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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to dried plums of „prune cultivars (Prunus domestica L.) and maintenance of normal bowel function (ID 1164, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to dried plums of ‘prune’ cultivars (*Prunus domestica* L.) and maintenance of normal bowel function (ID 1164, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

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 13.1 of Regulation (EC) No 1924/2006 in the framework of further assessment related to plums of ‘prune’ cultivars (*Prunus domestica* L.) and maintenance of normal bowel function. The food that is the subject of the claim, prunes (dried plums of ‘prune’ cultivars (*Prunus domestica* L.)) is sufficiently characterised. The claimed effect, maintenance of normal bowel function, is a beneficial physiological effect. The proposed target population is the general population. In weighing the evidence, the Panel took into account that two human intervention studies showed an effect of dried plums on bowel function, that one study with considerable limitations showed an effect of dried plums on stool consistency, but not on other measures of bowel function, that another study with considerable limitations did not show an effect of dried plums on bowel function when compared to dried apple, and that there is good evidence for plausible mechanisms by which some components of prunes may contribute to the claimed effect. On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of dried plums of ‘prune’ cultivars (*Prunus domestica* L.) and maintenance of normal bowel function. In order to obtain the claimed effect, about 100 g of dried plums (prunes) should be consumed daily. The target population is the general population.

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KEY WORDS

Prunes, dried plums, *Prunus domestica* L., bowel function, health claims.

¹ On request from the European Commission, Question No EFSA-Q-2012-00161, adopted on 25 April 2012.

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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. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of a health claim in relation to dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims, references that EFSA has received from Member States or directly from stakeholders and the additional information provided by the competent Authority of France for further assessment of this claim.

The food that is the subject of the health claim is prunes. The Panel considers that prunes, (dried plums of 'prune' cultivars (*Prunus domestica* L.)) are sufficiently characterised.

The claimed effect, which is eligible for further assessment, is maintenance of normal bowel function. The proposed target population is the general population. The Panel considers that maintenance of normal bowel function is a beneficial physiological effect.

In its earlier opinion the Panel considered two human intervention studies. In the framework of further assessment, two additional human intervention studies, which addressed the effect of dried plums alone on bowel function, were provided. References which addressed proposed mechanisms by which some components identified in prunes could contribute to exerting the claimed effect were also considered. This evaluation is based on the scientific references provided in the present and the previous submission which addressed the effects of dried plums of 'prune' cultivars (*Prunus domestica* L.) on maintenance of normal bowel function and on the mechanisms by which dried plums could exert the claimed effect in the target population.

In one human intervention study an effect of dried plums on bowel function as indicated by increased faecal weight was observed, in a further study dried plums showed an effect on bowel function similar to psyllium for which there is evidence to support a laxative effect, one study with considerable limitations showed an effect of dried plums on stool consistency but not on other measures of bowel function and one study with considerable limitations did not show an effect of dried plums on bowel function when compared to dried apple.

Prunes contain dietary fibre, both soluble and insoluble, and sorbitol. Insoluble components of the dietary fibre resist breakdown by the microflora and exert a physical effect on faecal bulk by their presence and by retaining water within the cellular structure, whereas the soluble components are extensively degraded by the microflora resulting in a substantial stimulation of microbial growth and thereby an increased faecal bulk. Increased faecal mass will increase the diameter of the lumen of the colon, thereby decreasing intraluminal pressure and allowing increased forward flow of the faeces. Sorbitol is poorly absorbed in the small intestine and acts as an osmotic laxative. The Panel considers that there is good evidence for plausible mechanisms by which some components of prunes (i.e. sorbitol and dietary fibre) may contribute to an improvement in bowel function.

In weighing the evidence, the Panel took into account that two human human intervention studies showed an effect of dried plums on bowel function, that one study with considerable limitations showed an effect of dried plums on stool consistency, but not on other measures of bowel function, that another study with considerable limitations did not show an effect of dried plums on bowel function when compared to dried apple, and that there is good evidence for plausible mechanisms by which some components of prunes may contribute to the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function.

The Panel considers that the following wording reflects the scientific evidence: "Dried plums/prunes can contribute to normal bowel function".

The Panel considers that, in order to obtain the claimed effect, about 100 g of dried plums (prunes) should be consumed daily. The target population is the general population.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	4
Background as provided by the European Commission	5
Terms of reference as provided by the European Commission	5
EFSA Disclaimer.....	5
Introduction	6
Assessment	6
1. Characterisation of the food/constituent (ID 1164).....	6
2. Relevance of the claimed effect to human health (ID 1164).....	6
3. Scientific substantiation of the claimed effect (ID 1164)	7
4. Panel’s comments on the proposed wording (ID 1164)	10
5. Conditions and possible restrictions of use (ID 1164)	10
Conclusions	10
Documentation provided to EFSA	10
References	10
Appendices	13
Glossary and Abbreviations	17

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

See Appendix A

EFSA DISCLAIMER

See Appendix B

INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ in which the Panel concluded that the evidence provided was insufficient to establish a cause and effect relationship between dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010), EFSA received additional information from the competent Authority of France for further assessment of this claim.

