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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to Preservation® and “ rapid recovery of cellular activity post stress ” 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 Preservation[®] and “rapid recovery of cellular activity post stress” 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 ICP Ltd, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Malta, 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 Preservation[®] and “rapid recovery of cellular activity post stress”. The Panel considers that Preservation[®], which contains an extract of prickly pear cactus *Opuntia ficus-indica*, is sufficiently characterised. The claimed effect is “rapid recovery of cellular activity post stress”. The claimed effect is general and non-specific, and the references provided did not provide information which could be used to define a specific beneficial physiological effect. The Panel considers that the claimed effect is general and non-specific, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

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KEY WORDS

Preservation[®], Prickly pear cactus, *Opuntia ficus-indica*, stress, heat shock proteins, health claims

¹ On request from the Competent Authority of Malta following an application by ICP Ltd, Question No EFSA-Q-2013-00021, adopted on 10 July 2013.

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SUMMARY

Following an application from ICP Ltd, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Malta, 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 Preservation[®] and “rapid recovery of cellular activity post stress”.

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

The food that is the subject of the health claim is Preservation[®], which contains an extract of prickly pear cactus *Opuntia ficus-indica*. The Panel considers that Preservation[®] is sufficiently characterised.

In the original application, the claimed effect was indicated as “improves the physiological response to stress by accelerating the appearance of heat shock proteins”. The Panel noted that “improved physiological response to stress” was not sufficiently defined. Upon request to define the claimed effect (i.e. the beneficial physiological effect), the applicant stated that the beneficial physiological effect is “the rapid recovery of cellular activity post stress to encounter cellular repair, which, although it is not localised to a particular organ of the body, is associated with the well-being of the individual following ‘that stressful event’”.

The outcome measures used in the three human studies provided were the appearance of heat shock proteins in blood after “thermal shock” or after diving, and a “hangover symptom index” following alcohol consumption.

The Panel notes that the claimed effect indicated by the applicant is general and non-specific, and that the references provided did not provide information which could be used to define a specific beneficial physiological effect.

The Panel considers that the claimed effect is general and non-specific, 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 03/01/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 14/02/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 14/03/2013, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 27/03/2013.
- On 31/05/2013, the EFSA NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application, and the clock was stopped on 12/06/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 26/06/2013, EFSA received the requested information and the clock was restarted, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- During its meeting on 10/07/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Preservation[®] and “rapid recovery of cellular activity post stress”.

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: Preservation[®] and “rapid recovery of cellular activity post stress”.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Preservation[®], a positive assessment of its safety, nor a decision on whether

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.

Preservation[®] 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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Institute of Cellular Pharmacology (ICP) Ltd, Unit F24/F25, MOSTA Technopark, Malta.

Food/constituent as stated by the applicant

According to the applicant, Preservation[®], which contains an extract (denominated as TEX-OE[®]) of prickly pear cactus *Opuntia ficus-indica*.

Health relationship as claimed by the applicant

According to the applicant, the ingestion of Preservation[®] can induce and amplify the rapid synthesis of heat shock proteins (HSPs) following a stressor, such as physical exercise, hot or cold conditions, high light intensity (i.e. sun exposure), pressure changes while diving or exposure to alcohol. This effect is claimed by the applicant to reduce the degree of cellular damage following a stressor.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “improves the physiological response to stress by accelerating the appearance of heat shock proteins (HSPs) and maintains an effective level of HSPs to ensure that the organism is primed should the cell encounter further stress”.

Specific conditions of use as proposed by the applicant

The applicant considers the following intake adequate in order to achieve the claimed effect: 6 mg of purified *Opuntia* extract per kg body weight, which corresponds to one tablet of Preservation[®] for a person of ≤ 55 kg. The food should be consumed prior to a stress factor, e.g. any physical activity. The target population proposed by the applicant is the general population.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is Preservation[®], which contains an extract (denominated as TEX-OE[®]) of prickly pear cactus *Opuntia ficus-indica*.

The starting material for the extraction process is the dried and powdered skins of prickly pear cactus fruits. An overview of the patented manufacturing process (EP 0 948 340 B1; US 6,737,086 B2) was provided.

The extract is standardised by its capacity to elevate the levels of heat shock proteins in a human keratinocyte cell line (i.e. HaCaT) as assessed by ELISA (HSP70 ELISA kit) (ICP, 2007, unpublished). Batch-to-batch variability of the extract was provided.

The Panel considers that the food, Preservation[®], which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

In the original application, the claimed effect was indicated as “improves the physiological response to stress by accelerating the appearance of heat shock proteins”. The target population proposed by the applicant is the general population.

The Panel noted that “improved physiological response to stress” is not sufficiently defined. The applicant was requested to define the claimed effect (i.e. the beneficial physiological effect), and to indicate the outcome measures which could be used to assess the claimed effect and the mechanism by which the food would exert the claimed effect. In reply, the applicant stated that the beneficial physiological effect is “the rapid recovery of cellular activity post stress to encounter cellular repair, which, although it is not localised to a particular organ of the body, is associated with the well-being of the individual following ‘that stressful event’”. With respect to the outcome measures, the applicant indicated that in the animal and *in vitro* studies death/mortality was used to assess the claimed effect. In human studies “where a stress activity was expected to bring adverse effects, the consumption [of Preservation[®]] brought about a general beneficial physiological effect”. According to the applicant, “the rapid appearance of heat shock proteins in the blood is the most reliable source of objective outcome”.

From the wording and the information provided in the application, the Panel understands that the accelerated appearance of heat shock proteins in the blood is the proposed mechanism by which the food would exert the claimed effect.

The Panel notes that the outcome measures used in the three human studies (Saliba et al., 1998a, unpublished; Saliba et al., 1998b; Wiese et al., 2004) provided were the appearance of heat shock proteins in the blood after “thermal shock” in a sauna (Saliba et al., 1998a, unpublished) or after diving (Saliba et al., 1998b), and a “hangover symptom index” following alcohol consumption (Wiese et al., 2004).

The Panel notes that the claimed effect indicated by the applicant is general and non-specific, and that the references provided did not provide information which could be used to define a specific beneficial physiological effect.

The Panel considers that the claimed effect is general and non-specific, 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, Preservation[®], which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “rapid recovery of cellular activity post stress”. The target population proposed by the applicant is the general population.
- The claimed effect is general and non-specific, and does not comply with the criteria laid down in Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Preservation[®] and “improves the physiological response to stress by accelerating the appearance of heat shock proteins” pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0373_MT). January 2013. Submitted by ICP Ltd.

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