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[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

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 lowering of blood LDL and total cholesterol. Oat beta-glucan is sufficiently characterised. Lowering blood LDL-cholesterol concentrations is a beneficial physiological effect by decreasing the risk of coronary heart disease. The applicant identified a total of 22 references, which included three meta-analyses and 19 randomised controlled trials, as being pertinent to the health claim. In weighing the evidence, the Panel took into account that most of the 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, 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 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.

KEY WORDS

Oat beta-glucan, fibres, blood cholesterol, LDL cholesterol, serum lipids, health claims.

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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.

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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.

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 ± 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.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of that Regulation and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of that Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of that Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, who will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

Steps taken by EFSA:

- The application was received on 04/09/2008.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- During the check for completeness[5] of the application, the applicant was requested to provide missing information on 10/10/2008.
- The applicant provided the missing information on 22/10/2008.
- The scientific evaluation procedure started on 15/11/2008.
- On 04/02/2009, the NDA Panel agreed on a list of questions which requested the applicant to provide additional particulars to accompany the application.
- The applicant submitted the responses to the NDA Panel's list of questions on 21/04/2009.
- On 03/07/2009, the NDA Panel agreed on a further list of questions which requested the applicant to provide additional particulars to accompany the application.
- The applicant submitted the responses to the NDA Panel's list of questions on 17/08/2010.
- During the meeting on 12/11/2010, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to oat beta-glucan and lowering blood cholesterol and reduced risk of (coronary) heart disease.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue 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".

[4] European Parliament and Council (2006). Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[5] In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of oat beta-glucan, a positive assessment of its safety, nor a decision on whether oat beta-glucan is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: CreaNutrition AG, Business Park, 6301 Zug, Switzerland.

The applicant indicates proprietary rights and confidentiality for three unpublished studies (Donazzolo et al., 2006; Frid et al., 2007; Mensink et al., 2005) and for one unpublished meta-analysis (Whitehead, 2008).

Food/constituent as stated by the applicant

According to the applicant, oat beta-glucan, the viscous soluble fibre present in different food products.

Health relationship as claimed by the applicant

According to the applicant, the consumption of food products which contain oat beta-glucan reduces blood LDL and total cholesterol concentrations without adverse effects on HDL cholesterol concentration.

Wording of the health claim as proposed by the applicant

The applicant proposed the following wording for the health claim: "The inclusion of oat beta-glucan as part of a balanced diet can actively lower/reduce blood LDL and total cholesterol".

Specific conditions of use as proposed by the applicant

The applicant specified as target population the general population, and especially people with increased risk of hypercholesterolaemia.

The applicant proposed a daily consumption of at least 3 g of oat beta-glucan per day, consuming a range of food products such as muesli, breakfast cereals, cereal bars, biscuits, bread, cereal drinks and powders at various meal occasions throughout the day as part of a balanced diet.

Similar claims as proposed/authorised by other entities

The US Food and Drug Administration (FDA 1997, FDA 2003), the JHCI (2006) in the UK, the French AFSSA (2008), the Swedish Nutrition Foundation (2004, 2007), and the Swiss Federal Office of Public Health (2006) have already approved health claims for oat beta-glucan which are essentially similar to that proposed in this application.

In the Netherlands, product-specific claims on reduction of LDL cholesterol or total cholesterol have been approved in 2005, 2007 and 2008 for oat beta-glucan containing Pró-Fit® bread, OatWell® bread, and OatWell® cereal products (Netherlands Voedingscentrum, 2005, 2007, 2008).

In the Czech Republic, based on the Dutch assessment, a health claim for cholesterol-lowering bread was approved in 2005 (Ministry for Health of the Czech Republic, 2005).

The Malaysian Ministry of Health has approved oat soluble fibre (beta-glucan) under its nutrient function claim section.

ASSESSMENT

1. Characterisation of the food/constituent

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

with mixed ß-(1→4) and ß-(1→3) links with an approximate relative distribution of 70 % to 30 %. The molecular weight of oat beta-glucan in various commercially available processed food preparations is generally less than the 2000 kDa reported for the source oats, and values range from about 100 kDa to 2000 kDa. The mixed linkages are important for the physical properties, such as solubility and viscosity. The viscosity is a function of the concentration of dissolved beta-glucans and of its molecular weight (Wood et al., 2000) and further depends on differences in raw materials, processing and methods of determination. 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.

