**SCIENTIFIC OPINION**

# Scientific Opinion on the substantiation of health claims related to konjac mannan (glucomannan) and reduction of body weight (ID 854, 1556, 3725), reduction of post-prandial glycaemic responses (ID 1559), maintenance of normal blood glucose concentrations (ID 835, 3724), maintenance of normal (fasting) blood concentrations of triglycerides (ID 3217), maintenance of normal blood cholesterol concentrations (ID 3100, 3217), maintenance of normal bowel function (ID 834, 1557, 3901) and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1558) pursuant to Article 13(1) 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

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[1] On request from the European Commission, Question No EFSA-Q-2008-1622, EFSA-Q-2008-1641, EFSA-Q-2008-2293, EFSA-Q-2008-2296, EFSA-Q-2008-3832, EFSA-Q-2008-3949, EFSA-Q-2008-4446, EFSA-Q-2008-4447, adopted on 30 April 2010 and Question No EFSA-Q-2008-1621, EFSA-Q-2008-2294, EFSA-Q-2008-2295, EFSA-Q-2008-4617, adopted on 10 September 2010.

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[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: 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. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg. The members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance: Kees de Graaf, Joanne Harrold, Mette Hansen, Mette Kristensen, Anders Sjödin and Inge Tetens.

[4] After publication of this opinion, the following changes have been made on page 1 of the opinion: In the acknowledgment section the reference to the members of the Claims Sub Working Group on Bone/Teeth/Connective Tissue has been replaced with a reference to the members of the Claims Sub-Working Group on Weight Management/Satiety/Glucose and Insulin Control/Physical Performance.

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## 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 (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to konjac mannan (glucomannan) and reduction of body weight, reduction of post-prandial glycaemic responses, maintenance of normal blood glucose concentrations, maintenance of normal (fasting) blood concentrations of triglycerides, maintenance of normal blood cholesterol concentrations, maintenance of normal bowel function and decreasing potentially pathogenic gastro-intestinal microorganisms. 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 constituent that is the subject of the health claims is konjac mannan (glucomannan). The Panel considers that konjac mannan (glucomannan) is sufficiently characterised.

**Reduction of body weight**

The claimed effects are "weight management" and "contributes to weight management". The target population is assumed to be overweight individuals. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the reduction of body weight. The Panel considers that the reduction of body weight is a beneficial physiological effect for overweight individuals.

In weighing the evidence, the Panel took into account that most of the intervention studies, which were of adequate sample size and duration, found a statistically significant effect of glucomannan on body weight loss in the context of a hypocaloric diet when administered as a pre-load before meals, and that the mechanism by which glucomannan could exert the claimed effect is established.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight in the context of an energy-restricted diet.

The Panel considers that in order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.

**Reduction of post-prandial glycaemic responses**

The claimed effect is "reduction of glycaemic response". The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, the Panel assumes that the claimed effect relates to the reduction of post-prandial glycaemic responses. The Panel considers that reduction of post-prandial glycaemic responses may be a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the reduction of post-prandial glycaemic responses.

**Maintenance of normal blood glucose concentrations**

The claimed effects are "glycaemic control" and "contributes to maintain a healthy blood sugar level". The target population is assumed to be the general population. In the context of the proposed

wordings, the Panel assumes that the claimed effect refers to the long-term maintenance or achievement of normal blood glucose concentrations. The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that only one small intervention study of short duration on a highly selected population sub-group was presented for the substantiation of the claimed effect, and that no evidence on the sustainability of the effect was provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal blood glucose concentrations.

**Maintenance of normal (fasting) blood concentrations of triglycerides**

The claimed effect is "helps to maintain physiological lipid levels in the blood". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect relates to the maintenance of normal (fasting) blood concentrations of triglycerides. The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that only one out of seven studies presented reported a significant decrease in plasma concentrations of triglycerides following consumption of glucomannan.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal blood concentrations of triglycerides.

**Maintenance of normal blood cholesterol concentrations**

The claimed effects are "helps to maintain physiological lipid levels in the blood" and "heart health". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations.

A claim on glucomannan and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome.

**Maintenance of normal bowel function**

The claimed effects are "bowel functions", "intestinal health/bowel function" and "bowel function/colonic function". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal bowel function by promoting intestinal regularity and reducing intestinal transit time. The Panel considers that maintenance of normal bowel function in the context of a reduction in intestinal transit time, and an increase in the frequency of bowel movements within the normal range might be a beneficial physiological effect.

No studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal bowel function.

