SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to plant sterols and plant stanols and maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140), and maintenance of normal prostate size and normal urination (ID 714, 1467, 1635) 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 plant sterols and plant stanols and maintenance of normal blood cholesterol concentrations, and maintenance of normal prostate size and normal urination. 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 subjects of the health claims is plant sterols and plant stanols. The Panel considers that plant sterols and plant stanols are sufficiently characterised.

1 On request from the European Commission, Question No EFSA-Q-2008-1337, EFSA-Q-2008-1500, EFSA-Q-2008-2203, EFSA-Q-2008-2370, EFSA-Q-2008-3642, EFSA-Q-2008-3872, adopted on 11 February 2010, Question No EFSA-Q-2008-1336, EFSA-Q-2008-1354, EFSA-Q-2008-1972, EFSA-Q-2008-1973, EFSA-Q-2008-2717, adopted on 30 April 2010 and Question No EFSA-Q-2008-1501, EFSA-Q-2008-2204, EFSA-Q-2008-2371, adopted on 10 September 2010.

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3 Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

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Maintenance of normal blood cholesterol concentrations

The claimed effects are "cholesterol", "cholesterol levels", "cholesterol metabolism", "heart health and artery health because of LDL cholesterol maintenance", "cardiovascular system", "cholesterol metabolism", "effet sur le taux de cholestérol sanguin", "heart health" and "helps to keep normal cholesterol level". The target population is assumed to be adults. In the context of the proposed wordings, the Panel notes that the claimed effects refer to the maintenance of normal blood cholesterol concentrations. The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

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

The Panel considers that in order to bear the claim, a food should provide at least 0.8 g per day of plant sterols/stanols in one or more servings. These amounts can be reasonably achieved in the context of a balanced diet. The target population is adults. The considerations regarding the food matrix expressed by the Panel in a previous opinion in relation to the blood LDL-cholesterol lowering effect of plant sterols and stanols also apply to the present opinion.

With respect to the specified conditions of use, it is suggested that the labelling provisions outlined in Commission Regulation (EC) No 608/2004 shall continue to apply for products making the proposed claim.

Food products containing plant sterols and/or plant stanols may not be nutritionally appropriate for pregnant and breastfeeding women, and for children under the age of five years.

Maintenance of normal prostate size and normal urination

The claimed effects are "prostate health" and "kidney and prostate health". The Panel assumes that the target population is adult males. In the context of the proposed wordings, the references submitted and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of a normal prostate size and normal urination. The Panel considers that maintenance of normal prostate size and normal urination is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the only intervention study using pure beta-sitosterol from which conclusions could be drawn found no effect on prostate size, peak urinary flow rate (Qmax) or post-void residual urine volume (PVR).

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of plant sterols and plant stanols and maintenance of normal prostate size and normal urination.

KEY WORDS

Plant sterols, plant stanols, blood cholesterol concentrations, prostate size, urination, 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 plant sterols and plant stanols.

In the context of this opinion, the term plant sterols (present as free sterols or esterified) refers specifically to plant sterols from natural sources with a composition as specified in the Commission Decisions authorising the placing on the market of food products with added plant sterols under Regulation (EC) No 258/97[6]. The term "plant stanol ester" refers to a blend of the plant stanols sitostanol and campestanol, which are obtained from the reduction of plant sterols from food grade plant oils (mainly soybean oil) or tall oil or blends thereof.

The Panel notes that claims ID 1234 and 1235 refer to polyphenols present or extracted from Maritime Pine (*Pinus pinaster* Aiton). However, the only reference cited in the list referring to procyanidins (a type of polyphenol) from French maritime pine bark was not accessible to the Panel after having made every reasonable effort to retrieve it (Assouad and Piriou, 2007), and no references on the effects of polyphenols present or extracted from Maritime Pine on blood lipids or any other health outcome were provided.

The Panel considers that the food constituent, plant sterols and plant stanols, that 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 cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140)

The claimed effects are "cholesterol", "cholesterol levels", "cholesterol metabolism", "heart health and artery health because of LDL cholesterol maintenance", "cardiovascular system", "cholesterol metabolism", "effet sur le taux de cholestérol sanguin", "heart health" and "helps to keep normal cholesterol level". The Panel assumes that the target population is adults.

[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
[6] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14.2.1997, p. 1–6.

In the context of the proposed wordings, the Panel notes that the claimed effects refer 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.

2.2. Maintenance of normal prostate size and normal urination (ID 714, 1467, 1635)

The claimed effects are "prostate health" and "kidney and prostate health". The Panel assumes that the target population is adult males.

