

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to oat beta-glucan and lowering blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Following an application from CreaNutrition AG submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to oat beta-glucan and “can actively lower/reduce blood LDL and total cholesterol”.

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

The food constituent, which is the subject of the health claim, is oat beta-glucan. Beta-glucans are non-digestible non-starch polysaccharides composed of glucose molecules in long linear polymers. The molecular weight of oat beta-glucan in commercially available processed food preparations ranges from about 100 kDa to 2000 kDa. Oat beta-glucan occurs naturally in the bran of oats and is measurable in foods by established methods. This opinion applies to oat beta-glucan naturally present in foods and those forms added to foods. The Panel considers that the food constituent, oat beta-glucan, which is the subject of the health claim, is sufficiently characterised.

The claimed effect is “oat beta-glucan can actively lower/reduce blood LDL and total cholesterol”. The applicant specified the target population as the general population, and in particular people with increased risk of hypercholesterolaemia. The Panel considers that lowering blood LDL-cholesterol concentrations is a beneficial physiological effect by decreasing the risk of coronary heart disease.

---

1 On request from the Competent Authority of the United Kingdom following an application by CreaNutrition AG, Question No EFSA-Q-2008-681, adopted on 12 November 2010.

2 Panel members: Carlo 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](mailto:nda@efsa.europa.eu)

3 Acknowledgement: The Panel wishes to thank Mariette Gerber, Antti Aro and the members of the Working Group on Claims: Carlo 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 for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to oat beta-glucan and lowering blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(12):1885. [15 pp.] doi:10.2903/j.efsa.2010.1885. Available online: [www.efsa.europa.eu/efsajournal.htm](http://www.efsa.europa.eu/efsajournal.htm)

The applicant identified a total of 22 references as being pertinent to the health claim. These references included three meta-analyses (one of which was unpublished) and 19 randomised controlled trials (three of which were unpublished).

The Panel has already issued a favourable opinion on beta-glucans of various sources, including oats, and maintenance of normal blood cholesterol concentrations pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

The first meta-analysis comprised 12 studies which included 1063 subjects. Study populations were both normo- and hypercholesterolaemic, with an age range from 20 to 73 years. The mean baseline blood cholesterol concentrations ranged from 4.6 to 7.1 mmol/L. The estimated daily consumption of oat beta-glucan amounted to 1.1-7.6 g/d, with a mean dosage of 3.7 g/d. The sources of oat beta-glucan included oat bran, oat meal and rolled oats, which were consumed as breakfast cereals, biscuits, bread, muesli, muffins, and powders. The intervention periods of the studies varied from 2.5 to 12 weeks, with a mean intervention period of 5.5 weeks. A summary effect size for change in blood total cholesterol concentrations of -0.13 mmol/L (95 % CI: -0.19, -0.07) was calculated.

The second meta-analysis comprised 25 studies on oat products and included 1600 subjects. Study populations (age range from 26 to 61 years) were healthy populations, subjects with hyperlipidaemia, and diabetic subjects. The amount of oat beta-glucan ranged from 1.5 to 13 g/d with a mean of 5 g/d. The intervention periods of the studies varied from 2 to 12 weeks, with a mean intervention period of 5.6 weeks. The sources of oat beta-glucan included oat bran, oat meal and rolled oats, which were consumed as breakfast cereals, biscuits, bread, muesli, muffins, and powders. The intake of 1 g oat beta-glucan per day resulted in changes of total and LDL cholesterol of -0.040 mmol/L (95 % CI: -0.054, -0.026) and -0.037 mmol/L (95 % CI: -0.040, -0.034), respectively. No effects on HDL-cholesterol concentrations were reported.

Nineteen further studies were submitted by the applicant. Eighteen of these studies were analysed in a third meta-analysis (unpublished) and accounted for a total of 1080 subjects. The study populations (age range from 16 to 77 years) included healthy people, those with hyperlipidaemia, diabetes, and overweight subjects. The estimated daily oat beta-glucan consumption ranged from 3 to 9 g/d, with an average dose of 5 g/d. The intervention periods varied from 2 to 12 weeks, with a mean intervention period of 5.7 weeks. The sources of oat beta-glucan included oat bran, oat meal and rolled oats, which were consumed as breakfast cereals, biscuits, bread, cereal bars, muesli, muffins, pasta and powders. The overall effect for all the 18 studies was a reduction of -0.34 mmol/L (95 % CI: -0.42, -0.25,  $p < 0.001$ ) for total cholesterol and a reduction of -0.28 mmol/L (95 % CI: -0.35, -0.22,  $p < 0.001$ ) for LDL cholesterol. When mean study differences were plotted against dose, estimates for effects of 3 g/d of oat beta-glucan, calculated from the fitted line, resulted in -0.23 mmol/L (95 % CI: -0.35, -0.10) for total cholesterol and -0.21 mmol/L (95 % CI: -0.31, -0.11) for LDL cholesterol. HDL-cholesterol concentrations did not decrease significantly.

In one randomised controlled trial, 75 hypercholesterolaemic men and women were assigned to consume either 6 g oat beta-glucan as oat bran concentrate ( $n=35$ ) or 6 g of dextrose monohydrate ( $n=40$ ) per day for six weeks. In the intervention group LDL-cholesterol concentrations were reduced significantly by  $-0.30 \pm 0.1$  mmol/L.

The evidence presented indicates that the cholesterol-lowering effect of oat beta-glucan may depend on the increased viscosity in the small intestine that reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating (LDL) cholesterol concentrations. Viscosity in the small intestine is determined by the concentration, molecular weight and solubility of oat beta-glucan. Oat beta-glucan may be degraded during purification and manufacturing of foods, affecting considerably its physicochemical properties. Consequently, the cholesterol-lowering effect of oat beta-glucan may be weakened or even disappear. Differences in viscosity may explain, at least in part, the large variation between the LDL-cholesterol lowering effects found in individual studies.

In weighing the evidence, the Panel took into account that most of the randomised controlled trials investigating the effects of oat beta-glucan at doses of at least 3 g/d have shown a statistically significant decrease in LDL-cholesterol concentrations in both normocholesterolaemic and hypercholesterolaemic subjects, and that there was strong evidence supporting the biological plausibility of the effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of oat beta-glucan and lowering of blood LDL-cholesterol concentrations.

The Panel considers that the following wording reflects the scientific evidence: “Oat beta-glucan has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease”.

The Panel considers that, in order to bear the claim, foods should provide at least 3 g of oat beta-glucan per day. This amount can reasonably be consumed as part of a balanced diet. The target population is adults who want to lower their blood cholesterol concentrations.