EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to “Transitech” and “improves transit and durably regulates it” 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 "Transitech®" and "improves transit and durably regulates it" 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 Vivatech submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to "Transitech®" and "improves transit and durably regulates it". The food that is the subject of the health claim is "Transitech®", a food supplement which contains dried parts of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids standardised for hydroxyanthracene derivatives, of *Althaea officinalis* L., of *Rosa centifolia* L., of *Ocimum basilicum* L., of *Coriandrum sativum* L., dried juice of *Cynara scolymus* L. standardised for cynarine, *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC, *Bifidobacterium longum* R0175 and *Lactobacillus helveticus* R0052. The information provided was insufficient to establish that *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC was sufficiently characterised. The Panel considers that if in a combination of several microorganisms and/or ingredients one microorganism or ingredient used in the combination is not sufficiently characterised, then the combination is considered to be not sufficiently characterised. The food, "Transitech®", which is the subject of the claim, is not sufficiently characterised. The Panel concludes that a cause and effect relationship cannot be established between the consumption of "Transitech®" and "improves transit and durably regulates it".

KEY WORDS

Transitech, hydroxyanthracene derivatives, cynarine, health claims.

[1] On request from the Competent Authority of France following an application by Vivatech, Question No EFSA-Q-2012-00296, adopted on 12 September 2012.

[2] Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck 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 Vivatech submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to "Transitech®" and "improves transit and durably regulates it".

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

The food that is the subject of the health claim is "Transitech®", a food supplement which contains per tablet on average 226.8 mg powdered dried underground parts of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids standardised for hydroxyanthracene derivatives (2.2 to 2.76 %, 5 mg/tablet), 38 mg of powdered dried root of *Althaea officinalis* L., 38 mg of powdered dried petals of *Rosa centifolia* L., 18 mg of powdered dried expressed juice from leaves of *Cynara scolymus* L. standardised for cynarine (2.5 %), 18 mg of powdered dried leaves of *Ocimum basilicum* L., 18 mg of powdered dried seeds of *Coriandrum sativum* L., $1.7x10^8$ CFU *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC, and $4x10^6$ CFU of each *Bifidobacterium longum* R0175 and *Lactobacillus helveticus* R0052.

During the validation period and the clock-stop procedure, the applicant was invited to comment on the plausibility of an effect on transit time of constituents other than hydroxyanthracene derivatives from *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids contained in "Transitech®". The applicant indicated that *Althaea officinalis* L., *Rosa centifolia* L., *Cynara scolymus* L., *Ocimum basilicum* L. and *Coriandrum sativum* L. are traditionally used to reduce gastro-intestinal discomfort and are added to support an effect on transit time. The applicant also clarified that microorganisms have been added in order to "restore and equilibrate the intestinal microflora", and requested that the evaluation be carried out on the combination of ingredients.

Upon request from EFSA during the validation period to provide information on the characterisation of the strain of *Saccharomyces cerevisiae* which is used in "Transitech®", the applicant identified the yeast at species level by sequencing analysis of the D2 domain of 26S rDNA. Upon further request from EFSA during the clock-stop procedure to provide information on the strain characterisation the applicant stated that the strain was identified as *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC without providing additional experimental data or references reporting on the characterisation of the yeast at strain level. The Panel notes that the information provided was insufficient to establish that *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC was sufficiently characterised. The Panel considers that *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC is not sufficiently characterised.

The Panel considers that if in a combination of several microorganisms and/or ingredients one microorganism or ingredient used in the combination is not sufficiently characterised, then the combination is considered to be not sufficiently characterised.

The Panel considers that the food, "Transitech®", which is the subject of the claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of "Transitech®" and "improves transit and durably regulates it".

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BACKGROUND

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 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 15/02/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and includes a request for the protection of proprietary data.
- On 15/03/2012, 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 21/05/2012.
- The scientific evaluation procedure started on 11/05/2012.
- On 24/05/2012, the Working Group on Claims of the 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 04/06/2012 in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- The clock was restarted on 19/06/2012. On 25/06/2012, EFSA received the requested information as submitted by the applicant.
- On 28/06/2012, the 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 04/07/2012 in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 16/07/2012, EFSA received the requested information as submitted by the applicant. The clock was restarted on 16/07/2012.
- During its meeting on 12/09/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to "Transitech®" and "improves transit and durably regulates it".

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

[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.

opinion on the scientific substantiation of a health claim related to "Transitech®" and "improves transit and durably regulates it".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of "Transitech®", a positive assessment of its safety, nor a decision on whether "Transitech®" 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: Vivatech, 8 rue Christophe Colomb, 75008 Paris - France.

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

Food/constituent as stated by the applicant

According to the applicant, the food which is the subject of the claim is "Transitech®". "Transitech®" mainly contains rhubarb (226.8 mg per tablet), mallow (38 mg per tablet) and artichoke (18 mg per tablet) but also contains pale rose, basil, yeasts (*Saccharomyces cerevisiae*) and lactic ferments such as *Bifidobacterium longum* I-3470 (commercial name: *Bifidobacterium* Rosell-175) and *Lactobacillus helveticus* I-1722 (commercial name: *Lactobacillus* Rosell-52).