ASSESSMENT

1. Characterisation of the food/constituent (ID 1164)

The food that is the subject of the health claim is prunes (dried plums of 'prune' cultivars (*Prunus domestica* L.)).

The content in prunes of water, total carbohydrates, protein, fat and amino acids, as well as a number of different sugars, minerals, vitamins, carotenoids, organic acids, and phenolic compounds, is given in the literature (Dikeman et al., 2004; Stacewicz-Sapuntzakis et al., 2001). The composition with regard to a number of components with purported effects can be measured. Prunes contain dietary fibre (according to four American studies: average 6.45 g/100 g, range 6.0–7.3 g/100 g) which includes soluble and insoluble fibre, sorbitol (average from six sources/varieties 14.7 g/100 g, range 9.4–19.3 g/100 g), and phenolic compounds (ca. 184 mg/100 g) such as neochlorogenic and chlorogenic acids. The water content of dried prunes is about 20–23 %⁵ (for data and references see also: Stacewicz-Sapuntzakis et al., 2001; US Department of Agriculture, 2009).

The Panel considers that the food, prunes (dried plums of 'prune' cultivars (*Prunus domestica* L.)) which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 1164)

The claimed effect, which is eligible for further assessment, is maintenance of normal bowel function. The proposed target population is the general population.

Changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk or softer stools may be a beneficial physiological effect.

The Panel considers that maintenance of normal bowel function is 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 Commission Regulation (EC) No 464/1999 of 3 March 1999 laying down detailed rules for the application of Council Regulation (EC) No 2201/96 as regards aid arrangements for prunes. OJ L 56, 4.3.1999, p. 8–14.

3. Scientific substantiation of the claimed effect (ID 1164)

In its earlier opinion (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010), a total of 16 references were cited to substantiate the claim, of which 14 were narrative reviews, publications providing only background information, or studies unrelated to the food for which the claim was made, from which no conclusions could be drawn for the scientific substantiation of the claim. Of the two human intervention studies provided which were considered as being pertinent to the claim, one reported no effect of dried plums on bowel function (Lucas et al., 2004), whereas the other showed some effect of dried plum consumption on faecal weight compared to grape juice (control) (Tinker et al., 1991). Based on the information initially submitted, the Panel concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function.

In the framework of further assessment, three additional human intervention studies as well as references which addressed proposed mechanisms by which some components identified in prunes could contribute to exert the claimed effect were provided. One human intervention study with a cross-over design (Sairanen et al., 2007) assessed the effect of consuming daily 260 g of a test yoghurt containing 12 g galacto-oligosaccharides, 12 g prunes and 6 g linseed, or 260 g of a control yoghurt without the afore-mentioned combined constituents, on defecation frequency in elderly subjects with self-reported constipation. The Panel considers that no conclusions can be drawn from a study on a fixed combination of constituents for the scientific substantiation of a claim on prunes alone. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Two references reported on human intervention studies (Attaluri et al., 2011; Howarth et al., 2010) investigating the effects of prunes on bowel function.

This evaluation is based on the scientific references provided in the present and the previous submission which addressed the effects of dried plums of 'prune' cultivars (*Prunus domestica* L.) on maintenance of normal bowel function, and on the mechanisms by which dried plums could exert the claimed effect in the target population.

In total, four human intervention studies which reported on the effects of prunes on measures of bowel function were submitted (Attaluri et al., 2011; Howarth et al., 2010; Lucas et al., 2004; Tinker et al., 1991).

The study by Tinker et al. (1991) was an eight-week, open-label, cross-over intervention in which 41 adult men (29-79 years) with mild hypercholesterolaemia were randomised to consume daily either 12 prunes (~100 g; ~6 g dietary fibre by analysis) or 360 ml grape juice (low-fibre control) for four weeks each in order to assess the effects of prunes on blood cholesterol concentrations. Biochemical parameters and 72-h faecal samples were collected at baseline and at the end of each intervention period. There were no drop-outs. Treatment differences were assessed by repeated-measures analysis of variance (RM-ANOVA) grouped by diet sequence. The baseline and prune periods were compared with the grape juice period. Faecal wet and dry weights were significantly higher after the prune period than after the grape juice period (faecal wet weight as g/72 h (mean±SEM): 628±44 vs. 514±34, respectively p=0.001; faecal dry weight as g/72 h: 140±9 vs. 120±8, respectively, p=0.006) and higher than baseline values (faecal wet weight as g/72 h (mean±SEM): 550±42.7; faecal dry weight as g/72h: 123±7.1). Interactions between diet sequence and dietary intervention were not statistically significant for faecal weight. The Panel considers that this study shows an effect of dried plums on bowel function as indicated by increased faecal weight.

