EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to rye fibre and changes in bowel function (ID 825), reduction of post-prandial glycaemic responses (ID 826) and maintenance of normal blood LDL-cholesterol concentrations (ID 827) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to rye fibre and changes in bowel function (ID 825), reduction of post-prandial glycaemic responses (ID 826) and maintenance of normal blood LDL-cholesterol concentrations (ID 827) 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 rye fibre and changes in bowel function, reduction of post-prandial glycaemic responses and maintenance of normal blood LDL-cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is rye fibre. The Panel considers that rye fibre is sufficiently characterised in relation to the claimed effects.

Changes in bowel function

The claimed effect is "gut health". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to changes in bowel function. The Panel considers that changes in bowel function such as

[1] On request from the European Commission, Question No EFSA-Q-2008-1612, EFSA-Q-2008-1613, EFSA-Q-2008-1614, adopted on 25 March 2011.

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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.

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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 results of all four human intervention studies considered showed an effect of rye fibre on various outcome measures related to bowel function. The Panel also notes the known mechanism by which rye fibre exerts the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of rye fibre and changes in bowel function.

The Panel considers that in order to bear the claim a food should be at least "high in fibre" as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

Reduction of post-prandial glycaemic responses

The claimed effect is "carbohydrate metabolism and insulin sensitivity". The target population is assumed to be individuals who wish 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 (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the three human intervention studies provided from which conclusions could be drawn for the scientific substantiation of the claim, did not show an effect of rye fibre on post-prandial glycaemic responses.

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

Maintenance of normal blood LDL-cholesterol concentrations

The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, 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 the only human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of rye fibre on blood LDL-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 rye fibre and maintenance of normal blood LDL-cholesterol concentrations.

KEY WORDS

Rye fibre, bowel function, post-prandial, glycaemic response, LDL-cholesterol, 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 claims is rye fibre.

The rye (*Secale cereale* L.) fibre is predominantly composed of non-starch polysaccharides. The main components of the non-starch polysaccharides in whole grain rye are arabinoxylan (8-12 %), fructan (4.6-6 %), beta-glucan (1.3-2.2 %) and cellulose (1.0-1.7 %) (Kamal-Eldin et al., 2009). More than 80 % of rye fibre is insoluble. Beta-glucan and arabinoxylan are the soluble types of fibre in rye.

Rye bran products may differ with regard to chemical composition and particle size depending on the milling process.

The Panel considers that the food constituent, rye fibre, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Changes in bowel function (ID 825)

The claimed effect is "gut health". The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers 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.

[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] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

2.2. Reduction of post-prandial glycaemic responses (ID 826)

The claimed effect is "carbohydrate metabolism and insulin sensitivity". The Panel assumes that the target population is individuals wishing 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.

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This function is a normal physiological response which varies in magnitude and duration, and which 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). Reducing post-prandial blood glucose responses may be beneficial, for example, to subjects with impaired glucose tolerance as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general population of adults.

The Panel considers that a reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

2.3. Maintenance of normal blood LDL-cholesterol concentrations (ID 827)

The claimed effect is "cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, 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 (>4.14 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.

3. Scientific substantiation of the claimed effect

3.1. Changes in bowel function (ID 825)

The references provided for the substantiation of the claim included two textbooks, one guideline document, one human study and one animal study, all of which reported on health outcomes unrelated to the claimed effect (e.g. faecal bile acids and formation of intestinal polyps). One reference was an abstract from a conference proceeding which did not provide sufficient information for a full scientific evaluation, and one reference on a human study was not accessible to the Panel after every reasonable effort had been made to retrieve it. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A randomised, cross-over intervention study conducted in 28 overweight men investigated the effect on faecal weight of consuming foods (90 g) which contained either whole-grain rye flour or whole-grain wheat flour and provided about 21 g/day of dietary fibre *vs*. consuming refined cereal foods which provided 6 g/day of dietary fibre, for four weeks (McIntosh et al., 2003). Total 24 h faecal weight after consumption of high rye fibre foods was significantly higher than after consumption of low-fibre refined cereal foods (mean ±SEM=278±16 g *vs*. 203±18 g, $p<0.005$).

