

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) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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

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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. This opinion addresses the scientific substantiation of health claims in relation to “prunes” 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 and references that EFSA has received from Member States or directly from stakeholders.

The food that is the subject of the health claim is “prunes”. The Panel considers that “prunes” in the meaning of “dried plums of ‘prune’ cultivars (*Prunus domestica* L.)” is sufficiently characterised.

The claimed effect is “normal bowel function/normal gastrointestinal function/normal colonic function”. The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to aspects of: “maintenance of bowel regularity, and laxative effect”. Changes in bowel function within the normal range e.g. reduced transit time, increased frequency of bowel movements or bulk of stools might be interpreted as improvement of bowel function. The Panel considers that maintenance of normal bowel function might be a beneficial physiological effect.

1 On request from the European Commission, Question No EFSA-Q-2008-1903, adopted on 15 October 2009.

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In weighing the evidence, the Panel took into account that one human intervention study did not find any significant difference between the two treatment groups or between different time-points within each group and that the other human intervention study showed some effect on faecal bulk but not on stool frequency or consistency. Another human intervention study cited used another intervention than dried “prunes” and the other references provided only background information and did not provide scientific data that could be used to substantiate the claim.

The Panel concludes that the evidence provided is 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.

KEY WORDS

Prunes, bowel function, 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 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. The information provided in the consolidated list for the health claims which are the subject of this opinion is given in Table 1.

Table 1. Main entry health claims related to dried plums of 'prune' cultivars (*Prunus domestica* L.), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1164	Prunes (dried plums)	Normal bowel function/normal gastrointestinal function/normal colonic function	<p>Prunes help the maintenance of healthy body functions.</p> <p>Prunes help maintain bowel regularity which can help to ensure a healthy digestion and bowel.</p> <p>Prunes are beneficial to the health of the stomach and digestive system.</p> <p>Prunes are good for healthy bowel function.</p> <p>Prunes are good for (regular) digestion.</p> <p>Prunes have a natural laxative effect that can contribute to a healthy digestion and bowel.</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - Beneficial when regularly ingested - Prune juice only provides fibre if it contains prune pulp or puree - Excessive consumption may cause diarrhoea - Gradually increase intake - Combine with adequate fluid intake and activity levels - Product must contain at least 3g fibre/100g - Recommended daily intake of 40g – 100g (5-12 prunes) - 3 dried prunes or 6 canned prunes = 1 portion of fruit. Dried fruit can only count towards one daily portion under the UK Governments '5 a day initiative, irrespective of quantities consumed - Consommation traditionnelle du fruit <i>Prunus domestica</i> cv dans le cadre d'une alimentation courante - Fruit : prunes and prunes juice - Usual consumption as traditional foodstuff in a normal diet. 			

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.

ASSESSMENT

1. Characterisation of the food

The food that is the subject of the claim is “prunes”. A prune is any of a variety of plum species. A plum is a stone fruit in the genus *Prunus*, subgenus *Prunus*, section *Prunus* (Old World plums). Most “plums” and “prunes” belong to the species *Prunus domestica* L. The species is not homogenous and is comprised of many cultivars. More than 1000 cultivars of plums are grown for drying, but only some cultivars of plum are called prunes when fresh or dried, others have always been called “dried plums” when dried. Prunes are characterised by a relatively small size, an oval shape, an easily removed pit (“free-stone plums”) and high sugar content. Thus, all prunes are plums, but not all plums are prunes (fresh or dried). Most industrially produced dried prunes today are produced from *Prunus domestica* cv. D’Agen, by dehydration at a temperature of 85-90°C. The content 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 in prunes is given in the literature (Stacewicz-Sapuntzakis et al., 2001; Dikeman et al., 2004). In 2000, the US FDA granted the permission to use ‘dried plums’ in marketing as an alternative to ‘prunes’.

The Panel considers that the food, “prunes” in the meaning of “dried plums of ‘prune’ cultivars (*Prunus domestica* L.)”, which is the subject of the health claims is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is “Normal bowel function/normal gastrointestinal function/normal colonic function”. The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to aspects of: “maintenance of bowel regularity, and laxative effect”. Changes in bowel function within the normal range e.g. reduced transit time, increased frequency of bowel movements or bulk of stools might be interpreted as improvement of bowel function.