In the context of the proposed wordings, the references submitted and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of a normal prostate size and normal urination.

An increase in size of the prostate (i.e. benign prostatic hyperplasia) is common in middle-aged and elderly men and may lead to abnormal storage and voiding of urine, which is characterised by a decrease in the peak urinary flow rate and by an increase in the residual urinary volume. Prostate size and urinary flow as well as storage (increase in urinary frequency, urgency, incontinence and nocturia) and voiding (weak urinary stream, hesitancy, intermittency, straining to void and dribbling) symptoms can be measured by established methods.

The Panel considers that maintenance of normal prostate size and normal urination is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140)

In the context of the procedure for the authorisation of health claims, EFSA has issued two opinions on applications for plant sterols (EFSA, 2008a) and plant stanol esters (EFSA, 2008b) pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA has also issued a general opinion regarding the conditions of use for health claims under Article 14 of Regulation (EC) No 1924/2006 in relation to the consumption of plant sterols and stanols and the reduction of LDL-cholesterol concentrations as a risk factor for coronary heart disease (EFSA, 2009).

The NDA Panel concluded that a clinically significant LDL-cholesterol lowering effect of between 7 % and 10.5 % could be expected by a daily intake of 1.5 - 2.4 g of plant sterols/plant stanols in an appropriate food matrix (e.g. margarine-type spreads, mayonnaise, salad dressings, and dairy products such as milk, yoghurts and cheese) (EFSA, 2009). The Panel also considered that the source of the sterols (vegetable or tall oil), the actual ratio between the most abundant sitosterol and campesterol and the source of fatty acids (butter or vegetable oil) do not have a relevant impact on the size of the blood LDL-cholesterol lowering effect (EFSA, 2008a, b), and that the efficacy in lowering LDL-cholesterol is similar for plant sterols and stanols in the intake range of 1.5 - 2.4 g per day (Katan et al., 2003; Demonty et al., 2009; EFSA, 2009).

In the most recent meta-analysis on the LDL-cholesterol lowering effects of plant sterols/stanols, 84 clinical trials were included (Demonty et al., 2009). In nine of the studies, daily doses of 0.80-1.0 g had been used. In seven of these studies a statistically significant reduction of LDL-cholesterol concentrations (range -0.19 to -0.33 mmol/L) was found (Beer et al., 2001; Hendriks et al., 1999; Hironaka et al., 2006; Niittynen et al., 2007; Sierksma et al., 1999; Ishizaki T, 2003; Vanhanen, 1994). In one study (Matsuoka et al., 2004) no effect was found with free sterols, and in the study by Miettinen and Vanhanen (1994) the reduction in LDL-cholesterol of 0.26 mmol/L was not statistically significant. Plant sterols were used in seven studies, stanols in one study and in another study a mixture of sterols and stanols was tested. The results of these studies indicate statistically significant lowering of LDL-cholesterol concentrations by consuming moderate doses (0.8-1.0 g per day) of plant sterols or stanols in subjects with normal or mildly elevated LDL-cholesterol concentrations. All but one (Hironaka et al., 2006) of the studies mentioned above were conducted with plant sterols or stanols added to foods such as margarine-type spreads, mayonnaise, and dairy products such as milk and yoghurts including low-fat yoghurts (Demonty et al., 2009; EFSA, 2009).

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

3.2. Maintenance of normal prostate size and normal urination (ID 714, 1467, 1635)

The references provided included narrative reviews, *in vitro* and animal studies on the mechanisms by which phytochemicals (including plant sterols) could protect against prostate cancer, case control and prospective cohort studies in humans on the relationship between the intake of various phytochemicals (including plant sterols) and the incidence of prostate cancer, and narrative reviews on the role of dietary factors other than plant sterols on prostate cancer risk. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two meta-analyses of randomised, placebo-controlled trials (Wilt et al., 1999, 2000) and two randomised, placebo-controlled trials (Berges et al., 1995; Klippel et al., 1997) on the effects of beta-sitosterols on prostate size, urinary flow and lower urinary tract symptoms (LUTS) in subjects with benign prostatic hyperplasia (BPH) were provided, together with a publication reporting on the follow-up of one of the studies (Berges et al., 2000). Both randomised controlled trials (Berges et al., 1995; Klippel et al., 1997) have been considered in the meta-analyses, and both meta-analyses are by the same authors and report on the same randomised controlled trials (Wilt et al., 1999, 2000).

