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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to fructooligosaccharides (FOS) from sucrose and decreasing potentially pathogenic gastro-intestinal microorganisms (ID 774), changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract (ID 775), changes in bowel function (ID 775, 778), reduction of gastro-intestinal discomfort (ID 775, 778), increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention (ID 776, 777), maintenance of normal blood LDL-cholesterol concentrations (ID 805) and maintenance of normal (fasting) blood concentrations of triglycerides (ID 805) 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

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 fructooligosaccharides (FOS) from sucrose and decreasing potentially pathogenic gastro-intestinal microorganisms, changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract, changes in bowel function, reduction of gastro-intestinal discomfort, increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention, maintenance of normal blood LDL-cholesterol concentrations and maintenance of normal (fasting)

[1] On request from the European Commission, Question No, EFSA-Q-2008-1561, EFSA-Q-2008-1562, EFSA-Q-2008-1563, EFSA-Q-2008-1564, EFSA-Q-2008-1565, EFSA-Q-2008-1592, adopted on 12 November 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.

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blood concentrations of triglycerides. 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 fructooligosaccharides (FOS) from sucrose. The Panel considers that fructooligosaccharides (FOS) from sucrose are sufficiently characterised.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 774)

The claimed effect is "prebiotic/bifidogenic". 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 increasing numbers of bacteria that are 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 the claimed effect, in the context of 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.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and decreasing potentially pathogenic gastro-intestinal microorganisms.

Changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract (ID 775)

The claimed effect is "improved intestinal conditions (pH, SCFA production) and intestinal functions". The target population is assumed to be the general population. The Panel notes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and pH in the bowel. The Panel considers that changes in SCFA production and pH in the bowel are not *per se* beneficial physiological effects, but need to be linked to a beneficial physiological or clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological 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 fructooligosaccharides from sucrose and a beneficial physiological effect related to changes in SCFA production and pH in the gastro-intestinal tract.

Changes in bowel function (ID 775, 778)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". The target population is assumed to be the general population. In the context of the proposed wording, the Panel assumes that the claimed effects refer to changes in bowel function. The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided these changes do not result in diarrhoea.

In weighing the evidence, the Panel took into account that the only relevant human study showed no effect of FOS on bowel function.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and changes in bowel function.

Reduction of gastro-intestinal discomfort (ID 775, 778)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". 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 reducing gastro-intestinal discomfort. The Panel considers that reduction of gastro-intestinal discomfort is 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 fructooligosaccharides from sucrose and reduction of gastro-intestinal discomfort.

Increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention (ID 776, 777)

The claimed effects are "increase mineral (Ca/Mg) absorption" and "mineral absorption". The target population is assumed to be the general population. The Panel notes that the claimed effect (improved nutrient absorption) is only considered beneficial where absorption is a limiting factor for the maintenance of adequate status of the nutrient, and where increased absorption leads to increased retention. The Panel considers that an increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that only two chronic studies in a low number of human subjects were provided and that these studies, though suggesting an effect on magnesium (but not calcium) absorption, do not show an effect of FOS from sucrose on mineral retention.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and an increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention.

Maintenance of normal blood LDL-cholesterol concentrations (ID 805)

The claimed effect is "blood lipids". 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 maintenance of normal blood LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that six out of the seven small intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not observe a significant effect of FOS from sucrose on blood cholesterol concentrations.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and maintenance of normal blood LDL-cholesterol concentrations.

Maintenance of normal (fasting) blood concentrations of triglycerides (ID 805)

The claimed effect is "blood lipids". The target population is assumed to be the general population. In the context of the references provided, the Panel assumes that the claimed effect refers 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 none of the seven intervention studies from which conclusions could be drawn for the scientific substantiation of the claim observed a significant effect of FOS from sucrose on blood concentrations of triglycerides.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and the maintenance of normal (fasting) blood concentrations of triglycerides.

KEY WORDS

Fructooligosaccharides, pathogenic microorganisms, bowel function, gastro-intestinal comfort, calcium absorption, magnesium absorption, LDL-cholesterol, triglycerides, 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[4] 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[5]. 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 claim is fructooligosaccharides obtained from sucrose.

