SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to guar gum and maintenance of normal blood glucose concentrations (ID 794), increase in satiety (ID 795) and maintenance of normal blood cholesterol concentrations (ID 808) 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 guar gum and maintenance of normal blood glucose concentrations, increase in satiety and maintenance of normal blood cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is guar gum. The Panel considers that guar gum is sufficiently characterised.

1 On request from the European Commission, Question No EFSA-Q-2008-1581, EFSA-Q-2008-1582, EFSA-Q-2008-1595, adopted on 4 December 2009.

2 Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen.
Correspondence: nda@efsa.europa.eu

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Maintenance of normal blood glucose concentrations

The claimed effect is "impact on blood glucose/glycaemic control/glycaemic response". 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 long-term maintenance or achievement of normal blood glucose concentrations. The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the only study presented investigated long-term effects of guar gum on fasting blood glucose and glycated haemoglobin, the latter being an appropriate measure to assess long-term blood glucose control, and found no effect of guar gum consumption at doses eight times higher than proposed in the conditions of use.

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

Increase in satiety

The claimed effect is "satiety". The target population is assumed to be individuals who need to control their energy intake. In the context of this opinion, satiety is interpreted as the decrease in the motivation to eat after consumption of food leading to a reduction in energy intake. The Panel considers that an increase in satiety might be a beneficial physiological effect.

In weighing the evidence, the Panel took into account that no controlled studies assessing the effects of guar gum consumption on appetite ratings and subsequent energy intake have been presented.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of guar gum and increased satiety.

Maintenance of normal blood cholesterol concentrations

The claimed effect is "cholesterol maintenance". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel notes that the claimed effect refers to maintenance of normal blood cholesterol concentrations. The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

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

In order to bear a claim, foods should provide at least 10 g per day of guar gum in one or more servings. The target population is adults.

KEY WORDS

Guar gum, blood glucose, satiety, 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 from similar health claims. The information provided in the consolidated list for the health claims which are the subject of this opinion is given in Table 1.

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

ID	Food or Food constituent	Health Relationship	Proposed wording
794	Guar Gum	Impact on blood glucose / Glycemic control / Glycemic response	- Low glycemic diet helps maintain insulin sensitivity - Low glycemic diet helps in the management of regular blood glucose levels - Low glycemic diet helps maintain and improve blood glucose control - Low glycemic diet supports body weight regulation -
	Conditions of use - Single dose of 1.8 g/day		
795	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Guar Gum	Satiety	- guar gum helps you to feel full for longer (to help maintain body weight) - guar gum promotes satiety
	Conditions of use - Provide at least 3,25 g/day		
808	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
	Guar Gum	Cholesterol maintenance	guar gum helps to maintain healthy cholesterol levels - guar gum helps to maintain healthy levels of blood lipids
	Conditions of use – 10 g/day		

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is guar gum. Guar gum is a water-soluble type of fibre, a galactomannan composed of a backbone of D-mannose units with D-galactose attached at every second mannose unit. It is derived from the cluster bean (*Cyamopsis tetragonoloba* (L.) Taub.). Guar gum is non-digestible in the human small intestine. The molecular weight is about

[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.

220 kDa. Guar gum is not naturally occurring in foods and is usually consumed in the form of food supplements. Guar gum has a high viscosity, it is used as a thickener by the food industry, and can be measured in foods by established methods.

The Panel considers that the food constituent, guar gum, which is the subject of the health claims is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood glucose concentrations (ID 794)

The claimed effect is "impact on blood glucose/glycaemic control/glycaemic response". 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 long-term maintenance or achievement of normal blood glucose concentrations.

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

2.2. Increase in satiety (ID 795)

The claimed effect is "satiety". The Panel assumes that the target population is individuals who need to control their energy intake.

Satiety understood as the decrease in motivation to eat after consumption of food varies in magnitude and duration and may include only changes in appetite ratings (hunger, fullness, satiety, and desire to eat) or also a reduction in subsequent energy intake. The effect may persist for up to several hours, may change energy intake either at the next meal or across the day and, if sustained, may lead to a reduction in body weight. In the context of this Opinion, satiety is interpreted as the decrease in the motivation to eat after consumption of food leading to a reduction in energy intake.

The Panel considers that an increase in satiety might be a beneficial physiological effect.

2.3. Maintenance of normal blood cholesterol concentrations (ID 808)

The claimed effect is "cholesterol maintenance". The Panel assumes that the target population is the general population.

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

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

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

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood glucose concentrations (ID 794)

The references provided include intervention studies and reviews on the health effects of specific fibres other than guar gum (e.g. partially hydrolysed guar gum), on the effects of guar gum on health outcomes unrelated to blood glucose control (e.g. blood lipids), or were opinions from authoritative bodies not specifically addressing the effects of guar gum on long-term blood glucose control. The Panel considers that no scientific conclusions can be drawn from these references for the substantiation of the claim.

