



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to prunes and contribution to normal bowel function pursuant to Article 14 of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to prunes and contribution to normal bowel function pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to prunes and contribution to normal bowel function. The food constituent, prunes, which is the subject of the health claim, is sufficiently characterised. Contribution to normal bowel function is a beneficial physiological effect without the occurrence of diarrhoea for infants and young children from six months to three years of age. No evidence was provided by the applicant to substantiate the effect of prunes on bowel function without the occurrence of diarrhoea for infants and young children. The Panel concludes that a cause and effect relationship has not been established between the consumption of prunes and contribution to normal bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age.

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#### KEY WORDS

prunes, dried plums, *Prunus domestica* L., infants, children, bowel function, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Specialised Nutrition Europe (formerly IDACE), Question No EFSA-Q-2008-193, adopted on 30 October 2014.

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## SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to prunes and contribution to normal bowel function.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The food constituent 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 proposed by the applicant is "contribute to normal bowel function". The target populations proposed by the applicant are infants and young children from birth to three years of age. The Panel considers that an improvement of bowel function, such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools, is a beneficial physiological effect, provided that it does not result in diarrhoea. The Panel considers that the target populations with respect to this claim are infants and children from 6 months to 36 months.

The Panel notes that no studies investigating the effect of prunes on bowel function in infants and young children were provided by the applicant.

The Panel considers that no evidence was provided by the applicant to substantiate the effect of prunes on bowel function without the occurrence of diarrhoea for infants and young children.

The Panel concludes that a cause and effect relationship has not been established between the consumption of prunes and contribution to normal bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## STEPS TAKEN BY EFSA

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- On 26/03/2008, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 22/07/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 03/12/2013.
- On 22/01/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 29/01/2014 and was restarted on 21/07/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 25/07/2014, EFSA received the requested information (which was made available to EFSA in electronic format on 23/07/2014).
- During its meeting on 30/10/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to prunes and contribution to normal bowel function.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to prunes and contribution to normal bowel function.

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<sup>4</sup> 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.

## **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of prunes, a positive assessment of its safety or a decision on whether prunes are, or are not, classified as a foodstuff. 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 wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

## INFORMATION PROVIDED BY THE APPLICANT

**Applicant's name and address:** Specialised Nutrition Europe (formerly IDACE), 9–31 Avenue des Nerviens, 1040 Brussels, Belgium.

### Food as stated by the applicant

According to the applicant, the food for which the claim is made is prunes (dried plums of “prune” cultivars (*Prunus domestica* L.)).

### Health relationship as claimed by the applicant

According to the applicant, the laxative effects of prunes can be explained by specific nutrients found in prunes including soluble and insoluble fibres, high amounts of sorbitol, a sugar alcohol with laxative effects, and possible phenolic compounds which may aid in the laxative action. The combination of soluble and insoluble fibre and sorbitol work to soften stools, increase stool bulk and facilitate mobility.

### Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “dried plums/prunes can contribute to normal bowel function”.

As equivalent alternative wordings, the applicant has also proposed: “prune helps to regulate intestinal transit”, “prune supports to maintain normal bowel function”, “prune promotes regularity/bowel transit”, “prune promotes healthy intestinal well-being”.

### Specific conditions of use as proposed by the applicant

According to the applicant, the target populations are infants and young children from birth to three years of age.

According to the applicant, the quantity needed to achieve the claimed effect is 1.4 g of dried plums/kg body weight. The normal body weight of infants and young children evolves from less than 5 kg, for girls of four to six months of age, up to 20 kg, for boys of three years of age. The recommended quantity of dried plums/prunes recommended to obtain the claimed effect therefore depends on the exact target population of the product, namely between 7 and 28 g.

## ASSESSMENT

### 1. Characterisation of the food

The food constituent 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 (6.45 g/100 g on average, ranging from 6.0 to 7.3 g/100 g, according to four American studies), which includes soluble and insoluble fibre, sorbitol (14.7 g/100 g on average, ranging from 9.4 to 19.3 g/100 g, from six sources/varieties), and phenolic compounds (c. 184 mg/100 g), such as neochlorogenic and chlorogenic acids. The water content of dried prunes is about 20–23 % (for data and references see 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

The claimed effect proposed by the applicant is “contribute to normal bowel function”. The target populations proposed by the applicant are infants and young children from birth to three years of age.

The Panel considers that an improvement of bowel function, such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools, is a beneficial physiological effect, provided that it does not result in diarrhoea. The Panel considers that the target populations with respect to this claim are infants and children from six months to 36 months.

The Panel considers that contribution to normal bowel function without the occurrence of diarrhoea is a beneficial physiological effect for infants and young children.

## 3. Scientific substantiation of the claimed effect

The Panel has previously assessed a claim on prunes and normal bowel function in adults with a favourable outcome (EFSA NDA Panel, 2012). This opinion was based on the results of studies on constipated adults and the plausible mechanisms by which some components of prunes may contribute to the claimed effect.

The applicant performed a literature search in PubMed, using the search terms “prune”, “bowel”, “laxation”, and “constipation”. Manual searching of web sites was also used.

Two studies provided investigated the effect of prune juice and a mixture containing prune and fig concentrate (the foods not being the subject of the claim) on gastrointestinal function (Maffia et al., 1955; Piirainen et al., 2007). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The Panel notes that no studies investigating the effect of prunes on bowel function in infants and young children were provided by the applicant.

The Panel considers that no evidence was provided by the applicant to substantiate the effect of prunes (dried plums of “prune” cultivars (*Prunus domestica* L.)) on bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age.

The Panel concludes that a cause and effect relationship has not been established between prune consumption and contribution to normal bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age.

## 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 proposed by the applicant is “contribute to normal bowel function”. The target populations proposed by the applicant are infants and young children from birth to three years of age. The Panel considers that the target populations with respect to this claim are infants and children from six months to 36 months. Contribution to normal bowel function without the occurrence of diarrhoea is a beneficial physiological effect for infants and young children.
- A cause and effect relationship has not been established between the consumption of prunes and contribution to normal bowel function without the occurrence of diarrhoea for infants and young children from six months to three years of age.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on prunes and contribution to normal bowel function pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0113\_FR). February 2008. Submitted by Specialised Nutrition Europe (formerly IDACE).

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