**Decreasing potentially pathogenic gastro-intestinal microorganisms**

The claimed effect is "prebiotic action/bifidogenic action". The target population is assumed to be the general population. In the context of the proposed wording, the Panel assumes that the claimed effect refers to the capacity of food(s)/food constituent(s) to increase the numbers of bacteria considered to be beneficial. The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect. The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

No human studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

The Panel concluded that a cause and effect relationship has not been established between the consumption of glucomannan and decreasing potentially pathogenic gastro-intestinal microorganisms.

**KEY WORDS**

konjac mannan, glucomannan, glycaemic control, weight management, body weight, blood lipids, blood glucose, bowel function, intestinal transit, potentially pathogenic organisms, health claims.

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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 1924/2006[5] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[6]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is glucomannan. Glucomannan (konjac mannan) is a water-soluble type of fibre composed of a straight chain of β-1→4 D-mannose and D-glucose units in a ratio of 1.6:1 with a small amount of branching (8 %) through β-(1→6)-glucosyl linkages. It is derived from the tuberous roots of the konjac plant (*Amorphophallus konjac* K. Koch). 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. It is a food additive used as an emulsifier and a thickener, and is also consumed in the form of food supplements (Katsuraya et al., 2003).

The Panel considers that the food constituent, konjac mannan (glucomannan), which is the subject of the health claims, is sufficiently characterised.

### 2. Relevance of the claimed effect to human health

### 2.1. Reduction of body weight (ID 854, 1556, 3725)

The claimed effects are "weight management" and "contributes to weight management". The Panel assumes that the target population is overweight individuals.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the reduction of body weight.

Weight loss in overweight subjects, even without achieving a normal body weight, is considered to be a beneficial physiological effect.

The Panel considers that reduction of body weight is a beneficial physiological effect for overweight individuals.

[5] 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.

[6] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf

### 2.2. Reduction of post-prandial glycaemic responses (ID 1559)

The claimed effect is "reduction of glycaemic response". The Panel assumes that the target population is individuals willing to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This is a normal physiological response that varies in magnitude and duration and may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). The evidence provided does not establish that decreasing post-prandial glycaemic responses in subjects with normal glucose tolerance is a beneficial physiological effect. However, it may be beneficial to subjects with impaired glucose tolerance as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance and hyperinsulinaemia are common in the general population of adults.

The Panel considers that the reduction of post-prandial glycaemic responses may be a beneficial physiological effect.

### 2.3. Maintenance of normal blood glucose concentrations (ID 835, 3724)

The claimed effects are "glycaemic control" and "contributes to maintain a healthy blood sugar level". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the long-term maintenance or achievement of normal blood glucose concentrations.

The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

### 2.4. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 3217)

The claimed effect is "helps to maintain physiological lipid levels in the blood". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal (fasting) blood concentrations of triglycerides.

Triglycerides in plasma are either derived from dietary fats or synthesised in the body from other energy sources like carbohydrates. In fasting conditions, serum triglycerides are mainly transported in very-low-density lipoproteins (VLDL) synthesised in the liver. Excess calorie intake with a meal is converted to triglyceride and transported to the adipose tissue for storage. Hormones regulate the release of triglycerides from adipose tissue in order to meet energy needs between meals. Normal values for blood concentrations of triglycerides have been defined.

The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

### 2.5. Maintenance of normal blood cholesterol concentrations (ID 3100, 3217)

The claimed effects are "helps to maintain physiological lipid levels in the blood" and "heart health". The Panel assumes that the target population is the general population.

A claim on glucomannan and maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009).

### 2.6. Maintenance of normal bowel function (ID 834, 1557, 3901)

The claimed effects are "bowel functions", "intestinal health/bowel function" and "bowel function/colonic function". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal bowel function by promoting intestinal regularity and reducing intestinal transit time.

Changes in bowel habits within the normal range, e.g. reduced intestinal transit time and increased frequency of bowel movements, might be considered as maintenance of normal bowel function.

The Panel considers that maintenance of normal bowel function in the context of a reduction in intestinal transit time and an increase in the frequency of bowel movements within the normal range might be a beneficial physiological effect.

### 2.7. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1558)

The claimed effect is "prebiotic action/bifidogenic action". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to the capacity of food(s)/food constituent(s) to increase the numbers of bacteria considered to be beneficial. The numbers/proportions of bacterial groups that would constitute a "beneficial" colon/intestinal flora have not been established. Increasing the number of any group of microorganisms, including bifidobacteria, is not in itself considered as a beneficial physiological effect. The Panel considers that the evidence provided does not establish that increasing numbers of gastro-intestinal microorganisms is a beneficial physiological effect.