Attaluri et al. (2011) described an eight-week cross-over study with blinded data analysis. Forty chronically constipated subjects (m/f=3/37, mean age 38 years) were recruited from the community. Subjects were instructed to maintain their usual lifestyle including diet and physical activity.

Laxatives and other remedies for constipation were discontinued for at least one week prior to study enrolment. Subjects were randomised to consume dried plums (50 g twice daily with meals (about 12 plums daily), equivalent to about 6 g per day of fibre) or psyllium (11 g twice daily with 240 ml of water, equivalent to 6 g per day of fibre) for three weeks each, with a wash-out period of one week in between, after a one-week run-in. Subjects were then followed for six weeks (no intervention), during which they were asked to continue with their usual diets and remedies to treat constipation. They were asked to maintain a daily stool and symptom diary during the eight-week study period and during the last week of the six-week follow up. At the end of each intervention period, subjects were asked to fill in a global constipation symptom score (a validated Rome III outcome measure). Rules for the use of rescue laxatives were defined and their use documented in the stool diaries. There were no drop-outs in the study. The investigators who analysed the data were blinded to treatment group allocation. The primary outcome measure of the study, which was used for power calculations, was the mean number of complete spontaneous bowel movements (CSBMs, defined as bowel movements with sensation of complete evacuation and with no laxative/enema in the preceding 24 h) per week. Secondary outcomes were global constipation symptom scores, taste survey scores, stool consistency (Bristol stool form scale), and straining scores. In addition, the number of bowel movements per week, the number of spontaneous bowel movements (no laxative/enema in the preceding 24 h) per week, and the number of complete bowel movements (sensation of complete evacuation) per week were also assessed from the stool diaries. One-week measurements obtained at baseline, during the third week of each intervention period, and at the end of follow-up were compared using two-tailed paired Student's *t*-test with Welch's correction for unequal variances and one-way analysis of variance. Negative binomial regression analysis was used to assess carry-over effects for primary and secondary outcome variables. No carry-over effects were identified for primary or secondary outcomes. The Panel notes that the statistical analysis performed was not appropriate for assessing differences between the two interventions, i.e. dried plums and psyllium. As compared to pre-intervention baselines, the intervention with either dried plums or psyllium resulted in a significant increase in mean CSBMs per week (1.8 vs. 3.5, $p=0.001$ and 1.6 vs. 2.8, $p=0.001$, respectively). For both interventions, CSBM-per-week values returned to pre-treatment baseline during the wash-out period. Significant changes with the dried plum intervention in some of the secondary outcome measures such as stool consistency and improved straining scores as compared to baseline are in line with the observed effect on bowel movements. The Panel notes that dried plums showed an effect on bowel function similar to psyllium, for which there is evidence to support a laxative effect (Brandt et al., 2005; Fleming and Wade, 2010; Ramkumar and Rao, 2005). The Panel considers that this study shows an effect of dried plums on bowel function.

One reference (Lucas et al., 2004) described a secondary study that was part of an intervention trial in 58 post-menopausal women not on hormone replacement therapy and free of any gastro-intestinal or eating disorders. The objective of the study was to evaluate the effects of dried plums on markers of bone turnover. Subjects were randomised to consume either 100 g of dried plums (*Prunus domestica* L.) (about 10-12 plums, 7 g dietary fibre) or 75 g of dried apples (6.5 g dietary fibre) daily for three months. Subjects were asked to fill in a validated questionnaire regarding their weekly bowel habits, including stool frequency, estimated faecal bulk, consistency of stool (7-point scale), strain and pain during bowel movement, and feeling of constipation after bowel movement. Mean stool frequency in this population sub-group was normal (around 11 per week). Data were analysed by RM-ANOVA. Thirty-eight women completed the study. No significant differences were found between the two treatment groups or between different time-points within each group for any of the parameters used to assess bowel function. The Panel notes that this study had a number of limitations. The study design reduced the likelihood that an effect of prunes on bowel function could be observed, for example, the effect of prunes was determined in comparison with dried apple which had a similar amount of dietary fibre, and self-reported outcomes are not a sensitive measure of changes in bowel function in this group which had normal bowel function. In addition, the Panel notes the high drop-out rate in this study, that no information was provided on how the missing data were taken into account in the statistical analysis, and that the information provided was insufficient to judge the appropriateness of

the statistical analyses. The Panel considers that this study with considerable limitations did not show an effect of dried plums on bowel function when compared to dried apple.