Fructooligosaccharides (FOS) obtained from sucrose are prepared by enzymatic elongation of sucrose, and consist of a mixture of kestose (glucose-fructose-fructose, GF2), nystose (GF3) and fructosylnystose (GF4), with an average degree of polymerisation (DPav) of 3.6, and are sometimes referred to as short-chain fructooligosaccharides. They differ from natural fructans by degree of polymerisation (DP) (only 10 % of native chicory inulins have a DP between 2 and 5) (Roberfroid, 2007), and from oligofructoses prepared by inulin hydrolysis (DP from 2 to 7, DPav 4) by the systematic presence of a glucose moiety.

The Panel considers that the food constituent, fructooligosaccharides (FOS) from sucrose, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 774)

The claimed effect is "prebiotic/bifidogenic". 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 increasing numbers of bacteria which are considered to be "beneficial".

The numbers/proportions of bacterial groups that would constitute a "beneficial" colon/gastro-intestinal flora have not been established. Increasing the number of any group of microorganisms, including lactobacilli and/or bifidobacteria, is not in itself considered to be 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 the claimed effect, in the context of decreasing potentially pathogenic gastro-intestinal microorganisms, might be a beneficial physiological effect.

[4] 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.

[5] 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. Changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract (ID 775)

The claimed effect is "improved intestinal conditions (pH, SCFA production) and intestinal functions". The Panel assumes that the target population is the general population.

The Panel notes that the claimed effect refers to changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract.

The Panel considers that changes in SCFA production and pH in the gastro-intestinal tract are not *per se* beneficial physiological effects, but need to be linked to a beneficial physiological or clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and a beneficial physiological effect related to changes in SCFA production and pH in the gastro-intestinal tract.

2.3. Changes in bowel function (ID 775, 778)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effects refer to changes in bowel function.

The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided these changes do not result in diarrhoea.

2.4. Reduction of gastro-intestinal discomfort (ID 775, 778)

The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effects refer to reducing gastro-intestinal discomfort.

The Panel considers that reduction of gastro-intestinal discomfort is a beneficial physiological effect.

2.5. Increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention (ID 776, 777)

The claimed effects are "increase mineral (Ca/Mg) absorption" and "mineral absorption". The Panel assumes that the target population is the general population.

The Panel notes that the claimed effect (improved nutrient absorption) is only considered beneficial where absorption is a limiting factor for the maintenance of adequate status of the nutrient, and where increased absorption leads to increased retention.

The Panel considers that an increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention may be a beneficial physiological effect.

2.6. Maintenance of normal blood LDL-cholesterol concentrations (ID 805)

The claimed effect is "blood lipids". 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 blood LDL-cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.1 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

2.7. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 805)

The claimed effect is "blood lipids". The Panel assumes that the target population is the general population.

In the context of the references provided, 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. 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.

3. Scientific substantiation of the claimed effect

3.1. Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 774)

Among the references provided were reviews, textbooks and opinions/guidelines from authoritative bodies which either did not address the claimed effect or did not contain any original data which could be used for the scientific substantiation of the claimed effect. Some human studies were not related to the food constituent that is the subject of the claim, or examined the effect of FOS in combination with other substances, and several human and animal studies addressed outcomes unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect. One conference report related to the effect of FOS on intestinal microbiota was not accessible to the Panel after having made every reasonable effort to retrieve it (Rochat et al., 1994).

Several human studies focused on the effects of FOS on faecal bifidobacteria (Bouhnik et al., 2004; Gibson and Wang, 1994a; Gibson and Wang, 1994b), or on bifidobacteria together with other bacterial groups (e.g. total aerobes, total anaerobes, staphylococci, enterococci, *Bacteroides*, enterobacteria, clostridia, fusobacteria, coliforms) (Bouhnik et al., 1996; Bouhnik et al., 1999; Bouhnik et al., 2006; Buddington et al., 1996; Gibson et al., 1995; Rao, 2001; Waligora-Dupriet et al., 2007). The Panel notes that the bacterial groups analysed in these studies are part of the commensal intestinal microbiota, and that the studies did not provide evidence for the characterisation of any of these groups as pathogens. In three human studies the effect of FOS on *Clostridium perfringens* was analysed (Mitsuoka et al., 1986; Mitsuoka et al., 1987; Tokunaga et al., 1993), but no information was given about the pathogenicity of the bacterial strains studied. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claimed effect.

The Panel notes that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claimed effect. The Panel considers that human studies are required for the substantiation of a claim, and that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of FOS consumption on decreasing potentially pathogenic intestinal microorganisms in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and decreasing potentially pathogenic intestinal microorganisms.

