SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to pectins and reduction of post-prandial glycaemic responses (ID 786), maintenance of normal blood cholesterol concentrations (ID 818) and increase in satiety leading to a reduction in energy intake (ID 4692) 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 pectins and reduction of post-prandial glycaemic responses, maintenance of normal blood cholesterol concentrations and increase in satiety leading to a reduction in energy intake. 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 pectins. The Panel considers that pectins are sufficiently characterised.

Reduction of post-prandial glycaemic responses

The claimed effect is "reduces the postprandial levels of glucose". The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. The Panel considers that

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[1] On request from the European Commission, Question No EFSA-Q-2008-1573, EFSA-Q-2008-1605, EFSA-Q-2010-00645, adopted on 09 July 2010.

[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

[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 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.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to pectins and reduction of post-prandial glycaemic responses (ID 786), maintenance of normal blood cholesterol concentrations (ID 818) and increase in satiety leading to a reduction in energy intake (ID 4692) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(10):1747. [17 pp.]. doi:10.2903/j.efsa.2010.1747. Available online: www.efsa.europa.eu/efsajournal.htm

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 the consistency of a post-prandial blood glucose-lowering effect of pectins consumed in foods or meals across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.

The Panel considers that, in order to bear the claim, foods should provide at least 10 g of pectins per meal. The target population is adults willing to reduce their post-prandial glycaemic responses.

Maintenance of normal blood cholesterol concentrations

The claimed effect is "cholesterol maintenance". The target population is assumed to be the general population. The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account the consistency of the total and LDL-cholesterol lowering effect of pectins across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

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

The Panel considers that, in order to bear the claim, foods should provide at least 6 g per day of pectins in one or more servings. The target population is adults.

Increase in satiety leading to a reduction in energy intake

The claimed effect is "satiety". The target population is assumed to be the general population. The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

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

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of pectins and a sustained increase in satiety leading to a reduction in energy intake.

KEY WORDS

Pectins, glycaemic response, cholesterol, satiety, 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 pectins. Pectins are composed of linear chains of alpha-(1,4)-galacturonic acid units with varying degrees of methylation and side chains including galacturonic and glucuronic acids. Pectins are viscous and water-soluble but unavailable for digestion in the human small intestine. Pectins are found in fruits and vegetables, and they are used as thickeners by the food industry.

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

2. Relevance of the claimed effect to human health

2.1. Reduction of post-prandial glycaemic responses (ID 786)

The claimed effect is "reduces the postprandial levels of glucose". The Panel assumes that the target population is individuals willing to reduce their post-prandial glycaemic responses.

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

The Panel considers that the reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may 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. Maintenance of normal blood cholesterol concentrations (ID 818)

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

The Panel notes that the claimed effect relates to the maintenance of normal blood cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.14 mmol/L), may compromise the normal structure and function of the arteries. High-density lipoproteins (HDL) act as cholesterol scavengers and are involved in the reverse transport of cholesterol in the body (from peripheral tissues back to the liver).

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

2.3. Increase in satiety leading to a reduction in energy intake (ID 4692)

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

Satiety is the decrease in the motivation to eat after consumption of food. The effect may persist up to several hours, may reduce energy intake either at the next meal or across the day and, if sustained**,** may lead to a reduction in body weight.

The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Reduction of post-prandial glycaemic responses (ID 786)

A review of 16 intervention studies in humans investigating the effects of pectins in post-prandial blood glucose responses was provided (Reiser, 1987). Four of these studies were conducted in diabetic subjects under pharmacological treatment for blood glucose control. Two studies were on the combined effects of pectins plus guar gum and one study was on guar gum alone. In four studies plasma insulin concentrations were not reported. The Panel considers that no conclusions can be drawn from these references for the substantiation of the claimed effect.