2. Relevance of the claimed effect to human health

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.

Coronary heart disease (CHD) is a leading cause of mortality and morbidity in European populations with over 1.9 million deaths in the European Union and over 4.35 million deaths in Europe each year (Pedersen et al., 2005). Elevated blood cholesterol is an important modifiable risk factor in the development of CHD (WHO, 2002a, b).

It has been shown that blood cholesterol concentrations can be decreased by drugs and by dietary and lifestyle changes (Denke, 2005; Gordon, 2000; Ornish et al., 1998; van Horn et al., 2008).

The Panel considers that lowering blood LDL-cholesterol concentrations is a beneficial physiological effect by decreasing the risk of coronary heart disease.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline/Pubmed (until November 2007) using the search terms "oat fibre, oat beta-glucan, oat bran, oat bran concentrate, oats, oatmeal" and "cholesterol/serum lipids", limiting the search to human studies published in English. Pertinent studies were selected using the following inclusion criteria: studies were randomised and controlled, control group appropriate, changes of diet and body weight during the trials were assessed, amount of oat beta-glucan indicated, mean base-line and after-intervention cholesterol concentrations and/or change in cholesterol concentrations provided, study populations healthy subjects, obese subjects, hyperlipidemics, or non-insulin dependent diabetics. Exclusion criteria included: soluble fibre used was not solely oat beta-glucan, exact amount of oat-beta glucan not retrievable, trial not sufficiently controlled, outcome measures not including blood lipids, confounders known to affect blood lipid concentrations, intervention period less than two weeks, no wash-out period in cross-over studies, insufficient information to assess the magnitude of the effect. In addition, the CreaNutrition AG data base was searched for relevant published and unpublished references, respectively.

The applicant identified a total of 22 references as being pertinent to the health claim. These references included two published meta-analyses, one unpublished meta-analysis, 16 published randomised controlled trials (RCT) and three unpublished RCT.

The Panel has already issued an 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 (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009). The Panel

concluded that a cause and effect relationship has been established between the consumption of beta-glucans and the maintenance of normal blood cholesterol concentrations.

The first meta-analysis (Ripsin et al., 1992) comprised 12 studies which included 1063 subjects. Trials were identified by a computerised literature search of articles published until March 1991. 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. Larger reductions were seen in trials in which subjects had higher baseline blood cholesterol concentrations.

In the second meta-analysis, Brown et al. (1999) analysed 67 trials on the effect of soluble fibre from different sources on total cholesterol and/or on LDL-cholesterol concentrations. Trials were identified by a computerised literature search of articles published from 1966 to June 1996. Twenty-five of these studies (including those reviewed by Ripsin et al., 1992) reported on oat products. The total number of subjects was 1600, including healthy populations, subjects with hyperlipidaemia, and diabetic subjects. The age range was from 26 to 61 years. The mean initial total, LDL- and HDL-cholesterol concentrations were 6.3, 4.4 and 1.3 mmol/L, respectively. The amount of oat beta-glucan used in these studies 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. Plotting of the net change in total and LDL-cholesterol concentrations against the mean daily dose of oat beta-glucan suggested a nonlinear dose response relationship, with significant non-linearity for doses of >10 g/d for total cholesterol and of >8 g/d for LDL cholesterol, respectively. For the "practical" dose range (<10 g/d), 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. These results would correspond to reductions of about 2 % for total cholesterol and of about 3 % for LDL cholesterol for an intake of 3 g oat beta-glucan per day. Contrary to Ripsin et al. (1992), Brown et al. (1999) found similarity of effects in normo- and hypercholesterolaemic subjects. No effects on HDL-cholesterol concentrations were reported.

Eighteen studies which were published after the meta-analysis by Brown et al. (1999) and considered as pertinent by the applicant were analysed in a third meta-analysis (Whitehead, 2008, unpublished, proprietary data). This meta-analysis included nine cross-over and ten parallel designs (one study had two intervention arms) and accounted for a total of 1080 subjects. The study populations comprised healthy, hyperlipidaemic, diabetic, and overweight subjects with an age range from 16 to 77 years. Mean baseline blood total and LDL-cholesterol concentrations ranged from 4.4 to 7.6 mmol/L and from 2.8 to 5.2 mmol/L, respectively. 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.