3.2. Changes in bowel function (ID 775, 778)

Among the references provided were reviews, textbooks and opinions from authoritative bodies which either did not address the claimed effect or did not contain any original data which could be used for the scientific substantiation of the claimed effect. A number of human studies addressed the effects of substances other than FOS or of a mixture of FOS with other substances, or addressed outcomes not related to the claimed effect (e.g. abdominal comfort). The provided animal and *in vitro* studies assessed endpoints not related to the claimed effect (e.g. butyrate content in faeces, SCFA content, number of selected microbiota, β-galactosidase, α-glucosidase, β-glucosidase and β-glucuronidase activity, colon crypts depth, numbers of epithelial and mitotic cells in the crypt columns, caecal wall weight, proliferation index and indices of artificially provoked colitis). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Bouhnik et al. (1996) found, in a randomised, placebo-controlled study in a group of healthy volunteers (n=20) with saccharose as placebo, that FOS consumption of 12.5 g/day did not significantly affect stool weight (FOS group: 134±22 g/day, placebo group: 121±19 g/day, $p>0.05$).

In a randomised, single-blind, parallel trial FOS (mean dose 0.74±0.39 g/day) was added to cereal formula intended for feeding infants and given for 28 days to a group of healthy term infants (n=27) aged 4–12 months (mean 8.3 months) (Moore et al., 2003). The effect of FOS addition to cereals was compared to the same cereals with the addition of the equivalent amount of maltodextrin (n=29). Stool frequency was recorded by parents. The Panel notes that the tool used for assessing bowel function (parent's assessment) was not validated, that the main aim of the study was to assess tolerance of FOS given to infants, and that the sample size was relatively small. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

In a single-blind study, Tokunaga et al. (1993) studied the effect of FOS (daily dose 1.3 or 5 g) on intestinal microbiota and bowel function in 27 healthy volunteers. The Panel notes that the study was not placebo-controlled, that no information about randomisation was given, and that multiple comparison testing was not included in the statistical analysis. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

In weighing the evidence, the Panel took into account that the only relevant human study showed no effect of FOS consumption on bowel function.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and changes in bowel function.

3.3. Reduction of gastro-intestinal discomfort (ID 775, 778)

All references considered in section 3.2. were also provided for the substantiation of this claim.

A number of human studies addressed the effects of substances other than FOS or of a mixture of FOS with other substances, or addressed outcomes not related to the claimed effect (e.g. stool frequency and intestinal microbiota). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Only one human study addressed the effect of FOS from sucrose on abdominal comfort.

Paineau et al. (2008) evaluated in a randomised, multicentre, double-blind, placebo-controlled study the effect of FOS from sucrose (5 g/day) *vs*. placebo (sucrose and maltodextrins) on the digestive comfort of subjects with minor functional bowel disorders (n=105, mean age 38 years, 85 % women). The prevalence and general frequency of digestive symptoms based on Rome II criteria were recorded in a questionnaire including questions about the presence and intensity of five abdominal symptoms (discomfort or pain; fullness, bloating or swelling; feeling of incomplete bowel movement; urgency; straining at stool). This questionnaire (called the initial questionnaire) was used for inclusion, and at the end of the study to determine changes in intensity of symptoms. The participants were also asked to complete a questionnaire (called the consultation questionnaire) designed to assess the frequency of digestive symptoms and stool quality before the intervention period and at the end of the study. Quality of life was assessed using the French language functional digestive disorders quality of life questionnaire (FDDQL). Baseline intensity of symptoms at the beginning of the study was similar in both studied groups. The participants took two packets daily containing 2.5 g FOS or placebo for six weeks. Eight subjects dropped out during the study (four in each group) and compliance was estimated as good for 50 subjects (24 in FOS and 26 in placebo group). Final results were presented only for these 50 subjects. The Panel notes that except for the quality of life questionnaire no information was provided on the validation of the other questionnaires, that the validated quality of life questionnaire alone is insufficient as an outcome measure, that a power calculation was not presented, that only the data obtained from 48 % of the participants included in the study were used for statistical analysis of the results, that no intention-to-treat analysis of the data was reported, and that in the statistical analysis correction for multiple testing was not performed. 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 fructooligosaccharides from sucrose and reduction of gastro-intestinal discomfort.

