

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to glucomannan and maintenance of normal blood cholesterol concentrations (ID 836, 1560) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to glucomannan (Konjac mannan) and the maintenance of normal blood cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food component that is the subject of the health claims is glucomannan (Konjac mannan). Glucomannan is a water-soluble type of fibre with high molecular weight and high viscosity in water solution. Glucomannan does not occur naturally in foods. The Panel considers that the food constituent, glucomannan, is sufficiently characterised.

The claimed effects are “cholesterol” and “cholesterol level”. The Panel assumes that the target population is the general population. The Panel considers that maintaining normal blood (LDL) cholesterol concentrations is beneficial to human health.

Eight randomised controlled trials, which investigated the effects of glucomannan on LDL and/or total cholesterol at daily doses of 3-15 g/d in either healthy, hypercholesterolaemic or diabetic adult human subjects were provided.

In weighing the evidence, the Panel took into account that a statistically significant effect on either total or LDL-cholesterol was not observed following the consumption of glucomannan in all of these studies, that reduction in total and/or LDL-cholesterol concentrations did not always lead to significant reductions in the total/HDL cholesterol ratio, that the vast majority of these studies had small sample sizes, and that no clear dose-response relationship was established between the

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consumption of glucomannan and the claimed effect. However, the Panel considers that most studies showed a consistent effect in the reduction of serum total and LDL-cholesterol concentrations at doses of about 4g/d of glucomannan, that the effect has been observed not only in hypercholesterolaemic subjects but also in healthy individuals, and that the mechanisms by which the consumption of the food may exert the claimed effect (biological plausibility) are established.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of blood cholesterol concentrations.

The following wording reflects the scientific evidence: “Regular consumption of glucomannan helps maintain normal blood cholesterol concentrations”.

In order to bear the claim, a food should provide at least 4 g/d of glucomannan in one or more servings. The target population is the general population.

KEY WORDS

Glucomannan, Konjac mannan, blood cholesterol, health claims.

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006³ submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims that are the subject of this opinion is given in Table 1.

Table 1. Main entry health claims related to glucomannan, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
836	Konjac mannan (glucomannan)	Cholesterol	Helps to control blood levels of cholesterol. Contributes to normal cholesterol levels. Helps to maintain healthy cholesterol levels. Helps to manage blood cholesterol.
	Conditions of use - Konjac mannan From 1 to 5 grams per day		
1560	Glucomannan (Konjac)	Cholesterol level	Glucomannan: - has beneficial effects on the cholesterol level (in the blood) - helps to maintain healthy cholesterol levels
	Conditions of use - 2.5-5.0 g / day		

ASSESSMENT

1. Characterisation of the food/constituent

The food component that is the subject of the health claims is glucomannan (Konjac mannan). Glucomannan is a water-soluble type of fibre composed of a straight chain of β -1 \rightarrow 4 D-mannose and D-glucose units in a ratio of 1.6:1 with a small amount of branching (8 %) through β -(1 \rightarrow 6)-glucosyl linkages. It is derived from the tuberous roots of the Konjac plant (*Amorphophallus konjac*). Glucomannan is non-digestible in the human small intestine. It has a high molecular weight (200-2000 kDa) and high viscosity in water solution. Glucomannan does not occur naturally in foods, is a food additive used as emulsifier and thickener, and is usually consumed in the form of food supplements.

³ 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. OJ L 404, 30.12.2006, p. 9–25.

The Panel considers that the food constituent, glucomannan, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effects are “cholesterol” and “cholesterol level”. The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel notes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160mg/dL, may compromise the normal function of the arteries.

The Panel considers that maintaining normal blood cholesterol concentrations is beneficial to human health.

3. Scientific substantiation of the claimed effect

Eight randomised controlled trials, which investigated the effects of glucomannan on LDL and/or total cholesterol at daily doses of 3-15 g/d in either healthy, hypercholesterolaemic or diabetic adult human subjects, were provided.

Zhang et al. (1990) randomised 110 elderly subjects with hyperlipidaemia to consume glucomannan-rich foods at doses 5-10 g/d glucomannan in addition to their usual diet (n=66) or their usual diet only (n= 44, controls) for 45 days. Serum total and LDL-cholesterol concentrations significantly decreased (by about 7%) in the glucomannan group as compared to controls at the end of the study.

Arvill and Bodin (1995) found a 10 % reduction in serum total cholesterol concentrations and a 7% reduction in LDL-cholesterol concentrations with 3.9 g/d glucomannan (n= 32) as compared to placebo (n = 31) in healthy men (parallel comparison). The study was planned to be a crossover trial with two 4-week intervention periods and a 2-week washout period. However, the results of the second intervention period (after cross-over) were not reported in the publication. The reason given was a carryover effect in the glucomannan group.

In the study by Vuksan et al. (1999), 11 diabetic subjects were given 0.7 g/100 kcal (on average 15 g/d) glucomannan and wheat bran (control) in a crossover comparison over periods of 3 weeks with a one-week washout period in between. During the glucomannan period, the total/HDL cholesterol ratio was significantly reduced as compared to the wheat bran control period. Serum total cholesterol and LDL-cholesterol concentrations appeared to be reduced during the glucomannan period by 11 % and 7 %, respectively, but the changes were not statistically significant as compared to the wheat bran control after Bonferroni adjustment for multiple comparisons.

