an effect of soy isoflavones on blood cholesterol concentrations was observed and therefore considers that the inclusion of the three study arms receiving isoflavone-containing soy protein isolate in the new meta-analysis provided by the applicant is not appropriate. The Panel notes that this study does not support an effect of the protein component of soy on LDL-cholesterol concentrations.

One study was designed to assess the effects of isoflavone-containing and of isoflavone-free soy protein isolate on markers of cardiovascular risk, including blood lipids. No significant differences were observed between the soy protein isolate with no isoflavones (or the soy protein isolate with isoflavones) and the control group with respect to changes in total or LDL-cholesterol concentrations during the study. The Panel notes that this study does not support an effect of the protein component of soy on LDL-cholesterol concentrations.

One study was designed to assess the effects of soy protein isolate containing isoflavones versus cow’s milk protein on blood lipids. No significant differences between the SPI and the control group were observed for changes in any of the cholesterol fractions during the study. The Panel notes that this study was not designed to assess the effects of the protein component of soy on LDL-cholesterol concentrations but, nevertheless, does not support an effect of the protein component of soy on LDL-cholesterol concentrations.

Another randomised double blind controlled parallel study was designed to assess the effects of isoflavone-containing soy protein isolate on LDL-cholesterol concentrations. A statistically significant decrease in total and LDL-cholesterol concentrations was reported in the SPI group compared to placebo at week 6 but not at week 12. The Panel notes that this study was not designed to assess the effects of the protein component of soy on LDL-cholesterol concentrations but, nevertheless, does not support an effect of the protein component of soy on LDL-cholesterol concentrations.

The Panel considers that results from these four intervention studies identified by the applicant as being controlled for the macronutrient composition of the test products do not support an effect of the protein

component of soy on LDL-cholesterol concentrations.

In weighing the evidence, the Panel took into account that the results from the four human intervention studies identified by the applicant as being controlled for the macronutrient composition of the test products do not support an effect of the protein component of soy on LDL-cholesterol concentrations, and that the proposed mechanism by which the protein component of soy would exert the claimed effect is not supported by available scientific evidence.

The Panel concludes that a cause and effect relationship has not been established between the consumption of soy protein and the reduction of LDL-cholesterol concentrations.