3.4. Increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention (ID 776, 777)

Among the references cited in relation to this claim were narrative reviews that either did not contain original data that could be used for the scientific substantiation of the claimed effect, or did not address the food constituent which is the subject of the claim. A number of references addressed outcomes not related to the claimed effect, or used different inulin-type fructans or a mixture of short-chain fructooligosaccharides and inulin. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

Five human studies explicitly used FOS from sucrose (Fukushima et al., 2002; Hosono et al., 1997; Ohta et al., 1999; Tahiri et al., 2001; 2003), which is the subject of the claim.

Three of the human intervention studies addressed the effects of FOS from sucrose on urinary excretion of calcium as a surrogate measure of calcium absorption after a single oral dose of calcium administered in different chemical forms (Fukushima et al., 2002; Hosono et al., 1997; Ohta et al., 1999). None of the studies provided measures of calcium retention. The Panel considers that no conclusions can be drawn from these acute and small-scale studies for the scientific substantiation of the claimed effect.

A first study by Tahiri et al. (2001) was conducted in 11 healthy postmenopausal women not receiving hormone replacement therapy who consumed 10 g/day of FOS for five weeks, and placebo for another five weeks, with a three-week wash-out period in between, following a cross-over, double-blind, randomised design. Magnesium absorption from the diet (providing around 250 mg Mg/day) was determined by ingestion of a stable isotope (^{25}Mg) and a faecal marker. The absorption of magnesium was significantly increased from 30.2±5 % to 33.9±7.2 % (i.e. a 12 % increase) in the FOS group. This increase was accompanied by an increase in ^{25}Mg plasma concentrations and by an increase in

magnesium urinary excretion. Isotope-labelled ^{25}Mg retention was reported to be significantly higher with FOS (27.5±5.6 mg) than without FOS (24.7±4.0 mg), however the increase in urinary excretion of magnesium was similar to the increase in magnesium absorption (10 mg/day). No significant increase in apparent magnesium retention was observed.

A second study by Tahiri et al. (2003) was a double-blind, cross-over, randomised control trial (RCT) conducted in 12 healthy post-menopausal women not receiving hormonal therapy who consumed 10 g FOS and placebo for five weeks each with a three-week wash-out period in between. Calcium absorption from the diet (providing about 900 mg Ca/day) was determined using oral isotope-labelled ^{44}Ca and a faecal marker. Changes in intestinal absorption of calcium were not different between groups. Calcium retention was not measured in this study.

Two studies in rats investigated the effects of FOS from sucrose of different chain length on calcium and magnesium absorption and excretion (Ohta et al., 1995; 1998). The Panel considers that evidence provided in rat studies is not sufficient to predict the occurrence of an effect of the consumption of FOS on mineral absorption in humans, especially when considering anatomical differences in the caecum and large intestine between rats and humans.

In weighing the evidence, the Panel took into account that only two chronic studies in a low number of human subjects were provided, and that these studies, though suggesting an effect on magnesium (but not calcium) absorption, do not show an effect of FOS from sucrose on mineral retention.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and an increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention.

3.5. Maintenance of normal blood LDL-cholesterol concentrations (ID 805)

Among the references cited in relation to this claim were general reviews on “prebiotic” substances, references addressing outcomes either not related to the claimed effect or using different oligosaccharides or polysaccharides than FOS from sucrose, which is the subject of the claim, and a meta-analysis on the effects of fructans on triglyceride concentrations in humans. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

A total of eight human studies addressed the effects of FOS from sucrose on blood cholesterol concentrations (Alles et al., 1999; Daubioul et al., 2005; Giacco et al., 2004; Hidaka et al., 1991; Luo et al., 1996; 2000; van Dokkum et al., 1999; Yamashita et al., 1984).

In the 2-week study by Yamashita et al. (1984), no direct comparison between the intervention (18 diabetic subjects consuming 8 g/day of FOS from sucrose) and control (10 subjects consuming 5 g/day of sucrose) groups with respect to changes in total and LDL-cholesterol concentrations was reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

In the randomised, controlled intervention by Hidaka et al. (1991), 46 hyperlipidaemic patients (20 men, 26 women) received either 8 g/day of FOS from sucrose or the same amount of sucrose (control) for five weeks. Total cholesterol concentrations were significantly decreased in the intervention group compared to placebo. In a second experiment reported in the same publication, seven hypercholesterolaemic subjects with type II hyperlipoproteinaemia received 8 g/day of FOS from sucrose for one month. This intervention was not controlled (one arm). The Panel considers that no conclusions can be drawn from the second experiment for the scientific substantiation of the claimed effect.