Several studies investigated the effects of pectins in various doses (between 10 and 20 g/meal) and in various types of meals (pectins incorporated in marmalade or juice or added to a glucose drink) compared to the same foods or meals without pectins (Jenkins et al., 1977, 1978; Gold et al., 1980; Sahi et al., 1985; Haber et al., 1977; Bolton et al., 1981) following a randomised cross-over design. Five of the studies showed significant reductions in postprandial blood glucose responses after consumption of pectin-containing foods or meals (Jenkins et al., 1977, 1978; Gold et al., 1980; Sahi et al., 1985; Bolton et al., 1981). In three of the studies postprandial insulin responses were significantly lower with the pectin-food or meal (Jenkins et al., 1977, 1978; Bolton et al., 1981), whereas no differences between interventions were observed in two studies (Gold et al., 1980; Sahi et al., 1985). The Panel notes that all the studies were small and included between five and ten healthy subjects.

The remaining studies were a meta-analysis of randomised controlled trials in humans and a rat study on the effects of different dietary fibres, including pectins, on blood cholesterol concentrations, a narrative review on the effects of pectins on human metabolism, a rat study on the action of various

pectins on glucose uptake in intestinally perfused rats and a human intervention study on the effects of pectins combined with guar gum on post-prandial blood glucose responses. None of these references investigated the effects of pectins alone on post-prandial blood glucose responses in humans. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The effect of pectins (a water-soluble fibre) on the post-prandial blood glucose concentrations is partly related to a decreased rate of diffusion of available carbohydrates to the absorptive mucosal surface partially due to a delay in gastric emptying.

In weighing the evidence, the Panel took into account the consistency of a post-prandial blood glucose-lowering effect of pectins consumed in foods or meals across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

The Panel concludes that a cause and effect relationship has been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.

3.2. Maintenance of normal blood cholesterol concentrations (ID 818)

All the studies presented in the consolidated list assessing the effects of pectins on blood cholesterol in humans have been considered in one review and one meta-analysis of randomised controlled trials (Reiser, 1987; Brown et al., 1999).

In a meta-analysis of randomised controlled intervention studies on the effects of different types of soluble fibre (including pectins) on the blood lipid profile (Brown et al.,1999), seven studies on pectins including 277 subjects (216 men) were considered (mean age 50 years, range 31-65 years). Four studies had a cross-over design (n=88) and three had a parallel design (95 and 94 subjects randomised to the pectins and control groups, respectively). Four studies were on healthy subjects, one in hypercholesterolaemic subjects, one in diabetics and one in subjects at high risk of coronary heart disease. The seven studies considered had total cholesterol and triglyceride concentrations as outcomes, whereas only six assessed changes in HDL-cholesterol concentrations and four in LDL-cholesterol concentrations. Initial serum total and serum LDL-cholesterol concentrations were 5.62 ± 0.7 mmol/L and 4.01 ± 0.59 mmol/L, respectively. The mean dose of pectins used in the studies was 4.7 g per day (range 2.2-9 g per day), and the average length of treatment was 34 days (range 28-42 days). Five studies used a low-fibre control, whereas in two the control was diet only. The meta-analysis showed a statistically significant effect of pectins on serum total and LDL-cholesterol concentrations at doses of 2.2 to 9 g per day. There was a significant dose-response relationship between the intake of soluble fibre (including pectins) and the total and LDL-cholesterol-lowering effect, whereas the dose-response relationship was not significant for HLD-cholesterol and triglycerides. It was estimated that one gram of pectins per day produced a change in total and LDL-cholesterol concentrations of -0.07 (95 %CI =-0.117 to -0.022) and -0.05 mmol/L (95 %CI=-0.087 to -0.022), respectively. These changes were statistically significant. No significant changes in HDL-cholesterol or triglycerides were observed in relation to pectin consumption.

In the review by Reiser (1987), 18 studies on pectins using doses of 2 to 40 g per day were included. The individual studies included 6 to 30 mostly healthy subjects. In 14 of them pectins showed a significant effect on serum total cholesterol concentrations. LDL-cholesterol concentrations were generally not assessed. In the dose-response study in 16 subjects by Palmer and Dixon (1966), doses of 2 to 10 g per day were used. Doses of 6 to 10 g per day significantly reduced serum total cholesterol concentrations by 4 to 6 %, whereas the effects of 2 to 4 g per day were statistically non significant.

Like for other water-soluble fibres, the effect of pectins 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.

In weighing the evidence, the Panel took into account the consistency of the total and LDL-cholesterol lowering effect of pectins across the studies considered, and that the mechanism by which pectins could exert the claimed effect is well known.