Among the references provided including measures of blood glucose control, two (Kovacs et al., 2002a and 2002b) describe the test product as "modified" guar gum. The Panel is uncertain on how the "modified" guar gum relates to the food which is the subject of the health claim but assumes that any modification to structure could affect function in relation to the claimed effect and therefore these references were not considered pertinent to the claim.

A number of references on the effects of guar gum on different outcomes in relation to blood glucose control were presented in insulin-dependent or non-insulin dependent diabetic subjects on either insulin or oral anti-diabetic therapy. The Panel considers that the evidence provided in these studies does not predict the occurrence of an effect of the food constituent on long-term maintenance or achievement of normal blood glucose concentrations in the general population. Also, a number of studies investigating the acute effects (after a single administration) of guar gum consumption on post-prandial glycaemic and/or insulinaemic responses were presented. The Panel considers that no scientific conclusions can be drawn from these studies in relation to long-term maintenance or achievement of normal blood glucose concentrations.

Only four of the studies cited investigated the long-term effects of guar gum consumption on measures of blood glucose (Beattie et al., 1988; Lalor et al., 1990; Makkonen et al., 1993; Uusitupa et al., 1984).

Three of the studies (Lalor et al. 1990; Makkonen et al., 1993; Uusitupa et al., 1984) assessed the effects of guar gum at doses between 7.5 g/d and 22.5 g/d for periods of six weeks to six months on fasting blood glucose concentrations in different population sub-groups (i.e., type 2 diabetic subjects on dietary treatment only, non-diabetic post-menopausal women). The Panel notes that the doses of guar gum used in these studies are several times higher than proposed in the conditions of use for this claim, and that fasting blood glucose concentrations alone are not an appropriate measure to assess long-term blood glucose control. The Panel considers that no scientific conclusions can be drawn from these studies in relation to long-term maintenance or achievement of normal blood glucose concentrations.

In a study by Beattie et al. (1988) 24 newly diagnosed overweight type 2 diabetics were randomised to one of three treatment groups. One group received a low fibre (15 g fibre) control diet throughout the 20-week study period. The second group received the control diet for four weeks before changing to a high cereal diet (same macronutrient content but supplemented with an additional 10-15 g of cereal fibre) for eight weeks after which they returned to the control diet supplemented with 15 g/d guar gum for eight weeks. The third group received the control diet for four weeks, the guar gum diet for eight weeks and the high cereal fibre diet for eight weeks. Samples of venous blood were taken every two weeks for measurement of fasting plasma glucose and glycated haemoglobin. Whilst the reduction in plasma blood glucose concentrations during the two high fibre diets was greater than during the low fibre diet at the end of the first eight weeks of the trial, this difference was not significant after 20 weeks. No differences were observed between groups in values of glycated haemoglobin at any time point during the intervention. The Panel notes the small number of subjects included in this study and that the daily doses of guar gum used are eight times higher than proposed in the conditions of use.

In weighing the evidence, the Panel took into account that the only study presented investigated the long-term effects of guar gum on fasting blood glucose and glycated haemoglobin, the latter being an appropriate measure to assess long-term blood glucose control, and found no effect of guar gum consumption at doses eight times higher than proposed in the conditions of use.

The Panel concludes that a cause and effect relationship has not been established between the consumption of guar gum and long-term maintenance of normal blood glucose concentrations.

3.2. Increase in satiety (ID 795)

The references provided in relation to this claim include intervention studies and reviews on the effects of dietary fibre in general, and on the effects of guar gum on outcomes other than measures of satiety (e.g., post-prandial insulin and glucose, insulin sensitivity, blood glucose control, blood pressure). The Panel considers that no scientific conclusions can be drawn from these references for the substantiation of the claim.

Among the references provided including measures of satiety, two (Kovacs et al., 2001 and 2002a) describe the test product as "modified" guar gum. The Panel is uncertain on how the "modified" guar gum relates to the food which is the subject of the health claim but assumes that any modification to structure could affect function in relation to the claimed effect and therefore these references were not considered pertinent to the claim.

One of the studies presented assessed the effects of guar gum on appetite ratings during 10 weeks of supplementation (Krotkiewski, 1984), and five additional studies investigated the effects of guar gum on appetite ratings after a single meal (French and Read, 1994; Wilmshurst and Crawley, 1980; Adam and Westerterp-Plantenga, 2005a; Adam and Westerterp-Plantenga, 2005b; Ellis et al., 1981). None of these studies addressed the effects of guar gum on subsequent energy intake. The Panel considers that no sientific conclusions can be drawn form these studies for the substantiation of the claim.