In the remaining six studies, 8-20 g/day of FOS from sucrose were consumed by 7-30 subjects (healthy or with type 2 diabetes) during two to eight weeks, using either a double-blind, randomised

controlled design or a cross-over design. These studies (91 subjects in total, including 24 healthy, 30 mildly hypercholesterolaemic, 30 with type 2 diabetes, and seven with non alcoholic liver steatosis) reported no significant differences on total blood cholesterol concentrations or cholesterol sub-fractions between the FOS and the control groups (Alles et al., 1999; Daubioul et al., 2005; Giacco et al., 2004; Luo et al., 1996; 2000; van Dokkum et al., 1999).

In weighing the evidence, the Panel took into account that six out of the seven small intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not observe a significant effect of FOS from sucrose on blood cholesterol concentrations.

The Panel concludes that a cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and maintenance of normal blood LDL-cholesterol concentrations.

3.6. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 805)

All references considered in section 3.5. were also provided for the substantiation of this claim.

A meta-analysis of randomised clinical trials on the effects of inulin-type fructans and FOS from sucrose on plasma concentrations of triglycerides (Brighenti, 2007) was provided. No separate conclusions on the effects of inulin-type fructans and FOS from sucrose were presented, and hence no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claimed effect.

In addition, eight human intervention studies which addressed the effects of FOS from sucrose on blood concentrations of triglycerides were provided (Alles et al., 1999; Daubioul et al., 2005; Giacco et al., 2004; Hidaka et al., 1991; Luo et al., 1996; 2000; van Dokkum et al., 1999; Yamashita et al., 1984).

In the two-week study by Yamashita et al. (1984), no direct comparison between the intervention (18 diabetic subjects consuming 8 g/day of FOS from sucrose) and control (10 subjects consuming 5 g/day of sucrose as placebo) groups with respect to changes in blood concentrations of triglycerides was reported. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claimed effect.

The remaining seven publications reported on randomised, controlled trials with either parallel or cross-over designs, in which 8-20 g/day of FOS from sucrose were consumed by 7-30 subjects during two to eight weeks. None of these studies (181 subjects in total, including 24 healthy, 120 mildly hypercholesterolaemic, 30 with type 2 diabetes, and seven with non alcoholic liver steatosis) reported statistically significant differences on blood concentrations of triglycerides between the FOS and the control group (Alles et al., 1999; Daubioul et al., 2005; Giacco et al., 2004; Hidaka et al., 1991; Luo et al., 1996; 2000; van Dokkum et al., 1999).

In weighing the evidence, the Panel took into account that none of the seven intervention studies from which conclusions could be drawn for the scientific substantiation of the claim observed a significant effect of FOS from sucrose on blood concentrations of triglycerides.

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

CONCLUSIONS

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

- The food constituent, fructooligosaccharides from sucrose, which is the subject of the health claims, is sufficiently characterised.

Decreasing potentially pathogenic gastro-intestinal microorganisms (ID 774)

- The claimed effect is "prebiotic/bifidogenic". 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 fructooligosaccharides from sucrose and decreasing potentially pathogenic gastro-intestinal microorganisms.

Changes in short chain fatty acid (SCFA) production and pH in the gastro-intestinal tract (ID 775)

- The claimed effect is "improved intestinal conditions (pH, SCFA production) and intestinal functions". The target population is assumed to be the general population. Changes in SCFA production and pH in the gastro-intestinal tract are not *per se* beneficial physiological effects, but need to be linked to a beneficial physiological or clinical outcome. No evidence has been provided to indicate the context in which the claimed effect could be considered as a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and a beneficial physiological effect related to changes in SCFA production and pH in the gastro-intestinal tract.

Changes in bowel function (ID 775, 778)

- The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". The target population is assumed to be the general population. In the context of the proposed wording, it is assumed that the claimed effects refer to changes in bowel function. Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided these changes do not result in diarrhoea.

- A cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and changes in bowel function.

Reduction of gastro-intestinal discomfort (ID 775, 778)

- The claimed effects are "improved intestinal conditions (pH, SCFA production) and intestinal functions", and "gastrointestinal conditions and functions". The target population is assumed to be the general population. In the context of the proposed wording, it is assumed that the claimed effects refer to reducing gastro-intestinal discomfort. Reduction of gastro-intestinal discomfort is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and reduction of gastro-intestinal discomfort.

