



Maisons-Alfort, 23 April 2010

OPINION

of the French Food Safety Agency related to the effect of soy protein extracts on cholesterolaemia

THE DIRECTOR GENERAL

1. REVIEW OF THE REQUEST

The French Food Safety Agency (AFSSA) issued an internal request for an assessment of the effect of soy protein extracts on cholesterolaemia.

2. BACKGROUND

At various times, the French Food Safety Agency (AFSSA) has issued Opinions related to claims made for the cholesterol-lowering effect of soy protein. In March 2005, it published a report entitled “*Sécurité et bénéfices des phyto-estrogènes apportés par l'alimentation – recommandations*” [Safety and Benefits of Phytoestrogens in Food – Recommendations], in which this issue was addressed. More recently, as part of the report “*Apport en protéines et en acides aminés: consommation, qualité, besoins et recommandations*” [Protein and amino acid intake: consumption, quality, requirements and recommendations] (AFSSA, 2007), AFSSA specified its analysis.

Given the evolution of the scientific data, a summary of the effect of soy protein extracts on cholesterolaemia was considered to be necessary.

3. METHOD OF ASSESSMENT

An internal assessment of the case was conducted by the Nutrition and nutritional risks assessment unit (UENRN) in consultation with the Scientific Panel (CES) on ‘Human nutrition’.

4. DISCUSSION

Soy proteins (whose exact composition is not always known) refer, in the vast majority of cases, to soy protein isolates (SPIs) which contain at least 90% pure proteins (*Codex Alimentarius*, 1989). They may contain isoflavones, among other substances (Anderson & Wolf, 1995; Francis *et al.*, 2002).

Observational studies in humans have shown negative correlations between the consumption of soy-based products and total and LDL blood cholesterol levels (Ho *et al.*, 2000; Nagata *et al.*, 1998). These observations have given rise to an interest in the potentially cholesterol-lowering effect of some soy compounds, including protein substances used in numerous intervention studies. Some of them show a significant reduction in LDL cholesterol in hypercholesterolaemic subjects receiving soy-based vegetable protein substances (Tonstad *et al.*, 2002; Teixeira *et al.*, 2000; Gardner *et al.*, 2007; Yang *et al.*, 2007 (a); Taku *et al.*, 2007). Other studies do not confirm these results and indicate instead that soy proteins have no beneficial effect on LDL cholesterol (Thorp *et al.*, 2008; Cuevas *et al.*, 2003; Taniguchi *et al.*, 2008) nor on other cardiovascular disease risk factors (Sacks *et al.*, 2006). Moreover, soy-based vegetable protein substances do not confer any additional benefit in hypercholesterolaemic subjects following a

low-fat, high-fibre diet (Cuevas *et al.*, 2003; West *et al.*, 2005). Lastly, when a cholesterol-lowering effect is observed, its amplitude is limited (between 3% and 6% reduction in LDL cholesterol) (Wang *et al.*, 2004; Sacks *et al.*, 2006; Harland & Haffner, 2008).

The effects on cholesterolaemia after consuming soy products, when they are observed, could be due to the combined and misidentified action of various compounds of this plant (Harland & Haffner, 2008; Sirtori *et al.*, 2009; Taku *et al.*, 2007; Anderson & Wolf, 1995; Francis *et al.*, 2002). Thus, the possibility that a soy compound other than proteins may have contributed to the observed effect cannot be ruled out (Sacks *et al.*, 2006). Furthermore, assuming that there is evidence of a cholesterol-lowering effect of soy protein extracts, the possible mechanisms of action have not been identified (AFSSA, 2008; Xiao *et al.*, 2008). In addition, it appears that the cholesterol-lowering effect of products containing soy proteins, when it is observed, is not correlated with the level of soy protein intake (Harland & Haffner, 2008). One study suggests that inflammation can aggravate hypercholesterolaemia (elevated LDL cholesterol) in moderately hypercholesterolaemic adults following a low fat diet, with soy proteins having no effect on this cholesterolaemia (Hilpert *et al.* 2005).

In addition, other animal or vegetable proteins (proteins from some lean meats, fish proteins, milk serum proteins, gluten proteins, rice proteins) might have a cholesterol-lowering effect, according to some authors (Nagaoka *et al.*, 1991; Nagaoka *et al.*, 1992; Zhang & Beynen, 1993; Anderson *et al.*, 1999; McCarty, 1999; Washburn *et al.*, 1999; Tomotake *et al.*, 2000; Wang *et al.*, 2004; Wergedahl *et al.*, 2004; Zhan & Ho, 2005; Choi *et al.*, 2005; Mayilvaganan *et al.*, 2004; Debry, 2004a; Debry, 2004b; Aziz *et al.*, 2008; Yang *et al.*, 2007(b)). These results would suggest a lack of specificity of soy proteins in lowering cholesterolaemia.

5. CONCLUSION

A review of the literature reveals controversy concerning the effect of soy protein products on lowering cholesterolaemia (total cholesterol and LDL cholesterol levels). Moreover, when a cholesterol-lowering effect is observed, the data do not enable scientific consensus to be reached on the compounds responsible; in addition, assuming that there is evidence of a specific cholesterol-lowering effect of soy protein extracts, the mechanisms of action involved are unknown.

Thus, although non-specific cholesterol-lowering effects of certain products made from soy proteins are sometimes observed, AFSSA considers that the link between consumption of soy vegetable proteins and reduction of cholesterol levels has not been established in humans to date.

The potential cholesterol-lowering effects of soy protein-based products should be evaluated on a case-by-case basis, subject to the submission of data that enable the compounds and mechanisms of action involved to be accurately identified.

The Director General

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KEYWORDS

Keywords: isoflavones, soy proteins, total cholesterol, LDL cholesterol.

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