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Fabenol® Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and 'reduces the absorption of carbohydrates': evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

Abstract

Following an application from Ecopharma BVBA, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 Fabenol[®] Max and 'reduces the absorption of carbohydrates'. The Panel considers that Fabenol[®] Max, which is an aqueous extract from *Phaseolus vulgaris* L. standardised by its content of α -amylase inhibitor, is sufficiently characterised. According to the applicant, consumption of the food 'offers potential benefits in the maintenance of healthy blood sugar levels'. The meaning of 'healthy blood sugar levels' was not specified. The target population proposed by the applicant is 'the general population that wants to manage their carbohydrate intake (for the maintenance of healthy blood sugar levels or optimal body composition)'. The Panel notes that the claimed effect was not sufficiently defined and that the applicant did not provide any further information. The Panel concludes that a cause and effect relationship cannot be established between the consumption of Fabenol[®] Max and a beneficial physiological effect.

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Keywords: Fabenol[®] Max, kidney bean extract, carbohydrate absorption, health claims

Requestor: Competent Authority of Belgium following an application by Ecopharma BVBA

Question number: EFSA-Q-2015-00123

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Summary

Following an application from Ecopharma BVBA, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 Fabanol[®] Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and 'reduces the absorption of carbohydrates'.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the general guidance for stakeholders on the evaluation of Article 13.5 and 14 health claims. The scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations are outlined in another EFSA guidance.

The food that is the subject of the health claim is an aqueous extract from *P. vulgaris* L. standardised by its content of α -amylase inhibitor and marketed under the brand name of Fabanol[®] Max. The Panel considers that the food is sufficiently characterised.

According to the applicant, consumption of the food 'offers potential benefits in the maintenance of healthy blood sugar levels'. The meaning of 'healthy blood sugar levels' was not specified. The target population proposed by the applicant is 'the general population that wants to manage their carbohydrate intake (for the maintenance of healthy blood sugar levels or optimal body composition)'.

From the information provided in the application, including the four human studies submitted for substantiation, the Panel could not establish whether the claim refers to (i) a reduction in post-prandial blood glucose responses; (ii) a (long-term) maintenance of normal blood glucose concentrations; or (iii) body weight, e.g. a reduction in body fat/body weight. Therefore, the applicant was requested to specify the claimed effect, i.e. the beneficial physiological effect, which is the subject of the application. The applicant did not reply to this request.

The Panel notes that the claimed effect is not sufficiently defined and that the applicant did not provide any further information as requested by EFSA.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of Fabanol[®] Max and a beneficial physiological effect.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006¹ 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, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction **of disease risk and to children's development and health**) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) 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).

1.2. Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) 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: Fabanol[®] Max (an aqueous extract from *Phaseolus vulgaris* L.) and 'reduces the absorption of carbohydrates'.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Fabanol[®] Max (an aqueous extract from *P. vulgaris* L.), a positive assessment of its safety, nor a decision on whether Fabanol[®] Max (an aqueous extract from *P. vulgaris* L.) is, or is 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 18(4) of Regulation (EC) No 1924/2006.

1.3. Additional information

Claims on phaseolamin and on a standardised aqueous extract from white kidney bean have already been assessed by the Panel with unfavourable outcomes (EFSA NDA Panel, 2011c, 2014).

2. Data and methodologies

2.1. Data

2.1.1. Information provided by the applicant

Food/constituent as stated by the applicant:

- According to the applicant, the food which is the subject of the claim is an extract from *P. vulgaris* (common bean, kidney bean) standardised by its content of α -amylase inhibitor and marketed under the brand name of Fabanol[®] Max.

Health relationship as claimed by the applicant:

- According to the applicant, the consumption of Fabanol[®] Max prevents the breakdown of complex carbohydrates into absorbable carbohydrates, resulting in a reduction in the

¹ 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.

absorption of such carbohydrates. According to the applicant, this 'offers potential benefits in the maintenance of healthy blood sugar levels'.

Wording of the health claim as proposed by the applicant:

- 'Fabenol[®] Max reduces the absorption of carbohydrates'.