The Panel considers that decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.

## 3. Scientific substantiation of the claimed effect

### 3.1. Reduction of body weight (ID 854, 1556, 3725)

A total of 45 references were cited for the scientific substantiation of this claim. Among them, six reported on intervention studies in humans investigating the effects of glucomannan on body weight (Birketvedt et al., 2005; Cairella and Marchini, 1995; Vido et al., 1993; Vita et al., 1992; Vuksan et al., 1999; Walsh et al., 1984). Also, the Panel identified three additional references cited in relation to other claims on glucomannan as being pertinent to this claim (Wood et al., 2007; Chen et al., 2003; Vuksan et al., 2001).

Walsh et al. (1984) conducted an eight-week double-blind, placebo-controlled, randomised trial in 20 obese subjects, who were randomly assigned to consume either glucomannan or placebo (starch) administered as 1 g doses (two capsules of 500 mg each) with 8 oz of water three times per day (before each meal) for eight weeks in the context of usual dietary patterns and levels of physical

exercise. Body weight loss during the study was significantly higher in the glucomannan group (-5.5±1.5 kg) than in the placebo group (1.5±1.5 kg; difference between groups 7.0±1.4 kg, $p<0.005$).

In a double-blind, placebo-controlled randomised intervention study (Cairella and Marchini, 1995), 30 overweight women (BMI=25-30 kg/m$^2$) were treated for 60 days with a 1,200 kcal/d (5,040 kJ/d) diet plus either placebo (n=15) or glucomannan (n=15). A total of four capsules of glucomannan or placebo were given daily with 1-2 glasses of water 30-60 minutes prior to the two main meals (appr. 4 g per day). Body weight loss during the study was statistically significantly ($p=0.0017$) higher in the glucomannan group (-4.3 kg) than in the placebo group (-2.7 kg, mean difference 1.6 kg, 95%CI=0.7-2.5).

In a double-blind, placebo-controlled randomised intervention study (Birketvedt et al., 2005), healthy overweight subjects were randomly assigned to consume either glucomannan (n=23) or placebo (n=29) for five weeks in the context of an energy-reduced diet providing 1,200 kcal per day. Glucomannan (1.24 g per day) and placebo were administered in tablets (n=6) with 250 mL of water 15 minutes before each meal (three times daily) and at 3 pm (n=4 tablets). Weight loss during the intervention was significantly higher in the glucomannan group (-3.8±0.9) than in the placebo group (-2.5±0.5, $p<0.01$).

In the study by Vita et al. (1992), 50 obese subjects (15 males) were randomly assigned to consume a hypocaloric diet (1,000 kcal/d or 4,200 kJ/d for women and 1,300 kcal or 5,460 kJ/d for men) either alone (control, n=25, 8 males) or together with glucomannan supplements (2+3+3 capsules with 300 mL water before meals, appr. 4 g per day in three doses) for three months. The authors reported a greater weight loss in the glucomannan group compared to controls at the end of the study ($p<0.02$) expressed as percentage of initial body weight from baseline. Mean changes are given as a histogram (approx. -25 % *versus* -20 % of initial body weight in the glucomannan and placebo groups respectively) and SD are not reported.

In a double-blind, placebo-controlled randomised intervention study (Vido et al., 1993), 60 overweight children under the age of 15 (mean age 11.2 years) were randomised to consume glucomannan (two capsules with two glasses of water one hour prior to each meal, 2 g/d, n=30) or placebo (n=30) for two months in the context of a normocaloric diet. The percentage of children being overweight significantly decreased during the study in both the intervention and the placebo groups with no significant differences between groups. No differences between groups in body weight changes were observed at the end of the study.

In a cross-over randomised controlled trial (RTC), 11 non diabetic, mildly hypertensive, free-living subjects with the insulin resistance syndrome (out of 278 subjects screened) consumed, in random order, test biscuits with glucomannan (0.5 g of glucomannan per 100 kcal of dietary intake, 8-13 g per day) or wheat bran fibre control biscuits for three weeks each separated by a 2-week washout (Vuksan et al., 2000). No statistically significant differences in body weight changes were observed between the glucomannan and the wheat bran fibre (control) interventions. In another study by the same authors with identical design, no statistically significant differences in body weight changes were observed between the glucomannan and the wheat bran fibre (control) interventions in a group of 11 type 2 diabetic subjects (Vuksan et al., 1999). The Panel notes the small number of subjects included in these studies, the short study duration, and that glucomannan was not given as pre-load before the meals but was rather consumed with the meals.