The Panel considers that maintenance of normal bowel function might be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Sixteen references were cited to substantiate the claimed effect, of which three references report on human intervention studies (Lucas et al., 2004; Tinker et al., 1991; Piirainen et al., 2007) whereas 13 references provide various background information.

One reference (Lucas et al., 2004) described an intervention study in which 58 post-menopausal women not on hormone replacement therapy and free of any gastrointestinal and eating disorders were randomised to consume either 100 g of dried plum (*Prunus domestica* L.) or 75 g of dried apples daily for three months. The women were asked to fill out a validated questionnaire regarding their weekly bowel habits. The parameters used to assess bowel habits included stool frequency, estimated faecal bulk, consistency of stool (7-point scale), strain and pain during bowel movement, and feeling of constipation after bowel movement. Thirty-eight women completed the study. The Panel notes that no significant differences were found between the two treatment groups or between different time-points within each group.

A second paper (Tinker et al., 1991) reported on 41 adult men (29-79 years, mean 46.5 years) recruited from the general population but with mild hypercholesterolaemia (fasting plasma cholesterol concentration between 5.2 and 7.5 mmol/L). An 8-week open crossover study was performed (four

weeks with normal diet plus 12 prunes daily (~ 100g; ~6 g dietary fibre by analysis), and four weeks with 360 mL grape juice per day). Biochemical parameters and faecal output were recorded. Faecal wet weight as well as dry weight was higher after the prune period than after the grape juice period and higher than baseline values, with no change in per cent water. The Panel notes that stool consistency, stool frequency and flatulence did not differ between study periods, and that no method for symptom record was provided.

A third paper (Pirainen et al., 2007) described a study with 'prune juice' (prepared from plum juice concentrate, prune puree, and water, and sweetened with fructose (7%)). The Panel notes that no scientific conclusions can be drawn for the substantiation of the claim from this study that used another food constituent for the intervention rather than dried "prunes".

Two references provided are general reviews of evaluation and treatment of constipation in children, two are reviews of carbohydrates in human nutrition and of tolerance of low-digestible carbohydrates, three are listings of drugs/remedies or plant-based medications, one is a listing of fruit portion sizes, one is a review of carbohydrate composition of plum and prune preparations (Dikeman et al., 2004), one is an extensive review of chemical composition and potential health effects of prunes and prune juice (Stacewicz-Sapuntzakis et al., 2001), one is a study on spent grain dietary fibre, two are clinical studies on fibre intake in general, faecal excretion and colonic function. The Panel notes that these references do not provide scientific data that could be used to substantiate the claim.

In weighing the evidence, the Panel took into account that one human intervention study did not find any significant difference between the two treatment groups or between different time-points within each group and that the other human intervention study showed some effect on faecal bulk but not on stool frequency or consistency. Another human intervention study cited used another food constituent for the intervention rather than dried "prunes" and the other references provided only background information and did not provide scientific data that could be used to substantiate the claim.

The Panel concludes that the evidence provided is 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.

CONCLUSIONS

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

- The food "prunes" in the meaning of "dried plums of 'prune' cultivars (*Prunus domestica* L.)" which is the subject of the health claims is sufficiently characterised.
- The claimed effect is "normal bowel function/normal gastrointestinal function/normal colonic function". The target population is assumed to be the general population. Maintenance of normal bowel function might be a beneficial physiological effect.
- The evidence provided is 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.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1903). 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>.

REFERENCES

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- Tinker LF, Schneeman BO, Davis PA, Gallaher DD and Waggoner CR, 1991. Consumption of prunes as a source of dietary fiber in men with mild hypercholesterolemia. *American Journal of Clinical Nutrition*, 53, 1259-1265.

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 foods⁵ (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 FOOD⁶

Foods are commonly involved in many different functions⁷ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁵ OJ L12, 18/01/2007

⁶ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁷ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B**EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

GLOSSARY/ABBREVIATIONS

FDA Food and Drug Administration

US United States