Subjects were normocholesterolaemic in five out of the 18 studies (Pick et al., 1996; Davy et al., 2002; Pins et al., 2002; Karmally et al., 2005; Frid et al., 2007, unpublished, proprietary data). In four out of the five studies a statistically significant reduction of total and LDL cholesterol after consumption of oat beta-glucan was observed. The values ranged from -0.24 to -0.30 mmol/L for total cholesterol and from -0.18 to -0.27 for LDL cholesterol for an intake of 3 g oat beta-glucan per day.

Subjects were mildly hypercholesterolaemic in 13 out of the 18 studies (Braaten et al., 1994; Gerhardt and Gallo, 1998; Önning et al., 1999; Lovegrove et al., 2000; Saltzman et al., 2001; Kabir et al., 2002; Berg et al., 2003; Kerckhoffs et al., 2003; Amundsen et al., 2003; Naumann et al., 2006; Theuwissen and Mensink, 2007; Donazzolo et al., 2006, unpublished, proprietary data; Mensink et al., 2005, unpublished, proprietary data). One parallel RCT did not find any effect when 31 subjects consumed 3 g oat beta-glucan as oat bran concentrate per day for eight weeks (Lovegrove et al., 2000). In one RCT with two interventions (Kerckhoffs et al., 2003), consumption of oat beta-glucan could only significantly reduce total and LDL-cholesterol concentrations when taken as oat bran concentrate in orange juice but not when oat beta-glucan was baked into bread and cookies. In one parallel RCT (Gerhardt and Gallo, 1998), reductions in total and LDL-cholesterol concentrations were particularly high (-0.94 mmol/L for total cholesterol and -0.84 mmol/L for LDL cholesterol) when 3.3 g oat beta-glucan were consumed daily. However, sample size was small with 13 subjects in the intervention group (oat bran) and 17 subjects in the control group (rice starch). In the remaining 10 studies conducted in mildly hypercholesterolaemic subjects, total and LDL-cholesterol concentrations were significantly reduced by -0.12 to -0.41 mmol/L and by -0.12 to -0.33 mmol/L, respectively, for an intake of 3 g oat beta-glucan per day. The Panel notes the large variation between the LDL-cholesterol lowering effects found in the individual studies.

The overall effect for all the 18 studies summarised in the meta-analysis of Whitehead (2008, unpublished, proprietary data) 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. These results would correspond to reductions of about 4 % for total cholesterol and of about 5 % for LDL cholesterol. HDL-cholesterol concentrations did not decrease significantly.

One further RCT (Queenan et al., 2007) was provided by the applicant and was not included in the meta-analysis. Seventy-five hypercholesterolaemic men and women were randomly 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. When compared to the control group, LDL-cholesterol concentrations were reduced significantly in the intervention group by -0.30 ± 0.1 mmol/L ($p=0.026$).

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 (MW) and solubility of oat beta-glucan. This is supported by a recent RCT (Wolever et al., 2010) which showed reduced cholesterol lowering efficacy of oat beta-glucan with low MW (210 kDa) compared to high MW (>2000 kDa) or medium MW (530 kDa) oat beta-glucan. Oat beta-glucan may be degraded during purification and manufacturing of foods, affecting considerably its physicochemical properties (Tosh et al., 2010). 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 could have reached this conclusion without considering the studies claimed by the applicant as proprietary.

4. Panel's comments on the proposed wording

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".

5. Conditions and possible restrictions of use

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.

CONCLUSIONS

On the basis of the data presented, the Panel concludes 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 target population was specified by the applicant as the general population, and in particular people with increased risk of hypercholesterolaemia. Lowering blood LDL-cholesterol concentrations is a beneficial physiological effect by decreasing the risk of coronary heart disease.
- A cause and effect relationship has been established between the consumption of oat beat-glucan and lowering of blood LDL-cholesterol concentrations.
- 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".
- 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.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on oat beta-glucan and "can actively lower/reduce blood LDL and total cholesterol" pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0220_UK). September 2008. Submitted by CreaNutrition AG.

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GLOSSARY / ABBREVIATIONS

CHD	Coronary heart disease
HDL	High-density lipoprotein
LDL	Low-density lipoprotein
MW	Molecular weight
RCT	Randomised controlled trial