In a randomised, cross-over study, Gråsten et al. (2000) compared the effect of a whole-meal rye bread diet *vs*. a wheat bread diet in 17 healthy volunteers (nine women). Both interventions lasted four weeks. Subjects were advised to eat a minimum of 20 % of their total daily energy intake in the form of the tested breads. The intake of total dietary fibre from the tested products was estimated as 17.4±2.1 g/day for the rye bread period and 3.9±0.9 g/day for the wheat bread period. Wet and dry faecal weight, faecal frequency and intestinal transit time measured by a radiopaque method were evaluated. Differences between interventions were assessed by the Wilcoxon signed-ranks test. The results were presented separately for women and men. Compared to the wheat bread diet, the whole-meal rye bread diet significantly increased faecal weight (women 203±58 *vs*. 151±63 g/day, $p<0.05$; men 335±921 *vs*. 198±61, $p<0.05$) and faecal frequency (women 1.2±0.4 *vs*. 0.9±0.4 times per day, $p<0.05$; men 1.6±0.6 *vs*. 1.4±0.6 times per day, $p<0.05$), and significantly shortened intestinal transit time (women 44.8±13.1 *vs*. 56.2±22.0 hours, $p<0.05$; men 30.9±12.1 *vs*. 39.4±15.6 hours, $p<0.05$), in both women and men.

In a randomised, parallel study, Hongisto (2006) evaluated the effect of rye bread (containing 12.3 g fibre/100 g) with or without the bacterial strain *Lactobacillus rhamnosus* GG (LGG, ATCC53103) *vs*. low-fibre toast (control) on bowel function in a group of 59 women with self-reported constipation (mean age 41 years). Rye bread provided 37 g/day of dietary fibre, while low-fibre toast provided 6.6 g/day. During the three-week dietary intervention, the frequency of bowel movements was significantly higher in the rye bread group (n=15) compared to the control group (n=15) (mean difference 0.3 defecations/day, CI 95 % 0.1 to 0.5, $p<0.001$). Total intestinal transit time (measured by radiopaque method) was significantly shorter in the rye bread group than in the low-fibre toast group (mean difference = -0.7 days, CI 95 % -1.1 to -0.2, $p=0.007$).

Gråsten et al. (2007) in a randomised, cross-over study in 39 post-menopausal women with hypercholesterolaemia (mean age 59 years) administered rye bread with high fibre content (approximately 17 %) and white wheat bread with low fibre content (approximately 2.8 %) at doses covering at least 20 % of daily energy intakes for eight weeks each, with an eight-week wash-out period in between. The Wilcoxon test with Bonferroni adjustments was used for comparisons between the two intervention periods. The mean fibre intake in the rye bread period was 21.5 g/day higher than in the white wheat bread period (47±9 and 15±4 g/day during the rye bread and the white wheat bread periods, respectively). Frequency of defecation was significantly higher during the rye bread period than during the white wheat bread period (11.3±2.7 *vs*. 8.5±2.1 times per week, $p<0.05$). The proportion of soft stools was significantly higher and the proportion of hard stools was significantly lower during the rye bread period than during the white wheat bread period ($p<0.05$).

The Panel notes that the mechanism by which rye fibre could exert an effect on faecal weight, transit time and stool consistency is known and relates to an increase in water holding capacity of the content of the intestine.

In weighing the evidence, the Panel took into account that the results of all four human intervention studies considered showed an effect of rye fibre on various outcome measures related to bowel function. The Panel also noted the known mechanism by which rye fibre exerts the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of rye fibre and changes in bowel function.

3.2. Reduction of post-prandial glycaemic responses (ID 826)

The references provided for the substantiation of the claim included one human intervention study which reported on health outcomes other than the claimed effect (e.g. bowel function); human intervention studies conducted in insulin-dependent diabetic patients or in ileostomy patients with ulcerative colitis; human intervention studies on post-prandial glycaemic and insulinaemic responses

to whole foods in which either the amount of rye fibre was not reported or a certain amount of rye fibre in bread was compared to the same amount of, for example, wheat fibre, and thus did not allow conclusions to be made on the effects of rye fibre *per se*; and human intervention studies in healthy subjects which did not assess post-prandial blood glucose responses following consumption of rye fibre, but rather the effects of longer-term consumption of rye fibre-containing food products on glucose tolerance (i.e. using the frequently sampled intravenous glucose tolerance test or the oral glucose tolerance test). The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Three intervention studies provided investigated the effects of rye fibre in rye products on post-prandial blood glucose and insulin responses (Juntunen et al., 2002; Juntunen et al., 2003; Leinonen et al., 1999).