Health relationship as claimed by the applicant

According to the applicant, the oral supplement "Transitech®" could play a role in the management of perturbed defecation, which is particularly widespread in industrialised countries and occurs in many situations of daily life, and could also re-establish a middle-term normal transit.

Wording of the health claim as proposed by the applicant

The following wording is proposed by the applicant: "Improves transit and durably regulates it."

Specific conditions of use as proposed by the applicant

According to the applicant, the product is intended for people suffering from occasional constipation with a disturbed defecation (2 to 5 stools per week) in the general population, and the recommended daily amount is two pills per day, representing 453 mg of rhubarb, including 10 mg of anthracene derivatives. The supplementation should be taken over 10 days.

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is "Transitech®", a food supplement which contains per tablet on average 226.8 mg powdered dried underground parts of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids standardised for hydroxyanthracene derivatives (2.2 to 2.76 %, 5 mg/tablet), 38 mg of powdered dried root of *Althaea officinalis* L., 38 mg of powdered dried petals of *Rosa centifolia* L., 18 mg of powdered dried expressed juice from leaves of *Cynara scolymus* L. standardised for cynarine (2.5 %), 18 mg of powdered dried leaves of *Ocimum basilicum* L., 18 mg of powdered dried seeds of *Coriandrum sativum* L., $1.7x10^8$ CFU *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC, and $4x10^6$ CFU of each *Bifidobacterium longum* R0175 and *Lactobacillus helveticus* R0052.

The applicant provided information on the batch-to-batch variability with respect to the hydroxyanthracene derivative content of the powdered dried underground parts of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, as well as with respect to the cynarine content of the dried expressed juice from leaves of *Cynara scolymus* L. used in "Transitech®". The applicant also provided a certificate of analysis of the hydroxyanthracene derivative and cynarine content of one

batch of "Transitech®". The applicant indicated that all ingredients of plant origin met the requirements set out in the European Pharmacopoeia monographs.

During the validation period and the clock-stop procedure, the applicant was invited to comment on the plausibility of an effect on transit time of constituents other than hydroxyanthracene derivatives from *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids contained in "Transitech®". The applicant indicated that *Althaea officinalis* L., *Rosa centifolia* L., *Cynara scolymus* L., *Ocimum basilicum* L. and *Coriandrum sativum* L. are traditionally used to reduce gastro-intestinal discomfort, and are added to support an effect on transit time. The applicant also clarified that microorganisms have been added in order to "restore and equilibrate the intestinal microflora", and requested that the evaluation be carried out on the combination of ingredients.

The strain *B. longum* R0175 is also known as *B. longum* subsp. *longum* CNCM I-3470. A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM I-3470) has been provided. The CNCM is a restricted-access non-public collection which has the status of an International Depositary Authority under the Budapest Treaty. Data on the identification and characterisation of *B. longum* subsp. *longum* CNCM I-3470 at species and strain level were considered in an earlier opinion of the Panel (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2012), where it was concluded that the strain *B. longum* subsp. *longum* CNCM I-3470 was sufficiently characterised.

The strain *L. helveticus* R0052 is also known as *L. helveticus* CNCM I-1722. A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM I-1722) has been provided. Data on the identification and characterisation of *L. helveticus* CNCM I-1722 at species and strain level were considered in an earlier opinion of the Panel (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2012), where it was concluded that the strain *L. helveticus* CNCM I-1722 was sufficiently characterised.

Upon request from EFSA during the validation period to provide information on the characterisation of the strain of *Saccharomyces cerevisiae* which is used in "Transitech®", the applicant provided data on the identification of the yeast at species level by sequencing analysis of the D2 domain of 26S rDNA. Upon further request from EFSA during the clock-stop procedure to provide information on the strain characterisation, the applicant stated that the strain was identified as *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC without providing additional experimental data or references reporting on the characterisation of the yeast at strain level. The Panel notes that the information provided was insufficient to establish that *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC was sufficiently characterised. The Panel considers that *Saccharomyces cerevisiae* subsp. *cerevisiae* UVAFERM SC is not sufficiently characterised.

The Panel considers that if in a combination of several microorganisms and/or ingredients one microorganism or ingredient used in the combination is not sufficiently characterised, then the combination is considered to be not sufficiently characterised.

The Panel considers that the food, "Transitech®", which is the subject of the claim, is not sufficiently characterised.

The Panel concludes that a cause and effect relationship cannot be established between the consumption of "Transitech®" and "improves transit and durably regulates it".

CONCLUSIONS

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

- The food, "Transitech®", which is the subject of the health claim, is not sufficiently characterised.
- A cause and effect relationship cannot be established between the consumption of "Transitech®" and "improves transit and durably regulates it".

DOCUMENTATION PROVIDED TO EFSA

Health claim application on "Transitech®" and "improves transit and durably regulates it" pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0328_FR). February 2012. Submitted by Vivatech.

REFERENCES

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2012. Scientific Opinion on the substantiation of health claims related to a combination of Lactobacillus helveticus CNCM I-1722 and Bifidobacterium longum subsp. longum CNCM I-3470 and alleviation of psychological stress (ID 938) and "maintains the balance of healthy microbiota that helps to strengthen the natural defence" (ID 2942) (further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 10(8):2849, 18 pp.