In a parallel-arm, double-blind, placebo-controlled intervention study by Wood et al., (2007), 30 overweight and obese men were randomly assigned to consume either glucomannan (3 g/d, n=15) or placebo (n=15) for 12 weeks in the context of a carbohydrate restricted diet for weight loss. No statistically significant differences in body weight changes were observed between the glucomannan and the placebo groups.

In the study by Chen et al. (2003), 22 diabetic subjects (12 female) with elevated blood cholesterol concentrations received, following a randomised, double-blind, crossover design, glucomannan and placebo (starch) for 28 days each with no washout period in between. Glucomannan and placebo were administered in gelatine capsules with a glass of water three times daily half an hour prior to meals. The dose of glucomannan increased progressively from 1.2 (for three days), 2.6 (for three days) to 3.6 g per day (for 22 days). No statistically significant differences in body weight changes were observed between the glucomannan and placebo groups. The Panel notes the short duration of the study and the absence of a washout period between interventions.

The Panel notes that no long-term studies (>3 months) on the effects of glucomannan on body weight are available.

The Panel also notes that glucomannan is a soluble-type of fibre which forms a viscous, gel-like mass in the stomach when hydrated, and that this "mass effect" could delay gastric emptying and induce satiety leading to a decrease in subsequent energy intake (Keithley and Swanson, 2005).

In weighing the evidence, the Panel took into account that most of the intervention studies, which were of adequate sample size and duration, found a statistically significant effect of glucomannan on body weight loss in the context of a hypocaloric diet when administered as a pre-load before meals, and that the mechanism by which glucomannan could exert the claimed effect is established.

Panel concludes that a cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight in the context of an energy-restricted diet.

### 3.2. Reduction of post-prandial glycaemic responses (ID 1559)

A total of 10 references were submitted in relation to this claim. Six were textbooks and consensus opinions in relation to the health effects of dietary fibre in general, one was a narrative review on the health effects of dietary fibre in general, one was a narrative review on the potential health effects of glucomannan and two reported on human intervention studies investigating the effects of glucomannan on health outcomes other than post-prandial glycaemic responses (e.g. fasting plasma and glucose concentrations, long-term blood glucose control). Also, some intervention studies on the effects of glucomannan on post-prandial glycaemic responses in type 2 diabetic subjects under pharmacological treatment for hyperglycaemia have been cited in relation to other claims on glucomannan. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One reference submitted (Magnati et al., 1984) reported on a randomised, placebo-controlled, cross-over intervention investigating the effects of glucomannan on post-prandial blood glucose responses during an oral glucose tolerance test (OGTT) with 75 g glucose in 24 obese normoglycaemic subjects (19 females). No measures of insulin responses were reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the reduction of post-prandial glycaemic responses.

### 3.3. Maintenance of normal blood glucose concentrations (ID 835, 3724)

A total of 18 references were submitted in relation to this claim. Six were textbooks and monographs not including original data on the effects of glucomannan on blood glucose control, one was a narrative review on the health effects of dietary fibre in general, four were narrative reviews on the potential health effects of glucomannan including diabetes prevention and treatment, and one reported on human intervention studies investigating the effects of glucomannan on health outcomes other than

post-prandial glycaemic responses. In addition, one human intervention study investigating the effects of glucomannan on post-prandial blood glucose responses and four human intervention studies on the effects of glucomannan on medium-term blood glucose concentrations in type 2 diabetic subjects under hypoglycaemic pharmacological treatment were presented. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

Only one of the references provided was considered by the Panel as pertinent to the claim (Vuksan et al., 2000).

In a cross-over randomised controlled trial (RTC), 11 non diabetic, mildly hypertensive, free-living subjects with the insulin resistance syndrome (out of 278 subjects screened) consumed, in random order, test biscuits with glucomannan (0.5 g of glucomannan per 100 kcal of dietary intake, 8-13 g per day) or wheat bran fibre control biscuits for three weeks each separated by a 2-week washout (Vuksan et al., 2000). A statistically significant decrease in plasma concentrations of fructosamine (a marker of blood glucose control) was observed with glucomannan compared to the wheat bran fibre control (between-group difference = 5.2±1.4 %, $p<0.002$). Changes in fasting glucose and insulin concentrations were not different between treatments. The Panel notes the small and highly selected sample of subjects recruited for this study, and that no evidence for a sustained effect was provided.

In weighing the evidence, the Panel took into account that only one small intervention study of short duration on a highly selected population sub-group was presented for the substantiation of the claimed effect, and that no evidence on the sustainability of the effect was provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal blood glucose concentrations.

