



Statement on the authorization of a health claim about soy protein and blood cholesterol lowering by the Health Canada's Food Directorate

Brussels 9 June 2015 - The European Natural Soyfoods Manufacturers Association (ENSA) and the European Vegetable Protein Federation (EUVEPRO) welcome the decision of the Health Canada's Food Directorate to authorise a 'Health claim about Soy Protein and Cholesterol Lowering'.¹ According to Health Canada's Food Directorate, scientific evidence exists to support this claim.

ENSA and EUVEPRO regret that the European Food Safety Authority (EFSA) rejected a similar application for a health claim on soy protein and reduction in blood LDL-cholesterol, despite numerous studies and meta-analyses demonstrating such a cholesterol lowering effect.

Recognition of the relevance of the studies identified by ENSA and EUVEPRO

The Health Canada's Food Directorate based its decision on literature research covering a period from 1980 to March 2010. Based on our analysis, more than 60% of the studies used by ENSA and EUVEPRO in its rejected application by EFSA in 2012 were considered by Health Canada's Food Directorate as scientifically sound and provided sufficient evidence to establish a cause and effect relationship between soy protein and reduction in blood cholesterol.

Broad understanding of soy protein's benefits on health

The Health Canada's Food Directorate considered that all foods containing soy protein such as isolated soy protein (ISP), soy protein concentrate (SPC), textured soy protein (TSP) and soy flour (SF) but also soyfoods made from the whole soybean are eligible for the health claim. Food containing at least 6g of soy protein per reference amount and per serving as well as complying with a list of conditions regarding the presence of recommended nutrients, maximum levels of cholesterol, alcohol, etc., are allowed to bear the health claim. ENSA welcomes the recognition of the benefits of soy protein to human health. Unfortunately EFSA adopted a different approach in 2012.

EFSA has rejected all the submitted meta-analyses, which demonstrate a significant cholesterol-lowering effect of soy protein, by dismissing them as irrelevant or inconclusive.

Overall we consider that EFSA failed to review the totality of the relevant data. The Health Canada's Food Directorate has clearly come to a different conclusion, stating in their summary report that "scientific evidence exists to support a claim about soy protein and blood cholesterol lowering".

Despite there being no EU cholesterol reduction claim for the protein in soyfoods, soyfoods are also low in saturated fat, and EFSA has acknowledged that low saturated fat foods are beneficial in



maintaining healthy blood cholesterol levels, which was the basis for the authorization of the health claim 'Reducing consumption of saturated fat contributes to the maintenance of normal blood cholesterol levels'.

Thanks to their low saturated fat content, soyfoods can therefore play a very important dietary role in helping to maintain healthy blood cholesterol levels, and have long been recognised as part of a healthy balanced diet.

Conclusion

ENSA and EUVEPRO welcome the decision of the Health Canada's Food Directorate recognising the scientific evidence to support the health claim that consumption of soy protein helps to lower blood cholesterol levels.

ENSA and EUVEPRO regret that European consumers cannot benefit from the same information as Canadian consumers since the European Food Safety Authority rejected an equivalent health claim in Europe despite numerous studies and meta-analyses demonstrating the cholesterol lowering effect of soy protein.

At a time when the EU and national governments call upon the food industry to innovate and find better formulations for healthier food products, this particular rejection by EFSA denies European consumers the benefit of a claim that has been approved for use, on the basis of sound science, in many countries outside the EU, which now also includes Canada.

In the light of this development, ENSA and EUVEPRO keep in mind the possibility of submitting a new application to EFSA, whilst continuing to highlight the divergent scientific opinion in Europe.

¹ Summary of Health Canada's Assessment of a Health Claim about Soy Protein and Cholesterol Lowering: http://www.hc-sc.gc.ca/fn-an/alt_formats/pdf/label-etiquet/claims-reclam/assess-evalu/Sum-Assessment-Soy-March-2015-eng.pdf

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