A cross-over study (Howarth et al., 2010) was designed to investigate the effect of different snacks on energy and nutrient intake, as well as their impact on body weight and bowel habits. A total of 29 females (25 to 54 years) were randomised to consume twice daily one 100 kcal snack of either prunes (84 g/day, number of plums not indicated; 6 g/day dietary fibre) or low-fat cookies (1 g/day dietary fibre) for two weeks each, with a two-week wash-out period in between after a three day baseline run-in. The primary outcome of the study (used for power calculations) was differences in energy intake between snack types. Intake of macronutrients, intake of dietary fibre, changes in body weight, and changes in bowel habits were secondary outcomes. Dietary intake (via food records) was assessed at baseline and every other day for a total of seven days per treatment period. Information on bowel habits (via a self-reported seven-day bowel habit questionnaire) was collected at baseline and daily during the second week of each treatment period. Bowel habit parameters included stool consistency, straining during bowel movement, pain during bowel movement, completeness of evacuation, overall feeling of constipation, and stool frequency. Mean stool frequency in this population sub-group was normal (around 1.2 per day). Twenty-six women completed the study and entered data analysis, which was performed in the population of completers only. Differences in dietary intake and bowel habits between baseline and the interventions were assessed by RM-ANOVA with *post hoc* paired-comparison t-tests. Subjects reported significantly softer stools with dried plum consumption compared to low-fat cookie intake and baseline values ($p \leq 0.05$). No other significant decreases were reported for any other bowel habit parameter. The Panel notes that this study had a number of limitations, for example, self-reported outcomes are not a sensitive measure of changes in bowel function in this group which had normal bowel function, and the information provided was insufficient to judge the appropriateness of the statistical analyses. The Panel considers that this study with considerable limitations showed an effect of dried plums on stool consistency but not on other measures of bowel function.

Several references which proposed mechanisms by which some components of prunes could contribute to the claimed effect were identified (Couteau et al., 2001; Livesey, 2001; Parkar et al., 2008; Stacewicz-Sapuntzakis et al., 2001; Welsch et al., 1989). Prunes contain dietary fibre, both soluble and insoluble, and sorbitol (Stacewicz-Sapuntzakis et al., 2001). Insoluble components of dietary fibre resist breakdown by the microflora and exert a physical effect on faecal bulk by their presence, and by retaining water within the cellular structure, whereas the soluble components are extensively degraded by the microflora resulting in a substantial stimulation of microbial growth and thereby an increased faecal bulk (Cummings, 2001). Increased faecal mass will increase the diameter of the lumen of the colon, thereby decreasing intraluminal pressure and allowing increased forward flow of the faeces (Gregory and Strong, 2005). Sorbitol is poorly absorbed in the small intestine and acts as an osmotic laxative (Livesey, 2001; Mahan and Escott-Stump, 2007; US Food and Drug Administration, 1993). While individual variation is observed with regard to the laxative threshold for sorbitol, laxative effects have regularly been observed with a dose of 20 g and more, and in some studies with a dose of 5-10 g (Badiga et al., 1990; Bauditz et al., 2008; Hyams, 1983; Jain et al., 1985). The Panel considers that there is good evidence for plausible mechanisms by which some components of prunes (i.e. sorbitol and dietary fibre) may contribute to an improvement in bowel function.

In weighing the evidence, the Panel took into account that two human intervention studies showed an effect of dried plums on bowel function, that one study with considerable limitations showed an effect of dried plums on stool consistency, but not on other measures of bowel function, that another study with considerable limitations did not show an effect of dried plums on bowel function when compared to dried apple, and that there is good evidence for plausible mechanisms by which some components of prunes may contribute to the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function.

4. Panel's comments on the proposed wording (ID 1164)

The Panel considers that the following wording reflects the scientific evidence: "Dried plums/prunes can contribute to normal bowel function".

5. Conditions and possible restrictions of use (ID 1164)

The Panel considers that, in order to obtain the claimed effect, about 100 g of dried plums (prunes) should be consumed daily. The target population is the general population.

CONCLUSIONS

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

- The food, prunes (dried plums of 'prune' cultivars (*Prunus domestica* L.)), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect, which is eligible for further assessment, is maintenance of normal bowel function. The proposed target population is the general population. Maintenance of normal bowel function is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of dried plums of 'prune' cultivars (*Prunus domestica* L.) and maintenance of normal bowel function.
- The following wording reflects the scientific evidence: "Dried plums/prunes can contribute to normal bowel function".
- In order to obtain the claimed effect, about 100 g of dried plums (prunes) should be consumed daily. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00161). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims, references that EFSA has received from Member States or directly from stakeholders and the additional information provided by the competent Authority of France for further assessment of this claim (available at: <http://www.efsa.europa.eu/en/topics/topic/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 foods⁶ (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 FOOD⁷

Foods are commonly involved in many different functions⁸ 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.

GLOSSARY AND ABBREVIATIONS

CSBM	Complete spontaneous bowel movement
RM-ANOVA	Repeated-measures analysis of variance
SEM	Standard error of the mean