In the study by Leinonen et al. (1999), the effects of wheat bread (61 g available carbohydrates; 2.3 g fibre), whole kernel rye bread (55 g available carbohydrates; 13.5 g fibre), wholemeal rye bread (43 g available carbohydrates; 10.1 g fibre) and wholemeal rye crispbread (45 g available carbohydrates; 12.1 g fibre) consumed with a standard breakfast were compared with respect to induced post-prandial glucose and insulin responses (measured every 30 min for three hours, and at 15 min post-prandial) in 20 subjects (10 female) with normal glucose tolerance using a randomised cross-over design. Direct comparisons were made between wheat bread and whole kernel rye bread (two types of cereals), and between wholemeal rye bread and wholemeal rye crispbread (two types of rye bread). The Panel considers that only the first comparison is appropriate for the scientific substantiation of the claim. No significant differences in post-prandial blood glucose responses at any time point, or measured as areas under the curve, were observed between wheat bread and whole kernel rye bread. Insulin concentrations were significantly lower at 45 ($p=0.025$), 60 ($p=0.002$), 90 ($p=0.0004$), 120 ($p=0.05$) and 150 ($p=0.033$) min after the whole kernel rye bread than after the wheat bread ($p=0.002$ for the area under the curve). The Panel notes that this study did not show an effect of rye fibre on post-prandial glycaemic responses.

In the study by Juntunen et al. (2002), the effects of wheat bread made from white wheat flour (3.1 g fibre), whole kernel rye bread (12.8 g fibre), wholemeal pasta (5.6 g fibre) and wholemeal rye bread containing oat beta-glucan concentrate (17.1 g fibre) were compared with respect to induced post-prandial glucose and insulin responses (measured every 30 min for three hours and at 15 min post-prandial) using a randomised cross-over design and standard portions containing 50 g of available carbohydrates for all test foods. Subjects were 20 healthy men and women (mean age 28±1 years; BMI 22.9±0.7 kg/m^2). The Panel notes that wholemeal rye bread containing oat beta-glucan concentrate cannot be used to address the effects of rye fibre, and that wheat bread is more appropriate than pasta to test the effects of rye fibre in whole kernel rye bread on post-prandial blood glucose responses. No significant differences in post-prandial blood glucose responses at any time point, or measured as areas under the curve, were observed between wheat bread and whole kernel rye bread. A significant decrease in post-prandial insulinaemic responses was observed after consumption of the whole kernel rye bread compared to the wheat bread ($p<0.05$). The Panel notes that this study did not show an effect of rye fibre on post-prandial glycaemic responses.

In the study by Juntunen et al. (2003) the effects of wheat bread made from white wheat flour (2.7 g fibre), endosperm rye bread (6.1 g fibre), traditional rye bread (15.2 g fibre) and high-fibre rye bread (29.0 g fibre) were compared with respect to induced post-prandial glucose and insulin responses (measured every 30 min for three hours, and at 15 min post-prandial) using a randomised cross-over design and standard portions containing 50 g of available carbohydrates for all test foods in a random order. Subjects were 19 healthy post-menopausal women aged 61±1 years and with a BMI of 26.0±0.6 kg/m^2. No differences in post-prandial blood glucose responses (measured as maximal response or as incremental areas under the curve) were observed between wheat bread and the different rye breads. A significant decrease in post-prandial insulinaemic responses was observed

after consumption of the endosperm rye bread and the traditional rye bread compared to the wheat bread ($p<0.05$). No significant difference was observed between the high-fibre rye bread and the wheat bread. The Panel notes that this study did not show an effect of rye fibre on the reduction of post-prandial glycaemic responses.
In weighing the evidence, the Panel took into account that the three human intervention studies provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of rye fibre on post-prandial glycaemic responses.