In the meta-analyses by Wilt et al. (1999, 2000), four double-blinded randomised controlled trials (RCTs) including 519 men with BPH were identified and met the inclusion criteria (Berges et al., 1995; Fischer et al., 1993; Kadow and Abrams, 1986; Klippel et al., 1997). Three of the studies used non-glucosidic beta-sistosterol mixtures (beta-sistosterol-beta-D-glucoside <5 %) from different plant extracts at concentrations of 50 % (Berges et al., 1995) and ≥ 70 % (Fischer et al., 1993; Klippel et al., 1997) and daily doses of 60 to 195 mg per day of beta-sitosterol. The Panel notes that beta-sitosterol has been proposed as the active constituent of certain plant preparations which have been investigated in humans with respect to their effects on LUTS in BPH, and that a number of mechanisms by which beta-sitosterol could exert the claimed effect in BPH tissues have been investigated *in vitro*. However, only a small amount of beta-sitosterol is absorbed (<5 %) and no evidence of a plausible mechanism by which it could exert a systemic effect in BPH has been provided. The Panel also notes that the exact composition of the plant preparations used in these studies has not been provided, and therefore the potential contribution of food constituents other than beta-sitosterol to the claimed effect cannot be evaluated. The Panel considers that no conclusions can be drawn from these studies (Berges et al., 1995; Fischer et al., 1993; Kippel et al., 1997) or the meta-analyses (Wilt et al., 1999, 2000) for the scientific substantiation of the claimed effect in relation to plant sterols or beta-sitosterol.

The RCT by Kadow and Abrams (1986) was conducted in 62 males (mean age 67 years, age range 53-81 years) with symptomatic BPH using pure beta-sistosterol-beta-D-glucoside at a dose of 0.30 mg per day as intervention for 24 weeks. Nine subjects dropped out after randomisation. No significant differences between groups were observed with respect to prostate size, peak urinary flow rate (Qmax) or post-void residual urine volume (PVR). Lower urinary tract symptom scores were not assessed.

No evidence of a biologically plausible mechanism by which plant sterols and plant stanols could exert the claimed effect has been provided.

In weighing the evidence, the Panel took into account that the only intervention study using pure beta-sitosterol from which conclusions could be drawn found no effect on prostate size, peak urinary flow rate (Qmax) or post-void residual urine volume (PVR) .

The Panel concludes that a cause and effect relationship has not been established between the consumption of plant sterols and plant stanols and maintenance of normal prostate size and normal urination.

4. Panel's comments on the proposed wording

4.1. Maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140)

The Panel considers that the following wording reflects the scientific evidence: "Plant sterols/stanols contribute to the maintenance of normal blood cholesterol levels".

5. Conditions and possible restrictions of use

5.1. Maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140)

The Panel considers that in order to bear the claim, a food should provide at least 0.8 g per day of plant sterols/stanols in one or more servings. These amounts can be reasonably achieved in the context of a balanced diet. The target population is adults. The considerations regarding the food matrix expressed by the Panel in a previous opinion (EFSA, 2009) in relation to the blood LDL-cholesterol lowering effect of plant sterols and stanols also apply to the present opinion.

With respect to the specified conditions of use, it is suggested that the labelling provisions outlined in Commission Regulation (EC) No 608/2004[7] shall continue to apply for products making the proposed claim.

Food products containing plant sterols and/or plant stanols may not be nutritionally appropriate for pregnant and breastfeeding women, and for children under the age of five years.

[7] Commission Regulation (EC) No 608/2004 of 31 March 2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters. OJ L 97, 1.4.2004, p. 44–45.

CONCLUSIONS

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

- The food constituent, plant sterols and plant stanols, which is the subject of the health claims, is sufficiently characterised.

Maintenance of normal blood cholesterol concentrations (ID 549, 550, 567, 713, 1234, 1235, 1466, 1634, 1984, 2909, 3140)

- The claimed effects are "cholesterol", "cholesterol levels", "cholesterol metabolism", "heart health and artery health because of LDL cholesterol maintenance", "cardiovascular system", "cholesterol metabolism", "effet sur le taux de cholestérol sanguine", "heart health" and "helps to keep normal cholesterol level". The target population is assumed to be adults. Maintenance of normal blood cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has been established between the consumption of plant sterols and plant stanols and reduction of blood cholesterol concentrations.

- The following wording reflects the scientific evidence: "Plant sterols/stanols help to maintain normal blood cholesterol levels".

- In order to bear the claim, a food should provide at least 0.8 g per day of plant sterols/stanols in one or more servings. These amounts can be reasonably achieved in the context of a balanced diet. The target population is adults. The considerations regarding the food matrix expressed by the Panel in a previous opinion in relation to the blood LDL-cholesterol lowering effect of plant sterols and stanols also apply to the present opinion. With respect to the specified conditions of use, it is suggested that the labelling provisions outlined in Commission Regulation (EC) No 608/2004 shall continue to apply for products making the proposed claim.