### 3.4. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 3217)

Among the 22 references cited in the list in relation to this claim, most addressed the effects of food/components other than glucomannan on claimed effects other than blood lipids. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Seven human studies which reported on the effects of glucomannan intake on blood concentrations of triglycerides have been presented (Vuksan et al., 1999, 2000; Chen et al., 2003; Vido et al., 1993; Walsh et al., 1984; Vita et al., 1992; Wood et al., 2007). The study designs have been described in section 3.1. Only one of the studies (Vita et al., 1992) reported a significant decrease in blood concentrations of triglycerides after consumption of glucomannan compared to placebo at the end of a three-month intervention, whereas five studies did not observe any differences between groups and one study reports a significant increase in the glucomannan group after two months of intervention (Vido et al., 1993).

Two animal studies cited in the list reported on changes in the lipid profile following consumption of glucomannan (Hou et al., 1990; Vorster et al., 1985). The Panel considers that the evidence provided in animal studies is not sufficient to predict the occurrence of an effect of glucomannan consumption on maintenance of normal blood concentrations of triglycerides in humans.

In weighing the evidence, the Panel took into account that only one out of seven studies presented reported a significant decrease in plasma concentrations of triglycerides following consumption of glucomannan.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal (fasting) blood concentrations of triglycerides.

### 3.5. Maintenance of normal bowel function (ID 834, 1557, 3901)

Among the references provided for the scientific substantiation of the claim were five human intervention studies, three animal studies and several reviews and textbooks.

In all five human studies a commercial glucomannan preparation was studied.

Marzio et al. (1989) evaluated mouth to caecum transit time measured by hydrogen breath test in constipated patients (n=13) after ingestion of glucomannan (daily dose 3 g). The Panel notes the small number of subjects in the study and the fact that the method used to assess transit time has several limitations (Cummings et al., 2004). Subjects with chronic constipation (n=78) participated in the multicentric, open and non-controlled study in which the effect of glucomannan (daily dose 2-3 g) on the frequency of bowel movements and enema use, and on abdominal symptoms, was studied (Passaretti et al., 1991). The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claimed effect. In the single-blind sequential study of Chen et al. (2006) glucomannan (daily dose 4.5 g) *versus* corn starch was given to eight subjects with low dietary fibre intake (<20 g/day). The frequency of defecations (mean number/day±SEM) was 1.1±0.2 in the placebo period and 1.4±0.2 in the glucomannan period ($p<0.05$). The Panel notes that the study was single-blinded and non-randomised with a small number of subjects. The Panel considers that no conclusions can be drawn from this uncontrolled study for the scientific substantiation of the claimed effect.

Two studies were performed with chronically constipated children (Loening-Baucke et al., 2004; Staiano et al., 2000). Loening-Baucke et al. (2004) evaluated in a double-blind, randomised, cross-over study the effect of glucomannan (100 mg/kg body weight) on the frequency of bowel movements in a group of children with chronic constipation. The Panel notes the high drop out rate (only 31 from 46 children completed the study), the fact that the children continued laxative treatment during the intervention period, and the fact that most of the children suffered also from encopresis accompanying constipation. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect. In another study, glucomannan was given to a group of children with severe brain damage (Staiano et al., 2000). The Panel considers that the evidence provided does not establish that children with severe brain damage are representative of the general population with regard to the autonomous nervous system and therefore bowel function, nor that results obtained in studies on subjects with severe brain damage can be extrapolated to the general population with regard to normal bowel function.

The Panel notes that no studies were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal bowel function.

### 3.6. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1558)

Among the 23 references provided for the scientific substantiation of the claim were five human intervention studies, two animal studies, seven reviews and nine textbooks or guideline opinions.

The human studies provided were related to endpoints not related to the claimed effect (e.g. stool bulk, intestinal transit time, abdominal comfort, number of lactobacilli and bifidobacteria). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of glucomannan and decreasing potentially pathogenic gastro-intestinal microorganisms.

## 4. Panel's comments on the proposed wording

### 4.1. Reduction of body weight (ID 854, 1556, 3725)

The Panel considers that the following wording reflects the scientific evidence: "Glucomannan contributes to the reduction of body weight in the context of an energy-restricted diet".

## 5. Conditions and possible restrictions of use

### 5.1. Reduction of body weight (ID 854, 1556, 3725)

The Panel considers that in order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.

## CONCLUSIONS

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

- The food constituent, konjac mannan (glucomannan), which is the subject of the health claims, is sufficiently characterised.