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

3.3. Maintenance of normal blood LDL-cholesterol concentrations (ID 827)

The references provided for the substantiation of the claim included textbooks, a meta-analysis and a review paper on the consumption of wholegrain foods and cardiovascular disease, a meta-analysis on the effect of oat products on blood lipids, a review on viscous fibres, and human intervention studies in ileostomy patients with ulcerative colitis. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

One randomised, cross-over study in humans was provided which investigated the effects of rye fibre on blood cholesterol concentrations (Leinonen et al., 2000). A total of 30 subjects (22 women) consumed rye and wheat breads (20 % of energy intake) for four weeks each with a four-week wash-out period in between. Men consumed on average 219 g of rye bread daily containing 22.1 g fibre (*vs*. 4.7 g/day fibre from wheat bread), and women 163 g of rye bread daily containing 16.4 g fibre (*vs*. 3.6 g/day fibre from wheat bread). The estimated daily amounts of beta-glucan were 2 g/day in men and 1.5 g/day in women. Data were analysed separately for men and women. No significant changes in total, LDL- or HDL-cholesterol concentrations were observed during the rye bread intervention compared to the wheat bread intervention. The Panel notes that this study did not show an effect of rye fibre consumption on blood cholesterol concentrations.

In weighing the evidence, the Panel took into account that the only human intervention study provided from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of rye fibre on blood LDL-cholesterol concentrations.

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

4. Panel comments on the proposed wording

4.1. Changes in bowel function (ID 825)

The Panel considers that the following wording reflects the scientific evidence: “Rye fibre contributes to normal bowel function”.

5. Conditions and possible restrictions of use

5.1. Changes in bowel function (ID 825)

The Panel considers that in order to bear the claim a food should be at least “high in fibre” as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

CONCLUSIONS

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

- The food constituent, rye fibre, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

Changes in bowel function (ID 825)

- The claimed effect is "gut health". The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is assumed that the claimed effect refers 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 been established between the consumption of rye fibre and changes in bowel function.

- The following wording reflects the scientific evidence: "Rye fibre contributes to normal bowel function".

- In order to bear the claim a food should be at least "high in fibre" as per Annex to Regulation (EC) No 1924/2006. The target population is the general population.

Reduction of post-prandial glycaemic responses (ID 826)

- The claimed effect is "carbohydrate metabolism and insulin sensitivity". The target population is assumed to be individuals who wish to reduce their post-prandial glycaemic responses. In the context of the proposed wordings, it is assumed that the claimed effect relates to the reduction of post-prandial glycaemic responses. A reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of rye fibre and reduction of post-prandial glycaemic responses.

Maintenance of normal blood LDL-cholesterol concentrations (ID 827)

- The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, 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 rye fibre and maintenance of normal blood LDL-cholesterol concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1612, EFSA-Q-2008-1613, EFSA-Q-2008-1614). 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.

[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).

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 rye fibre, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
825	Rye grain fibre.	Gut health. Clarification provided Promotes bowel function. Helps to maintain normal bowel function.	Promotes gut activity.
	Conditions of use - Bakery products with ≥6g/100g of rye grain fibre. Germination and fermentation improve the amount and utilisation of bioactive compounds (final report of VTT to Tekes).		
	Comments from Member States Health relationship defined.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
826	Rye fibre.	Carbohydrate metabolism and insulin sensitivity.	Long-lasting energy. Levels out the blood sugar increase after meals. Low glycemic index.
	Conditions of use - Coarse rye flour with 14g/100g of fibre, 8g/dl (serving). Rye flakes with 13g/100g of fibre, 3.9g/dl (serving). Rye bran with 39g/100g of fibre, 1.2-1.6g/tbs (serving). Coarse particles slow down absorption.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
827	Rye fibre	Cardiovascular system Clarification provided Rye contributes to healthy cholesterol levels. Rye fiber contrinutes to healthy cholesterol levels. Rye fiber helps to control cholesterol levels.	Helps to maintain healthy cholesterol level. Brand name which contains the claim: Sydänystävä 'Friend of the heart'. Clarification provided Helps to maintain healthy cholesterol level. Brand name which contains the claim: Sydänystävä 'Friend of the heart'.
	Conditions of use - Rye bran and flakes 13-39g/100g of rye fibre, 1.2-3.9g/serving		
	Comments from Member States Health relationship defined		

GLOSSARY AND ABBREVIATIONS

HDL	High-density lipoproteins
LDL	Low-density lipoproteins
BMI	Body mass index