- Food products containing plant sterols and/or plant stanols may not be nutritionally appropriate for pregnant and breastfeeding women, and for children under the age of five years.

Maintenance of normal prostate size and normal urination (ID 714, 1467, 1635)

- The claimed effects are "prostate health" and "kidney and prostate health". The target population is assumed to be adult males. In the context of the proposed wordings, the references submitted and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of a normal prostate size and normal urination. Maintenance of normal prostate size and normal urination is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of plant sterols and plant stanols and maintenance of normal prostate size and normal urination.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1336, EFSA-Q-2008-1337, EFSA-Q-2008-1354, EFSA-Q-2008-1500, EFSA-Q-2008-1501, EFSA-Q-2008-1972, EFSA-Q-2008-1973, EFSA-Q-2008-2203, EFSA-Q-2008-2204, EFSA-Q-2008-2370, EFSA-Q-2008-2371, EFSA-Q-2008-2717, EFSA-Q-2008-3642, EFSA-Q-2008-3872). 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 (EC) No 1924/2006 on nutrition and health claims made on foods[8] (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[9]

Foods are commonly involved in many different functions[10] 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.

[8] OJ L12, 18/01/2007
[9] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[10] 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 plant sterol/plant stanols, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
549	Plant Sterols	Heart Health Clarification provided Plant Sterols improve blood cholesterol levels Daily Phytosterols intake helps achieve acceptable LDL- cholesterol levels	Shown to reduce levels of cholesterol by reducing its absorption into the blood.
	Conditions of use - 800mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
550	Plant sterols	Cholesterol levels	Plant sterols may help support healthy blood cholesterol levels
	Conditions of use - 2 g/day - Taimsete steroolide sisaldus tootes 2 g/100 g, maksimaalselt võib päevas tarbida 3 g taimseid steroole - 200-300mg is the daily minimum dose recommended from dietary sources for optimum health. The most recent study used 1.3g. A meta-analysis of 41 trails - No RDA / RNI - 20 – 100 milligram (mg)		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
567	Plant stanol ester	Cardiovascular system Clarification provided For cholesterol management Inhibits/blocks the absorption of dietary cholesterol	Contains plant stanols that effectively reduce cholesterol. Reduces effectively cholesterol levels Actively reduces cholesterol. Proven to reduce cholesterol. Clinically proven to reduce cholesterol. Lowers cholesterol. Reduces blood cholesterol. Lowers blood cholesterol. Reduces LDL (bad) cholesterol. For cholesterol management. Symbol included in the claim: Benecol (see previous)

	Conditions of use - 2 g/day - Consume 2g of plant stanol, provided as plant stanol ester foods, per day preferably with a meal. Consumption at the recommended intake. Mandatory labelling statements required as per Commission Regulation EC No 608/2004 - Consume 2g of plant stanol, provided as plant stanol ester, per day preferably with a meal. Consumption at the recommended intake. Mandatory labelling statements required as per Commission Regulation EC No 608/2004: Intended exclusively for people who want to lower their cholesterol level; patients on cholesterol lowering medication should only consume the product under medical supervision; products may not be nutritionally appropriate for pregnant and breast feeding women and children under the age of 5 years; the product is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels; consumption of more than 3g/d should be avoided).		
	Comments from Member States FI comments: Cholesterol reduction claims are considered to be in the scope of Art. 14. Claim Ref.nr 60849 is not a cholesterol lowering claim and that's why this claim must be addressed separately. Other subclaims under ID 567 do not support the subclaim Ref.nr 60849 and should therefore be eddressed separately. (Ref.nr 52212 phytostanols/sterols claim: heart healths, different conditons of use, different substance; Ref.nr 63259 sterols/stanols and their esters claim: heart health, different substance). Under the claim ID 561 there is a subclaim Ref.nr 60848. It does not belong under ID 561 but should be under ID 567.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
713	Phytosterols (mixture of Beta-sitosterol,Campesterol, Stigmasterol, Brassicasterol, Stigmastanol, Ergostanol, Campestanol)	Cholesterol metabolism	Contributes to normal cholesterol level in blood
	Conditions of use - Min. 1 g per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
714	Phytosterols (mixture of Beta-sitosterol, Campesterol, Stigmasterol, Brassicasterol, Stigmastanol, Ergostanol, Campestanol)	Prostate health Clarification provided Phytosterols contribute to the normal functioning of the prostate: Help to reduce oxidative damage of prostate cells and tissue Help to keep your prostate in shape	Contributes to normal functioning of prostate and urinary tract
	Conditions of use - 280 mg/day		