Specific conditions of use as proposed by the applicant:

- According to the applicant, 350 mg Fabenol[®] Max should be taken with each carbohydrate-rich meal, up to a daily dose of 700 mg.
- The target population proposed by the applicant is the general population that 'wants to manage their carbohydrate intake (for the maintenance of healthy blood sugar levels or optimal body composition)'.

2.1.2. Data provided by the applicant

Health claim application on Fabenol[®] Max, a standardised aqueous extract from *P. vulgaris* L., and 'reduces the absorption of carbohydrates' pursuant to Article 13.5 of Regulation 1924/2006, presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011a).

As outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b), it is the responsibility of the applicant to provide the totality of the available evidence.

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in EFSA's general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011b).

The scientific requirements for health claims related to appetite ratings, weight management and blood glucose concentrations are outlined in a specific EFSA guidance (EFSA NDA Panel, 2012).

3. Assessment

3.1. Characterisation of the food/constituent

The food that is the subject of the health claim is an extract from *P. vulgaris* L. (common bean) standardised by its content of α -amylase inhibitor and marketed under the brand name of Fabenol[®] Max.

Fabenol[®] Max is extracted from *P. vulgaris* L. by water (the extraction yield was provided) and standardised to 20,000 α -amylase inhibiting units per gram.

An overview of the manufacturing process and information on the stability and batch-to-batch analyses were provided.

The Panel considers that the food, an aqueous extract from *P. vulgaris* L. standardised by its α -amylase inhibitory activity and marketed as Fabenol[®] Max, which is the subject of the health claim, is sufficiently characterised.

3.2. Relevance of the claimed effect to human health

According to the applicant, consumption of the food 'offers potential benefits in the maintenance of healthy blood sugar levels'. The meaning of 'healthy blood sugar levels' was not specified. The target population proposed by the applicant is 'the general population that wants to manage their carbohydrate intake (for the maintenance of healthy blood sugar levels or optimal body composition)'.

From the information provided in the application, including the four human studies submitted for substantiation (Boivin et al., 1987; Vinson and Shuta, 2001; Udani et al., 2004; Vinson et al., 2009),

the Panel could not establish whether the claim refers to (i) a reduction in post-prandial blood glucose responses; (ii) a (long-term) maintenance of normal blood glucose concentrations; or (iii) body weight, e.g. a reduction in body fat/body weight (EFSA NDA Panel, 2012).

Therefore, the applicant was requested to specify the claimed effect, i.e. the beneficial physiological effect, which is the subject of the application. The applicant did not reply to this request.

The Panel notes that the claimed effect is not sufficiently defined and that the applicant did not provide any further information as requested by EFSA.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of Fabenol[®] Max and a beneficial physiological effect.

4. Conclusions

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

- The food, an aqueous extract from *P. vulgaris* L. standardised by its α -amylase inhibitory activity and marketed as Fabenol[®] Max, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect was not sufficiently defined in the application and no further information was provided. A cause and effect relationship cannot be established between the consumption of Fabenol[®] Max and a beneficial physiological effect.

Steps taken by EFSA

1. Health claim application on Fabenol[®] Max (a standardised aqueous extract from *Phaseolus vulgaris* L.) and 'reduces the absorption of carbohydrates' pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0433_BE). Submitted by Ecopharma BVBA, Ambachtsstraat 1, 9700 Oudenaarde, Belgium.
2. The application was received by EFSA on 23 February 2015.
3. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
4. On 27 March 2015, during the validation of the application, EFSA sent a request to the applicant to provide missing information. EFSA did not receive any reply by the applicant.
5. On 7 May 2015, 18 June 2015, 26 June 2015, 17 July 2015, 24 August 2015 and 13 October 2015, EFSA sent reminders to the applicant, inviting the applicant to reply to the missing information request. EFSA did not receive any reply by the applicant.
6. The scientific evaluation procedure started on 28 October 2015.
7. On 25 November 2015, 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 and the scientific evaluation was suspended on 7 December 2015. EFSA did not receive any reply by the applicant. In compliance with Article 18(3) of Regulation (EC) No 1924/2006, the scientific evaluation was restarted on 22 December 2015. The applicant was informed accordingly.
8. During its meeting on 2 February 2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to Fabenol[®] Max and '**reduces the absorption of carbohydrates**'.

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