



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to spermidine and prolongation of the growing phase (anagen) of the hair cycle 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 spermidine and prolongation of the growing phase (anagen) of the hair cycle pursuant to Article 13(5) 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 an application from Giuliani S.p.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to spermidine and prolongation of the growing phase (anagen) of the hair cycle. The scope of the application was proposed to fall under a health claim referring to a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data. The food constituent that is the subject of the health claim is spermidine, which is sufficiently characterised. The claimed effect is prolongation of the growing phase (anagen) of the hair cycle. The target population proposed by the applicant is “healthy people affected by chronic telogen effluvium”. Following EFSA’s request to provide a rationale why subjects with chronic telogen effluvium would be an appropriate study population for the scientific substantiation of a health claim intended for the general population, the applicant indicated that telogen effluvium is caused by multifactorial triggers, occurs in both sexes at any age, and that it could be considered to affect the general population. From the evidence provided by the applicant the Panel considers that the claimed effect is related to the treatment of pathological conditions leading to shortening of the anagen phase of hair growth. The Panel concludes that the claimed effect is related to the treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006. © European Food Safety Authority, 2011

KEY WORDS

Spermidine, hair cycle, anagen, health claims

¹ On request from the Competent Authority of Italy following an application by Giuliani S.p.A., Question No EFSA-Q-2011-00896, adopted on 23 November 2011.

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SUMMARY

Following an application from Giuliani S.p.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to spermidine and prolongation of the growing phase (anagen) of the hair cycle.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.

The food constituent that is the subject of the health claim is spermidine. Spermidine (N-(3-aminopropyl)butane-1,4-diamine) is a polyamine which is present in nearly all eukaryotic cells. The Panel considers that spermidine, which is the subject of the health claim, is sufficiently characterised.

After clarification requested by EFSA, the applicant indicated that the claimed effect to be considered for evaluation is “prolongation of the growing phase (anagen) of the hair cycle”. The target population proposed by the applicant is “healthy people affected by chronic telogen effluvium”.

The applicant was asked to provide a rationale why subjects with chronic telogen effluvium would be an appropriate study population for the scientific substantiation of a health claim intended for the general population. The applicant indicated that telogen effluvium is caused by multifactorial triggers, occurs in both sexes at any age, and that it could be considered to affect the general population.

From the evidence provided by the applicant the Panel considers that the claimed effect is related to the treatment of pathological conditions leading to shortening of the anagen phase of hair growth. The Panel concludes that the claimed effect is related to the treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ 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).

STEPS TAKEN BY EFSA:

- The application was received on 07/07/2011.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.
- On 21/07/2011, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 05/08/2011.
- The scientific evaluation procedure started on 30/08/2011.
- During the meeting on 23/11/2011, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to spermidine and prolongation of the growing phase (anagen) of the hair cycle.

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: spermidine and prolongation of the growing phase (anagen) of the hair cycle.

EFSA DISCLAIMER

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

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Giuliani S.p.A., Via Palagi 2, 20129 Milano, Italy.

The application includes a request for the protection of proprietary data for the use of spermidine in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food constituent for which the claim is made is spermidine.

Health relationship as claimed by the applicant

According to the applicant, spermidine “induces hair growth during life cycle, stimulates cell proliferation at hair bulb improving the growth phase (anagen), reduces hair loss and increases hair resistance” (as described in the first submission). Following EFSA’s request the claimed effect was clarified as “prolongs the growing phase (anagen) of the hair cycle”.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “Spermidine prolongs the growing phase (anagen) of the hair cycle”.

Specific conditions of use as proposed by the applicant

According to the applicant, the pattern of consumption is 0.5 mg of spermidine per day that can be supplied by one tablet of food supplement. The proposed target population is healthy people affected by a condition of hair loss (chronic telogen effluvium; CTE).

ASSESSMENT

1. Characterisation of the food/constituent

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

Spermidine (N-(3-aminopropyl)butane-1,4-diamine) is a polyamine which is present in nearly all eukaryotic cells. Under physiological conditions, polyamines are totally protonated and behave as natural polycations. The cellular content of these amines is closely regulated and they are synthesised by a highly regulated pathway from ornithine after decarboxylation (Agostinelli et al., 2010; Morgan, 1999; Pegg, 2009).

The applicant markets spermidine as salt - spermidine trihydrochloride (molecular formula $C_7H_{19}N_3 \cdot 3HCl$), in the form of tablets containing 0.50 mg of spermidine trihydrochloride corresponding to 0.285 mg of spermidine free base. Complete specifications such as flow chart of the manufacturing process, stability and purity information, and bioavailability data have been provided.

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

2. Relevance of the claimed effect to human health

Initially the claimed effect was described as “induces hair growth during life cycle, stimulates cell proliferation at hair bulb improving the growth phase (anagen), reduces hair loss and increases hair resistance”. Following EFSA’s request to clarify the claimed effect, the applicant indicated that the effect to be considered for evaluation is “prolongation of the growing phase (anagen) of the hair cycle”. The target population proposed by the applicant is “healthy people affected by chronic telogen effluvium (CTE)”.

Telogen effluvium is a form of non-scarring alopecia characterised by diffuse hair shedding. Acute telogen effluvium is characterised by an abrupt onset, and rapid, diffuse, self-limited, excessive

shedding of normal club hair, usually seen 2-3 months after a triggering event e.g. febrile illness, emotional stress, chronic systemic illness. The term chronic telogen effluvium refers to the situation in which telogen hair shedding persists for longer than six months and the triggering factor is often less apparent (Messenger et al., 2010). Premature progression of anagen into catagen and telogen hair follicle is the main mechanism behind telogen effluvium.

During the validation step of the application, the applicant was asked to provide a rationale why subjects with chronic telogen effluvium would be an appropriate study population for the scientific substantiating of a health claim intended for the general population. The applicant indicated that telogen effluvium is caused by multifactorial triggers, occurs in both sexes at any age, and that it could be considered to affect the general population.

From the evidence provided by the applicant, the Panel considers that the claimed effect is related to the treatment of pathological conditions leading to shortening of the anagen phase of hair growth.

The Panel concludes that the claimed effect is related to the treatment of a disease and 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, spermidine, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect refers to reducing net hair loss by prolongation of the anagen phase of the hair cycle. The target population is “healthy people affected by chronic telogen effluvium”.
- The claimed effect is related to the treatment of a disease and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on spermidine and prolongation of the growing phase (anagen) of the hair cycle pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0308_IT). August 2011. Submitted by Giuliani S.p.A.

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GLOSSARY / ABBREVIATIONS

CTE Chronic Telogen Effluvium