The Panel considers that a cause and effect relationship has been established between the consumption of pectins and maintenance of normal blood cholesterol concentrations.

3.3. Increase in satiety leading to a reduction in energy intake (ID 4692)

Only a narrative review on the chemistry of pectins and their pharmaceutical uses, which did not include original data on the effects of pectins on satiety and subsequent energy intake, was cited for the substantiation of this claim (Sriamornsak, 2003).

The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

The Panel considers that a cause and effect relationship has not been established between the consumption of pectins and a sustained increase in satiety leading to a reduction in energy intake.

4. Panel's comments on the proposed wording

4.1. Reduction of post-prandial glycaemic responses (ID 786)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of pectins contributes to the reduction of the blood glucose rise after meals".

4.2. Maintenance of normal blood cholesterol concentrations (ID 818)

The Panel considers that the following wording reflects the scientific evidence: "Consumption of pectins contributes to the maintenance of normal blood cholesterol levels".

5. Conditions and restrictions of use

5.1. Reduction of post-prandial glycaemic responses (ID 786)

The Panel considers that, in order to bear the claim, at least 10 g of pectins per meal should be consumed. The target population is adults willing to reduce their post-prandial glycaemic responses.

5.2. Maintenance of normal blood cholesterol concentrations (ID 818)

The Panel considers that, in order to bear the claim, at least 6 g per day of pectins should be consumed 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, pectins, which is the subject of the health claims is sufficiently characterised

Reduction of post-prandial glycaemic responses (ID 786)

- The claimed effect is "reduces the postprandial levels of glucose". The target population is assumed to be individuals willing to reduce their post-prandial glycaemic responses. 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 been established between the consumption of pectins and a reduction of post-prandial glycaemic responses.
- The following wording reflects the scientific evidence: "Consumption of pectins contributes to the reduction of the blood glucose rise after meals".
- In order to bear the claim, at least 10 g of pectins per meal should be consumed. The target population is adults willing to reduce their post-prandial glycaemic responses.

Maintenance of normal blood cholesterol concentrations (ID 818)

- 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 pectins and maintenance of normal blood cholesterol concentrations.
- The following wording reflects the scientific evidence: "Consumption of pectins contributes to the maintenance of normal blood cholesterol levels".
- In order to bear the claim, at least 6 g per day of pectins should be consumed in one or more servings. The target population is adults.

Increase in satiety leading to a reduction in energy intake (ID 4692)

- The claimed effect is "satiety". The target population is assumed to be the general population. An increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of pectins and a sustained increase in satiety leading to a reduction in energy intake.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1573, EFSA-Q-2008-1605, EFSA-Q-2010-00645). 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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Sriamornsak P, 2003. Chemistry of Pectin and its Pharmaceutical Uses: A Review. Silpakorn University International Journal, 3, 206–228.

Venn BJ and Green TJ, 2007. Glycemic index and glycemic load: measurement issues and their effect on diet-disease relationships. European Journal of Clinical Nutrition, 61 Suppl 1, S122-131.

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

ID	Food or Food constituent	Health Relationship	Proposed wording
786	Pectins	Reduces the postprandial levels of glucose	Help to manage your blood glucose levels
	Conditions of use - Daily serving: 100 miligrams citrus apple pectin, 20 miligrams lactobacillus acidophilus, 250 miligrams physillum seed, 30 miligrams aloe vera - Weight of average daily food serving: 4 miligram(s) - Daily amount to be consumed to produce claimed effect: 120 miligram(s) - Number of food portions this equates to in everyday food portions: 4 - Do not store above 25 degrees C - Length of time after consumption for claimed effect to become apparent: It is apparent after a period of regular use. Number of days: 3 - 10 g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
818	Pectins	Cholesterol maintenance	Pectins help to maintain normal blood cholesterol levels.
	Conditions of use - Where a daily value is indicated the amount per serving is typicaly 25% unless otherwise stated - 6g/ day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4692	Pectins	Satiety	Induce satiety sensation
	Conditions of use - 6 g a day		

GLOSSARY AND ABBREVIATIONS

HDL	High-density lipoprotein
LDL	Low-density lipoprotein