Only two of the studies cited investigate the effects of guar gum supplementation on subsequent energy intake. Lavin and Read (1995) provided 10 healthy male volunteers with 30% glucose drinks with and without the addition of guar gum (2%) and compared appetite ratings over 3 h post consumption as well as energy intake at a test meal consumed 3.5 hours after the drinks. Whilst guar gum supplementation reduced hunger and desire to eat and increased fullness and satiety, energy intake at the test meal was unchanged. In contrast, in a single-blind randomised cross-over intervention (Evans and Miller, 1975), 10 volunteers (three overweight) received either guar gum (~9 g) or methylcellulose (~10 g) 30 minutes before lunch and dinner for one week each. Each treatment week was preceeded by a treatment-free baseline period and food intake was measured over the entire 4-week duration of the study. The effects of the interventions on appetite ratings were not assessed. The Panel notes that it is unclear from the publication whether measurements of food intake were undertaken in the laboratory or were self-reported, although the fact that individuals were allowed to follow their normal way of life and choose their own diet *ad libitum* points towards the latter, the validity of which is questionable, particularly taking into account that the effect of both interventions (guar gum and methylcellulose) was more pronounced in overweight subjects. The Panel notes that no scientific conclusions can be drawn form this study for the substantiation of the claim.

In weighing the evidence, the Panel took into account that no controlled studies assessing the effects of guar gum consumption on appetite ratings and subsequent energy intake have been presented.

The Panel concludes that a cause and effect relationship has not been established between the consumption of guar gum and increased satiety.

3.3. Maintenance of normal blood cholesterol concentrations (ID 808)

The references provided include human studies on the effects of dietary fibre on different outcomes, and on the effects of guar gum on blood glucose control in type 2 diabetic subjects under pharmacological treatment. The Panel considers that no scientific conclusions can be drawn from these references for the substantiation of the claim.

The references provided reporting on randomised controlled trials (RCTs) conducted in humans and investigating the effects of guar gum on blood cholesterol concentrations have been reviewed in the meta-analysis by Brown et al. (1999). The meta-analysis included 18 RCTs (13 with parallel design, five with a cross-over design) on the effects of guar gum at doses of 6.6 to 30 g/d (average dose 17.5 g/d) on total (n=17) and LDL (n=12) cholesterol concentrations for intervention periods of two weeks or longer. The studies included healthy (normocholesterolaemic), hypercholesterolaemic, and diabetic subjects. In 13 out of the 17 studies, serum total cholesterol concentrations were significantly reduced after the administration of guar gum as compared to the low-fibre control group. The four studies not showing a significant effect on blood cholesterol used doses of 6.6 g/d (one study) and of 15 g/d (three studies). The meta-analysis showed a statistically significant effect of guar gum on serum total and LDL-cholesterol at doses of 9-30 g/d. An inverse (non-linear) association was found between the dose of guar gum consumed and the changes in total and LDL cholesterol concentrations. After controlling for initial blood cholesterol values, type of study design, type of control, treatment length, background diet, type of subject, weight change, or changes in dietary intake of fat and cholesterol were not significant predictors of the effects of guar gum intake on blood lipids. In a weighted dose-response model, it was estimated that one gram of guar gum lowered serum total cholesterol by 0.026 mmol/L and LDL cholesterol by 0.033 mmol/L. HDL cholesterol significantly (but minimally) decreased (by 0.003 mmol/L per gram, 15 studies considered), whereas triglyceride concentrations were not affected.

The effect of water-soluble fibre on blood (LDL) cholesterol concentrations is likely to depend on its viscosity, which reduces the reabsorption of bile acids, increases the synthesis of bile acids from cholesterol, and reduces circulating blood cholesterol concentrations.

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

4. Panel's comments on the proposed wording

4.1. Maintenance of normal blood cholesterol concentrations (ID 808)

The following wording reflects the scientific evidence: "Consumption of guar gum contributes to maintainance of normal blood cholesterol levels.".

5. Conditions and restrictions of use

5.1. Maintenance of normal blood cholesterol concentrations (ID 808)

In order to bear a claim, foods should provide at least 10 g per day of guar gum in one or more servings. The target population is adults.

CONCLUSIONS

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

- The food constituent, guar gum, that is the subject of the health claims is sufficiently characterised.

Maintenance of normal blood glucose concentrations (ID 794)

- The claimed effect is "impact on blood glucose/glycaemic control/glycaemic response". The target population is assumed to be the general population. Long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of guar gum and long-term maintenance of normal blood glucose concentrations.

Increase in satiety (ID 795)

- The claimed effect is "satiety". The target population is assumed to be individuals who need to control their energy intake. An increase in satiety might be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of guar gum and increased satiety.

Maintenance of normal blood cholesterol concentrations (ID 808)

- The claimed effect is "cholesterol maintenance". The target population is assumed to be the general population. Maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of guar gum and the reduction of blood cholesterol concentrations.

- The following wording reflects the scientific evidence: "Regular consumption of guar gum contributes to the maintainance of normal blood cholesterol levels".

- In order to bear a claim, foods should provide at least 10 g per day of guar gum in one or more servings. The target population is adults.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1581, EFSA-Q-2008-1582, EFSA-Q-2008-1595). 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[5] (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[6]

Foods are commonly involved in many different functions[7] 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.

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

GLOSSARY / ABBREVIATIONS

LDL	Low density lipoproteins
HDL	High density lipoproteins
RCT	Randomised controlled trials