In a second controlled crossover study by the same group of investigators with similar design, 11 subjects with the metabolic syndrome were randomly assigned to consume either glucomannan fibre-enriched test biscuits (0.5 g of glucomannan per 100 kcal of dietary intake or 8–13 g/day) or wheat bran fibre (control) for 3 weeks, each separated by a 2-week washout. Serum total cholesterol was significantly reduced by 12.4 % and LDL-cholesterol by 22 % during the glucomannan intervention as compared to the wheat bran (control) intervention (Vuksan et al., 2000).

In another study, 22 type 2 diabetic subjects with elevated blood cholesterol concentrations but not on lipid-lowering medication were recruited to participate in a two 28-day period, randomized, double-blind, crossover clinical trial. Glucomannan at doses 3.6 g/d significantly reduced serum cholesterol

concentrations by 11 % and LDL-cholesterol concentrations by 20 % as compared to placebo (Chen et al., 2003).

In a placebo-controlled crossover study consisting of four phases of 21 days, each phase separated by a 28-day washout, Yoshida et al. (2006) investigated the effects of glucomannan, both alone and in combination with plant sterols, in mildly hypercholesterolaemic non-diabetic (n=18) and type II diabetic (n=16) individuals aged 38-74 years. Results showed a significant 9.5% reduction in serum total cholesterol and a significant 11% reduction in serum LDL-cholesterol with 10 g/d glucomannan (alone) as compared to placebo.

Using a parallel-arm, double-blind, placebo-controlled design, 30 overweight and obese men were randomly assigned to consume either glucomannan (3g/d, n = 15) or placebo (n = 15) for 12 weeks in the context of a low-carbohydrate diet for weight loss (Wood et al., 2007). Results showed a small significant 4% reduction in serum total cholesterol and a significant 8% reduction in serum LDL-cholesterol in the glucomannan group as compared to placebo, with no significant effect on the total/HDL-cholesterol ratio.

In a randomized, placebo-controlled trial (Martino et al., 2005), 40 hypercholesterolaemic children below 14 years of age were randomly allocated to consume glucomannan (2 g/d to children \leq 6y of age, 3 g/d to children > 6y of age) in gelatine capsules or no capsules (control) in the context of a Step-One-Diet for 8 weeks. Serum total cholesterol and LDL-cholesterol significantly decreased in the glucomannan group as compared to controls after 8 weeks of intervention. The percentage decrease showed a statistically significant difference between sexes. Decreases were observed in female and male children respectively in total (24% vs. 9%) and LDL-cholesterol (30% vs.9%).

An additional study, designed to test the effects of glucomannan consumption on blood lipids with or without physical exercise, was presented (Kraemer et al., 2007). However, the Panel notes that there was no control group, and therefore no conclusions can be drawn from this study in relation to the claimed effect.

The effect of water-soluble fibre types, such as glucomannan, on blood cholesterol probably depends on viscosity, which reduces the re-absorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating (LDL) cholesterol concentrations. Glucomannan has a high viscosity and high molecular weight and physiological effects seem to be similar to other types of high-viscosity water-soluble fibres (Jenkins et al., 2000).

In weighing the evidence, the Panel took into account that a statistically significant effect on either total or LDL-cholesterol was not observed following the consumption of glucomannan in all of these studies, that reduction in total and/or LDL-cholesterol concentrations did not always lead to significant reductions in the total/HDL cholesterol ratio, that the vast majority of these studies had small sample sizes, and that no clear dose-response relationship was established between the consumption of glucomannan and the claimed effect. However, the Panel considers that most studies showed a consistent effect in the reduction of serum total and LDL-cholesterol concentrations at doses of about 4g/d of glucomannan, that the effect has been observed not only in hypercholesterolaemic subjects but also in normocholesterolemic individuals, and that the mechanisms by which the consumption of the food may exert the claimed effect (biological plausibility) are established.

The Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of blood cholesterol concentrations.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence: "Regular consumption of glucomannan helps maintain normal blood cholesterol concentrations"

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claim, a food should provide at least 4 g/d of glucomannan in one or more servings. The target population is the general population.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, glucomannan, which is the subject of the health claim, is sufficiently characterised.
- The claimed effects are "cholesterol" and "cholesterol level". The target population is assumed to be the general population. Maintenance of normal blood cholesterol concentrations is beneficial to human health.
- A cause and effect relationship has been established between the consumption of glucomannan and the reduction of blood cholesterol concentrations.
- The following wording reflects the scientific evidence: "Regular consumption of glucomannan helps maintain normal blood cholesterol concentrations"
- In order to bear the claim, a food should provide at least 4 g/d of glucomannan in one or more servings. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1623, EFSA-Q-2008-2297). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁴ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁵

Foods are commonly involved in many different functions⁶ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁴ OJ L12, 18/01/2007

⁵ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁶ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.

- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B**EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.