ID	Food or Food constituent	Health Relationship	Proposed wording
1234	Barre céréalière diététique contenant des stérols végétaux et des polyphénols de pin maritime(OPC)	effet sur le taux de cholestérol sanguin,	anti-oxydant, Les stérols végétaux sont reconnus pour maîtriser l'excès de cholestérol. Les polyphénols extrait de l'écorse de pin permettent la réduction des lipides oxydés à la surface des artères
	Conditions of use - 750 g de stérols et 30 mg de polyphénol par portion, 3 portions maximum par jour soit 2, 25 g de stérol et 90 mg de polyphénol (OPC) produit ciblé adulte présentant un taux élevé de cholestérol		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1235	Stérols et polyphénols (Complément alimentaire sous forme de comprimé)	effet sur le taux de cholestérol sanguin,	anti-oxydant, Les stérols végétaux sont reconnus pour maîtriser l'excès de cholestérol. Les polyphénols extrait de l'écorse de pin permettent la réduction des lipides oxydés à la surface des artères
	Conditions of use - 350 mg de stérols et 30 mg de polyphénols (OPC) par comprimé. 4 comprimés par jour à prendre de façon régulière		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1466	Beta sitosterol	Cholesterol	functions by displacing cholesterol from intestinal micelles, thus reducing cholesterol absorption
	Conditions of use - 1 g/day - Bakery products with ≥6g/100g of wheat grain fibre		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1467	Beta sitosterol	Kidney and prostate health Clarification provided Kidney and prostate health: Nucleotides modulate the immune response by enhancing the production of immunoglobulins and improve T-cell function Nucleotides are immunostimulating agents	Helps maintain normal kidney and prostate function

		Beta sitosterol contributes to the normal functioning of the prostate	
	Conditions of use - Amount of consumption: 60 mg/Tag - Min 60 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1634	Phytosterols (mixture of Beta-sitosterol, Campesterol, Stigmasterol, Brassicasterol, Stigmastanol, Ergostanol, Campestanol)	Cholesterol metabolism	Contributes to normal cholesterol level in blood
	Conditions of use - minimum of 800 mg phytosterols/stanols - Min. 1 g per day - At least 700 mg per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1635	Phytosterols (mixture of Beta-sitosterol, Campesterol, Stigmasterol, Brassicasterol, Stigmastanol, Ergostanol, Campestanol)	Prostate health Clarification provided Prostate health. Phytosterols contribute to the normal functioning of the prostate. Help to reduce oxidative damage of prostate cells and tissue.	Contributes to normal functioning of urinary tract
	Conditions of use - 280 mg/day - 100 mg tägl Nahrungsergänzung–		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1984	Phytostanols / sterols	heart health Clarification provided Cholesterol metabolism: contributes to normal cholesterol level in blood (Health relationship and example claims altered to be in line with claim 1634 which has no comment from EFSA.)	Plant sterols/ stanols help to maintain a healthy heart
	Conditions of use		

	- At least 800mg stanols/sterols per daily dose - only with a minimum of 800 mg phytosterols / stanols /day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2909	Sterols/ stanols and their esters	Heart health and artery health because of LDL cholesterol maintenance	Sterols/ stanols and their esters promote heart health/keep your arteries healthy/l
	Conditions of use - Consume at least 2g plant sterols/stanols provided as plant sterol ester, per day. Consumption at the recommended intake for optimal effect. Mandatory labelling statements required as per Commission Regulation EC no 608/2004; Intended exclusively for people who want to lower their cholesterol level; patients on cholesterol lowering medication should only consume the product under medical supervision; products may not be nutritionally appropriate for pregnant and breast feeding women under the age of 5 years; the product is to be used as part of a balanced diet, including regular consumption of fruit and vegetables; consumption of more than 3 g/d is not efficacious		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3140	betasitosterol	helps to keep normal cholesterol level	helps to keep normal cholesterol level, helps to keep passage of vessels, natural way to avoid risks caused by high cholesterol values
	Conditions of use - 1080 mg of betasitosterol per day		

GLOSSARY AND ABBREVIATIONS

HDL	High-density lipoprotein
LDL	Low-density lipoprotein
LUTS	Lower urinary tract symptoms
BPH	Benign prostatic hyperplasia
RCT	Randomised controlled trial
Qmax	Peak urinary flow rate
PVR	Post-void residual urine volume