**Reduction of body weight (ID 854, 1556, 3725)**

- The claimed effects are "weight management" and "contributes to weight management". The target population is assumed to be overweight subjects. Reduction of body weight is a beneficial physiological effect for overweight individuals.
- A cause and effect relationship has been established between the consumption of glucomannan and the reduction of body weight.
- The following wording reflects the scientific evidence: "Glucomannan contributes to the reduction of body weight in the context of an energy-restricted diet".
- In order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.

**Reduction of post-prandial glycaemic responses (ID 1559)**

- The claimed effect is "reduction of glycaemic response". The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. The reduction of post-prandial glycaemic responses may be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of glucomannan and the reduction of post-prandial glycaemic responses.

**Maintenance of normal blood glucose concentrations (ID 835, 3724)**

- The claimed effects are "glycaemic control" and "contributes to maintain a healthy blood sugar level". The target population is assumed to be the general population. Long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal blood glucose concentrations.

**Maintenance of normal (fasting) blood concentrations of triglycerides (ID 3217)**

- The claimed effect is "helps to maintain physiological lipid levels in the blood". The target population is assumed to be the general population. Maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal (fasting) blood concentrations of triglycerides.

**Maintenance of normal blood cholesterol concentrations (ID 3100, 3217)**

- The claimed effects are "helps to maintain physiological lipid levels in the blood" and "heart health". The target population is assumed to be the general population.
- A claim on glucomannan and the maintenance of normal blood cholesterol concentrations has already been assessed with a favourable outcome.

**Maintenance of normal bowel function (ID 834, 1557, 3901)**

- The claimed effects are "bowel functions", "intestinal health/bowel function" and "bowel function/colonic function". The target population is assumed to be the general population. Maintenance of normal bowel function in the context of a reduction in intestinal transit time and an increase in frequency of bowel movements within the normal range might be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of glucomannan and the maintenance of normal bowel function.

**Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 1558)**

- The claimed effect is "prebiotic action/bifidogenic action". The target population is assumed to be the general population. Decreasing potentially pathogenic gastro-intestinal microorganisms might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of glucomannan and decreasing potentially pathogenic gastro-intestinal microorganisms.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1621, EFSA-Q-2008-1622, EFSA-Q-2008-1641, EFSA-Q-2008-2293, EFSA-Q-2008-2294, EFSA-Q-2008-2295, EFSA-Q-2008-2296, EFSA-Q-2008-3832, EFSA-Q-2008-3949, EFSA-Q-2008-4446, EFSA-Q-2008-4447, EFSA-Q-2008-4617). 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.

## REFERENCES

Birketvedt GS, Shimshi M, Erling T and Florholmen J, 2005. Experiences with three different fiber supplements in weight reduction. Medical Science Monitor, 11, PI5-8.

Cairella M and Marchini G, 1995. Evaluation of the action of glucomannan on metabolic parameters and on the sensation of satiation in overweight and obese patients. La Clinica Terapeutica, 146, 269-274.

Chen HL, Sheu WH, Tai TS, Liaw YP and Chen YC, 2003. Konjac supplement alleviated hypercholesterolemia and hyperglycemia in type 2 diabetic subjects-a randomized double-blind trial. Journal of the American College of Nutrition, 22, 36-42.

Chen HL, Cheng HC, Liu YJ, Liu SY and Wu WT, 2006. Konjac acts as a natural laxative by increasing stool bulk and improving colonic ecology in healthy adults. Nutrition, 22, 1112-1119.

Cummings JH, Antoine JM, Azpiroz F, Bourdet-Sicard R, Brandtzaeg P, Calder PC, Gibson GR, Guarner F, Isolauri E, Pannemans D, Shortt C, Tuijtelaars S and Watzl B, 2004. PASSCLAIM – Gut health and immunity. European Journal of Clinical Nutrition, 43, 18-173.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2009. 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 1924/2006 on request from the European Commission. EFSA Journal, 7(9):1258, 14 pp.

Hou YH, Zhang LS, Zhou HM, Wang RS and Zhang YZ, 1990. Influences of refined konjac meal on the levels of tissue lipids and the absorption of four minerals in rats. Biomedical and Environmental Sciences, 3, 306-314.

Katsuraya K, Okuyama K, Hatanaka K, Oshima R, Sato T and Matsuzaki K, 2003. Constitution of konjac glucomannan: chemical analysis and 13C NMR spectroscopy. Carbohydrate Polymers, 53, 183-189.

Keithley J and Swanson B, 2005. Glucomannan and obesity: a critical review. Alternative Therapies in Health and Medicine, 11, 30-34.

