European Food Safety Authority

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TECHNICAL REPORT OF EFSA

Response to comments on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of health claims related to water and reduced risk of development of dehydration and of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, EFSA was asked to review the scientific comments received on the Scientific Opinion of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) on the scientific substantiation of health claims related to water and reduced risk of development of dehydration and of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No 1924/2006.

Comments submitted to EFSA via the European Commission Services originated from Cognis GmbH and were related to the risk factor of the proposed claim.

EFSA has reviewed the comments and shared them with the chair of the NDA Panel and the chair of the NDA Working Group on Claims.

In its opinion adopted on 28 January 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) considered that the proposed claim does not comply with the requirements for a disease risk reduction claim pursuant to Article 14 of Regulation (EC) No 1924/2006. The comments received do not change the consideration of the NDA Panel.

KEY WORDS

Water, dehydration, disease, health claims, comments.

[1] On request from the European Commission, Question No EFSA-Q-2011-00337, issued on 30 June 2011.

[2] Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank Albert Flynn, Sean Strain and EFSA staff member Juliane Kleiner for the support provided to this technical report.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Article 16(6) of Regulation (EC) No 1924/2006 on nutrition and health claims states that: "The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public. The applicant or members of the public may make comments to the Commission within 30 days from such publication."

The Regulation does not foresee a consultation on the EFSA opinion. It does, however, allow for the applicant or members of the public to make comments to the Commission relating to the EFSA opinion. The Commission's services have established a practice for handling the comments provided by applicants and members of the public in order to allow their full consideration by the regulators in the health claims' authorisation process. More particularly, whenever the comments relate to the scientific assessment, they are transmitted to EFSA for consideration. The Commission and the Member States await the EFSA response to the comments before proceeding with the final discussion and the vote in the Standing Committee on the Food Chain and Animal Health on the draft measure authorising or rejecting the health claims for which comments were made.

The procedure briefly outlined above is in line with the procedure foreseen in Article 31 of Regulation (EC) No 178/2002, whereby the Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission, and when the matter does not require scientific evaluation by a Scientific Committee or a Scientific Panel.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Commission requests EFSA, within the framework of scientific and technical assistance to the Commission foreseen in Article 31 of Regulation (EC) No 178/2002, to evaluate the comments of a scientific nature received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 and to provide the Commission with a response.

Relevant actions performed under this mandate will be carried out in good cooperation between the Commission and EFSA in accordance with the procedure set out in the Annex to the Mandate (to be found in the EFSA Register of Question under the mandate number M-2011-0063).

CONSIDERATION

1. Introduction

On 28 January 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) adopted a scientific opinion on the scientific substantiation of health claims related to water and reduced risk of development of dehydration and of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No 1924/2006[4] following an application for authorisation from Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn submitted via the Competent Authority of Germany (Claims serial number: 0287_DE, EFSA-Q-2008-05014).

In accordance with Article 16 of Regulation (EC) 1924/2006 the applicants or members of the public may make comments to the European Commission on opinions published by Authority pursuant to Article 16 and 18 of the Regulation. On 26 April 2011, the European Commission requested EFSA to respond to the scientific comments received during the commenting period specified in Article 16 of the Regulation. Comments submitted to EFSA via the European Commission Services originated from Cognis GmbH.

EFSA has reviewed the comments and shared them with the chair of the NDA Panel, Prof. Albert Flynn, and the chair of the NDA Working Group on Claims, Prof. Sean (J.J.) Strain. The report clarifies the specific scientific issue raised by Cognis GmbH.

2. Comments on the risk factor of the proposed claim

In its opinion the Panel notes that dehydration was identified as the disease by the applicant and that the risk factor was proposed as "water loss in tissues" or "reduced water content in tissues". The Panel considered that the proposed risk factors are measures of water depletion and thus are measures of the disease (dehydration).

Comments by Cognis GmbH indicate that an undersupply with water might be considered as a risk factor for the proposed claim, since a sufficient water supply would reduce the risk of developing dehydration and the concomitant disease related conditions.

For reduction of disease risk claims, the beneficial physiological effect (which the Regulation requires to be shown for the claim to be permitted) is the reduction (or beneficial alteration) of a risk factor for the development of a human disease (not reduction of the risk of disease). However, undersupply with water would not be considered as a risk factor for dehydration (the disease) in this context as the beneficial alteration of the factor (increased consumption of water) is not a beneficial physiological effect as required by the Regulation.

It should be noted that the NDA Panel has positively evaluated a general function claim on water and maintenance of normal physical and mental performance[5].

[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.

[5] EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of health claims related to water and maintenance of normal physical and cognitive function (ID 1102, 1209, 1294, 1331), maintenance of normal thermoregulation (ID 1208) and "basic requirement of all living things" (ID 1207) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2075, 16 pp.

CONCLUSIONS

In its opinion adopted on 28 January 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) considered that the proposed claim on water and reduced risk of development of dehydration and of concomitant decrease of performance does not comply with the requirements for a disease risk reduction claim pursuant to Article 14 of Regulation (EC) No 1924/2006. The comments received do not change the consideration of the NDA Panel.

DOCUMENTATION PROVIDED TO EFSA

Comments submitted to the European Commission by Cognis GmbH.