Increase in calcium and/or magnesium absorption leading to an increase in magnesium and/or calcium retention (ID 776, 777)

- The claimed effects are "increase mineral (Ca/Mg) absorption" and "mineral absorption". The target population is assumed to be the general population. An increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention may be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and an increase in magnesium and/or calcium absorption leading to an increase in magnesium and/or calcium retention.

Maintenance of normal blood LDL-cholesterol concentrations (ID 805)

- The claimed effect is "blood lipids". The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of fructooligosaccharides from sucrose and maintenance of normal blood LDL-cholesterol concentrations.

Maintenance of normal (fasting) blood concentrations of triglycerides (ID 805)

- The claimed effect is "blood lipids". The target population is assumed to be the general population. In the context of the references provided, it is assumed that the claimed effect refers to the maintenance of normal (fasting) blood concentrations of triglycerides. 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 fructooligosaccharides from sucrose and the maintenance of normal (fasting) concentrations of triglycerides.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1561, EFSA-Q-2008-1562, EFSA-Q-2008-1563, EFSA-Q-2008-1564, EFSA-Q-2008-1565, EFSA-Q-2008-1592). 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 foods[6] (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[7]

Foods are commonly involved in many different functions[8] 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.

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

[6] OJ L12, 18/01/2007
[7] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[8] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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 fructooligosaccharides from sucrose, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
774	Fructooligosaccharides from sucrose	Prebiotic / Bifidogenic	-fructoligosaccharides from sucrose / oligofructose stimulates the growth of Bifidobacteria in the colon; -fructoligosaccharides/ oligofructose beneficially affects the intestinal flora; -fructoligosaccharides/ oligofructose are prebiotics; -fructoligosaccharides/ oligofructose promote healthy/good/balanced gut bacteria.
	Conditions of use - 2 g/Tag, aus Sucrose - beginnt bei 5g/Tag - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 2.5g/day - 2.5g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
775	Fructooligosaccharides from sucrose	Improved intestinal conditions (pH, SCFA production) and intestinal functions	-fructoligosaccharides from sucrose/ oligrofructose promote healthy conditions in the colon; -fructoligosaccharides/ oligrofructose improve bowel function; -fructoligosaccharides/ oligrofructose improve gut comfort.
	Conditions of use - 5 g/Tag, FOS aus Sukrose - 5g/Tag - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 5g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
776	Fructooligosaccharides from sucrose	Increase mineral (Ca/ Mg) absorption	-fructooligosaccharides/ oligrofructose enhance/ promote/ increase magnesium absorption; -fructooligosaccharides/ oligrofructose enhance/ promote/ increase calcium absorption; -fructooligosaccharides/ oligrofructose support isoflavone activity on bone health
	Conditions of use - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 10g/day. - 8 g/Tag.		

	- 10 g/Tag aus Sucrose.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
777	Fructooligosaccharides from sucrose	Mineral absorption	Fructooligosaccharides/oligofructose enhance/promote/ increase magnesium absorption Fructooligosaccharides/oligofructose enhance/promote/ increase magnesium absorption Fructooligosaccharides/oligofructose support isoflavone activity on bone health
	Conditions of use - Min. 10 g per day. - 8 g/Tag.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
778	Fructooligosaccharides from sucrose	Gastrointestinal conditions and functions	Fructooligosaccharides /oligofructose promote intestinal health/ healthy conditions in the colon Fructooligosaccharides/oligofructose improve digestive comfort Fructooligosaccharides/oligofructose help maintain a healthy digestive system Fructooligosaccharides/oligofructose improve bowel function Fructooligosaccharides/oligofructose improve intestinal well-being
	Conditions of use - Min. 5g per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
805	Fructooligosaccharides from sucrose	Blood lipids	fructooligosaccharides/oligofructose support the regulation of blood lipid levels fructooligosaccharides/oligofructose support the regulation of lipid metabolism - combined to a balanced diet contribute to healthy blood cholesterol level; - contribute to / support the regulation of the blood lipid level; - contribute to / support the regulation of the cholesterol level
	Conditions of use - Min. 8 g/day. - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated 8g/day		

GLOSSARY AND ABBREVIATIONS

DPav	Average degree of polymerization
DP	Degree of polymerization
FDDQL	Functional digestive disorders quality of life
FOS	Fructooligosaccharides
LDL	Low-density lipoproteins
RCT	Randomised control trial
SCFA	Short chain fatty acid
VLDL	Very-low-density lipoproteins