Loening-Baucke V, Miele E and Staiano A, 2004. Fiber (Glucomannan) is beneficial in the treatment of childhood constipation. Pediatrics, 113, e259-e264.

Magnati G, Arsenio L, Bodria P, Lateana M and Strata A, 1984. [Dietary fiber and OGTT: blood sugar variations after administration of a new purified glucomannane]. Acta Bio-Medica de l'Ateneo Parmense, 55, 5-14.

Marzio L, Del Bianco R, Donne MD, Pieramico O and Cuccurullo F, 1989. Mouth-to-cecum transit time in patients affected by chronic constipation: effect of glucomannan. American Journal of Gastroenterology, 84, 888-891.

Passaretti S, Franzoni M, Comin U, Donzelli R, Rocca F, Colombo E, Ferrara A, Dinelli M, Prada A and Curzio M, 1991. Action of glucomannans on complaints in patients affected with chronic constipation: a multicentric clinical evaluation. Italian Journal of Gastroenterology, 23, 421-425.

Staiano A, Simeone D, Del Giudice E, Miele E, Tozzi A and Toraldo C, 2000. Effect of the dietary fiber glucomannan on chronic constipation in neurologically impaired children. Journal of Pediatrics, 136, 41-45.

Venn BJ and Green TJ, 2007. Glycemic index and glycemic load: measurement issues and their effect on diet-disease relationships. European Journal of Clinical Nutrition, 61, 122-131.

Vido L, Facchin P, Antonello I, Gobber D and Rigon F, 1993. Childhood obesity treatment: double blinded trial on dietary fibres (glucomannan) versus placebo. Pädiatrie und Pädologie, 28, 133-136.

Vita PM, Restelli A, Caspani P and Klinger R, 1992. Chronic use of glucomannan in the dietary treatment of severe obesity. Minerva Medica, 83, 135-139.

Vorster HH, Kruger HS, Frylink S, Botha BJ, Lombaard WA and De Jager J, 1985. Physiological effects of the dietary fibre component konjac glucomannan in rats and baboons. Journal of Plant Foods, 6, 263-274.

Vuksan V, Jenkins DJ, Spadafora P, Sievenpiper JL, Owen R, Vidgen E, Brighenti F, Josse R, Leiter LA and Bruce-Thompson C, 1999. Konjac-mannan (glucomannan) improves glycemia and other associated risk factors for coronary heart disease in type 2 diabetes. A randomized controlled metabolic trial. Diabetes Care, 22, 913-919.

Vuksan V, Sievenpiper JL, Owen R, Swilley JA, Spadafora P, Jenkins DJ, Vidgen E, Brighenti F, Josse RG, Leiter LA, Xu Z and Novokmet R, 2000. Beneficial effects of viscous dietary fiber from konjac-mannan in subjects with the insulin resistance syndrome: results of a controlled metabolic trial. Diabetes Care, 23, 9-14.

Vuksan V, Sievenpiper JL, Xu Z, Wong EY, Jenkins AL, Beljan-Zdravkovic U, Leiter LA, Josse RG and Stavro MP, 2001. Konjac-mannan and American ginsing: emerging alternative therapies for type 2 diabetes mellitus. Journal of the American College of Nutrition, 20, 370S-380S.

Walsh DE, Yaghoubian V and Behforooz A, 1984. Effect of glucomannan on obese patients: a clinical study. International Journal of Obesity, 8, 289-293.

Wood RJ, Fernandez ML, Sharman MJ, Silvestre R, Greene CM, Zern TL, Shrestha S, Judelson DA, Gomez AL, Kraemer WJ and Volek JS, 2007. Effects of a carbohydrate-restricted diet with and without supplemental soluble fiber on plasma low-density lipoprotein cholesterol and other clinical markers of cardiovascular risk. Metabolism, 56, 58-67.

# APPENDICES

## APPENDIX A

### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[7] (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 FOOD[8]

Foods are commonly involved in many different functions[9] 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.

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] 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.

