EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to zinc and “the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity” pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) 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

ABSTRACT

Following an application from EJP Pharmaceutical ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath. The Panel considers that the proposed claim is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

KEY WORDS

Zinc, bad breath, health claims.

[1] On request from the Competent Authority of Denmark following an application by EJP Pharmaceutical ApS, Question No EFSA-Q-2010-01092, adopted on 13 May 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank 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 for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from EJP Pharmaceutical ApS, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Denmark, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity".

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

The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath.

The Panel notes that health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 are required to describe or refer to, among other roles, the role of a nutrient or other substance in the functions of the body. Thus, the applicant was requested to clarify how the proposed claim might comply with this requirement. The applicant replied by expressing the view that the production of volatile sulphur compounds and halitosis as part of the bacterial flora of the mouth and oral cavity is related to the function of the mouth and oral cavity, and thus to a function of the body. The Panel notes that the applicant did not provide any additional evidence that the chemical neutralisation of volatile sulphur compounds in the mouth in order to improve bad breath constitutes a physiological effect in relation to a function of the body.

The Panel considers that the claim "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006.

The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[4] 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 Art 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).

STEPS TAKEN BY EFSA

- The application was received on 03/09/2010.
- EFSA sent a request for clarification to the Competent Authority of Denmark on 11/10/2010.
- The Competent Authority of Denmark provided its reply to EFSA on 01/03/2011.
- A revised application was received on 01/03/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 20/03/2011.
- EFSA sent a request for information to the applicant on 30/03/2011.
- The applicant provided a reply to EFSA on 15/04/2011.
- During the meeting on 13/05/2011, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity".

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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: zinc and "the prevention of bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of zinc, a positive assessment of its safety, nor a decision on whether zinc 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.

[4] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: EJP Pharmaceutical ApS, Ulvshalevej 70, 4780 Stege, Denmark.

Food/constituent as stated by the applicant

According to the applicant, zinc was identified as the food/constituent.

Health relationship as claimed by the applicant

According to the applicant, zinc reduces or inhibits oral malodour via its interaction with sulphur. The proposed mechanism is that the zinc ions oxidize the thiol groups in the precursors of volatile sulphur-containing compounds resulting from the microbial degradation of oral organic substrates.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the claim: "Prevents bad breath by neutralising of volatile sulphur compounds (VSC) in the mouth and oral cavity".

Specific conditions of use as proposed by the applicant

The applicant has proposed a maximum of one lozenge containing 6.8 mg zinc per day. The lozenge should be kept in the mouth until dissolved (for approximately 10 min). The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is zinc.

Zinc is a well recognised nutrient and is measurable in foods by established methods. Zinc occurs naturally in foods and is authorised for addition to foods (Annex I of the Regulation (EC) No 1925/2006[5] and Annex I of Directive 2002/46/EC[6]). This evaluation applies to zinc naturally present in foods and those forms authorised for addition to foods (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, zinc, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over 18 years of age who wish to improve their bad breath.

[5] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.

[6] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

The Panel notes that health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 are required to describe or refer to, among other roles, the role of a nutrient or other substance in the functions of the body.

Thus, the applicant was requested to clarify how the proposed claim might comply with this requirement. The applicant replied by expressing the view that the production of volatile sulphur compounds and halitosis as part of the bacterial flora of the mouth and oral cavity is related to the function of the mouth and oral cavity, and thus to a function of the body. The Panel notes that the applicant did not provide any additional evidence that the chemical neutralisation of volatile sulphur compounds in the mouth in order to improve bad breath constitutes a physiological effect in relation to a function of the body.

The Panel considers that the claim "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006.

The Panel considers that the claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

CONCLUSIONS

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

- The food constituent, zinc, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity". The target population, as proposed by the applicant, is adults over the age of 18 who wish to improve their bad breath.
- The claim is related to breath odour rather than to a function of the body as required by Article 13 of Regulation (EC) No 1924/2006. The claim does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on zinc and "prevents bad breath by neutralising of volatile sulphur compounds in the mouth and oral cavity" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0290_DK). September 2010. Submitted by EJP Pharmaceutical ApS.