

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim 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<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

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#### ABSTRACT

Following an application from Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to water and reduced risk of development of dehydration and of concomitant decrease of performance. The scope of the application was proposed to fall under a health claim referring to disease risk reduction. The food, water, which is the subject of the health claim, is sufficiently characterised. The claimed effect is “regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance”. The target population is assumed to be the general population. The Regulation (EC) No 1924/2006 defines reduction of disease risk claims as claims which state that the consumption of a food “significantly reduces a risk factor in the development of a human disease”. Thus, for reduction of disease risk claims, the beneficial physiological effect results from the reduction of a risk factor for the development of a human disease. The Panel notes that dehydration was identified as the disease by the applicant. Dehydration is a condition of body water depletion. The Panel notes that the proposed risk factors, “water loss in tissues” or “reduced water content in tissues”, are measures of water depletion and thus are measures of the disease. The Panel considers 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. © European Food Safety Authority, 2011

#### KEY WORDS

Water, dehydration, performance, health claims.

<sup>1</sup> On request from the Competent Authority of Germany following an application by Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn, Question No EFSA-Q-2008-05014, adopted on 28 January 2011.

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## SUMMARY

Following an application from Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Germany, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to water and reduced risk of development of dehydration and of concomitant decrease of performance.

The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

The food that is the subject of the health claim is water. The Panel considers that water is sufficiently characterised.

The claimed effect is “regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance”. The Panel assumes that the target population is the general population.

The Regulation (EC) No 1924/2006 defines reduction of disease risk claims as claims which state that the consumption of a food “significantly reduces a risk factor in the development of a human disease”. Thus, for reduction of disease risk claims, the beneficial physiological effect (which the Regulation requires to be shown for the claim to be permitted) results from the reduction of a risk factor for the development of a human disease.

The Panel notes that dehydration was identified as the disease by the applicant. Dehydration is a condition of body water depletion. Upon request for clarification on the risk factor, the applicant proposed “water loss in tissues” or “reduced water content in tissues” as risk factors, the reduction of which was proposed to lead to a reduction of the risk of development of dehydration. The Panel notes that the proposed risk factors are measures of water depletion and thus are measures of the disease (dehydration).

The Panel considers 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.

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## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006<sup>4</sup> 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, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation 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 19/09/2008.
- EFSA sent a request for clarification to the Competent Authority of Germany on 08/10/2008.
- The Competent Authority of Germany provided its reply to EFSA on 26/03/2009.
- The applicant sent a request for information to EFSA on 15/06/2009.
- EFSA provided a reply to the applicant on 21/07/2009.
- The applicant sent a request for information to EFSA on 27/07/2009.
- EFSA provided a reply to the applicant on 23/09/2009.
- EFSA sent a request for information to the Competent Authority of Germany on 09/10/2009.
- The applicant sent a request for information to EFSA on 15/10/2009.
- EFSA provided a reply to the applicant on 23/11/2009.
- The applicant sent a request for information to EFSA on 15/01/2010.
- EFSA provided a reply to the applicant on 27/01/2010.
- The Competent Authority of Germany provided its reply to EFSA on 10/02/2010.
- EFSA sent a request for information to the Competent Authority of Germany on 21/04/2010.
- The Competent Authority of Germany provided its reply to EFSA on 30/07/2010.
- EFSA sent a request for information to the applicant on 01/10/2010.
- The applicant provided a reply to EFSA on 27/10/2010.
- The scientific evaluation procedure started on 15/11/2010.
- EFSA informed the applicant about the start of the evaluation procedure on 17/11/2010.
- During the meeting on 28 January 2011, the NDA Panel, after having evaluated the overall data submitted, adopted an opinion on the scientific substantiation of a health claim related to

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<sup>4</sup> 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.

water and reduced risk of development of dehydration and of concomitant decrease of performance.

#### **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 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: water and reduced risk of development of dehydration and of concomitant decrease of performance.

#### **EFSA DISCLAIMER**

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of water, a positive assessment of its safety, nor a decision on whether water 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 17 of Regulation (EC) No 1924/2006.

## INFORMATION PROVIDED BY THE APPLICANT

### Applicants' names and addresses:

Prof. Dr. Moritz Hagenmeyer, Krohn Rechtsanwälte, Esplanade 41, 20354 Hamburg, Germany.

Prof. Dr. Andreas Hahn, Leibniz Universität Hannover, Institut für Lebensmittelwissenschaft und Humanernährung, Am Kleinen Felde 30, 30167 Hannover, Germany.

### Food/constituent as stated by the applicant

According to the applicant, "water (chemical formula  $H_2O$ ,  $M_w=18.015$ ), a transparent, odourless and tasteless liquid (melting point:  $0^\circ C=273,15$  K; boiling point:  $100^\circ C=373,15$  K). In small quantities colourless, the colour of water in thick layers is of a slight blue hue. Water is generally considered an essential nutrient."

(Original version submitted in German: "Wasser (Wasserstoffoxid,  $H_2O$ ,  $M_R$  18,015), eine klare, geruch- und geschmacklose, generell farblose, in dicker Schicht bläulich schimmernde Flüssigkeit (Schmelzpunkt  $0^\circ C=273,15$  K, Siedepunkt  $100^\circ C=373,15$  K), die ernährungswissenschaftlich allgemein als essentieller Nährstoff gilt.")

### Health relationship as claimed by the applicant

According to the applicant, the regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance.

(Original version submitted in German: "Regelmäßiger Verzehr signifikanter Mengen von Wasser kann das Risiko für die Entwicklung von Dehydratation und damit einhergehendem Leistungsabfall deutlich senken".)

### Wording of the health claim as proposed by the applicant

The applicant proposed the following wording for the health claim: "Regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance".

(Original version submitted in German: "Regelmäßiger Verzehr signifikanter Mengen von Wasser kann das Risiko für die Entwicklung von Dehydratation und damit einhergehendem Leistungsabfall deutlich senken".)

### Specific conditions of use as proposed by the applicant

The applicant proposed a regular consumption of significant amounts of water.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food that is the subject of the health claim is water.

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

## 2. Relevance of the claimed effect to human health

The claimed effect is “regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance”. No target population has been specified by the applicant. The Panel assumes that the target population is the general population.

The Regulation (EC) No 1924/2006<sup>5</sup> defines reduction of disease risk claims as claims which state that the consumption of a food “significantly reduces a risk factor in the development of a human disease”. Thus, for reduction of disease risk claims, the beneficial physiological effect (which the Regulation requires to be shown for the claim to be permitted) results from the reduction of a risk factor for the development of a human disease.

The Panel notes that dehydration was identified as the disease by the applicant. Dehydration is a condition of body water depletion. Upon request for clarification on the risk factor, the applicant proposed “water loss in tissues” or “reduced water content in tissues” as risk factors, the reduction of which was proposed to lead to a reduction of the risk of development of dehydration. The Panel notes that the proposed risk factors are measures of water depletion and thus are measures of the disease (dehydration).

The Panel considers 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.

## CONCLUSIONS

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

- The food constituent, water, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance”. The target population is assumed to be the general population. Dehydration is a condition of body water depletion. The proposed risk factors are measures of water depletion and thus are measures of the disease. 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.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on water and reduced risk of development of dehydration and of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0287\_DE). September 2008. Submitted by Prof. Dr. Moritz Hagenmeyer and Prof. Dr. Andreas Hahn.

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<sup>5</sup> 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.