## APPENDIX C

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

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|---|---|---|---|
| **834** | konjac mannan (glucomannan) | Bowel functions | Helps to maintain normal bowel/colonic function.<br>Helps to promote intestinal regularity.<br>Helps to ensure healthy digestive functions.<br>Helps to support gastrointestinal health.<br>Helps to support intestinal function. |
| | **Conditions of use**<br>- konjac mannan From 1 to 5 grams per day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **835** | konjac mannan (glucomannan) | Glycemic control | Induces a low glycemic response.<br>Helps to control/ balance blood glucose/insulin level.<br>Sustain steady blood sugar levels.<br>Helps to maintain and improve blood glucose control.<br>Helps in the management of regular blood glucose level.<br>Helps to maintain insulin sensitivity.<br>Helps to support glycemic control. |
| | **Conditions of use**<br>- konjac manan From 1 to 5 grams per day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **854** | Glucomanan | Weight management | Contributes to reduce the appetite/Can help in the management of weight control/<br>By expanding in the stomach, glucomannan might be useful for people trying to lose weight, by helping to reduce the appetite. |

| | | | |
|---|---|---|---|
| | **Conditions of use**<br>- 3 g per day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **1556** | Glucomanan | Weight management | Contributes to reduce the appetite.<br>Can help in the management of weight control.<br>By expanding in the stomach, glucomannan might be useful for people trying to lose weight, by helping to reduce the appetite. |
| | **Conditions of use**<br>- 3 g per day<br>- konjac manan From 1 to 5 grams per day<br>- 4g pro Tag<br>- 3 Kapseln zu je 330 mg Glucomannan mit ¼ – ½ Liter Wasser eine halbe Stunde vor jeder Mahlzeit | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **1557** | Glucomannan (konjac) | Bowel / colonic function | -Helps to restore / promote / regulate normal intestinal function<br>- Facilitates the intestinal transit - promotes regularity of the bowel/colonic function<br>-Helps to maintain normal bowel/colonic function<br>- Ensures a healthy digestive system /function |
| | **Conditions of use**<br>- 2.5 - 5.0 g / day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **1558** | Glucomannan (konjac) | Prebiotic action / Bifidogenic action | Glucomannan:<br>-Helps to restore the intestinal flora<br>-Has a prebiotic effect<br>-Helps to stimulate the growth of beneficial colon bacteria<br>-Helps to stimulate the growth of Bifidobacteria<br>-Helps to stimulate the growth of bacteria in the colon |

| | | | |
|---|---|---|---|
| | **Conditions of use**<br>2.5 – 5.0 g / day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **1559** | Glucomannan (konjac) | Reduction of glycemic response | Glucomannan:<br>- helps to control/ balance blood insulin/ glucose level<br>- can help to reduce the glycemic index of a meal<br>- has beneficial effects on blood glucose and blood insulin level<br>- is suitable for diabetics |
| | **Conditions of use**<br>- 2.5-5.0 g / day | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **3100** | Glucomannan | Heart health<br>Clarification provided<br>Heart health. Contributes to heart health and artery health by helping maintain normal blood LDL-cholesterol levels. Helps reduce cholesterol levels in people with elevated blood cholesterol. | For people with elevated blood cholesterol;Helps maintain normal blood cholesterol levels. |
| | **Conditions of use**<br>- 3 – 13 g/d | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **3217** | Amorphophallus konjac Koch | Helps to maintain physiological lipid levels in the blood | Through balanced diets helps the control of lipidic metabolism (cholesterol and triglycerides).<br>Natural source maintaining the physiological fats balance in blood. |
| | **Conditions of use**<br>- 30-60 mg/kg/day, divided in 2 doses | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **3724** | Amorphophallus konjac Koch | Contributes to maintain a healthy blood sugar level | Helps the physiological sugars balance. |
| | **Conditions of use**<br>- Tuber / 2 -3 g of glucomannan daily, equivalent preparations | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **3725** | Amorphophallus konjac Koch | Contributes to weight | Contributes to weight |

| | | | |
|---|---|---|---|
| | | management | management, reducing the appetite. Adjuvant during a hypocaloric diet for the control weight. |
| | **Conditions of use**<br>- 30-60 mg/kg/day, divided in 2 doses<br>- Tuber / 2 -3 g of glucomannan daily; equivalent preparations | | |
| **ID** | **Food or Food constituent** | **Health Relationship** | **Proposed wording** |
| **3901** | Amorphophallus konjac KOCH (Common Name : konjac) | Intestinal health / Bowel function | Helps to regulate transit time<br>Helps to maintain a good transit |
| | **Conditions of use**<br>- Tuber / 2 -3 g of glucomannan daily; equivalent preparations | | |

## GLOSSARY AND ABBREVIATIONS

| | |
|---|---|
| BMI | Body mass index |
| CI | Confidence interval |
| LDL | Low-density lipoproteins |
| OGTT | Oral glucose tolerance test |
| RTC | Randomised controlled trial |
| SD | Standard deviation |
| SEM | Standard error of the mean |
| VLDL | Very-low-density lipoproteins |