

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) , 2013. Scientific Opinion on the substantiation of a health claim related to Transitech® and improvement of bowel function which is maintained after cessation of consumption of the food 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 improvement of bowel function which is maintained after cessation of consumption of the food 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 Vivatch, 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 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 Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food. The food, Transitech[®], that is the subject of the health claim is sufficiently characterised. The claimed effect, improvement of bowel function which is maintained after cessation of consumption of the food, is a beneficial physiological effect. In weighing the evidence, the Panel considered that the one study that investigated the claimed effect did not show an effect of Transitech[®] on bowel function which is maintained after cessation of consumption of the food. A cause and effect relationship has not been established between the consumption of Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

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KEY WORDS

Transitech, bowel function, maintenance, health claims

¹ On request from the Competent Authority of France following an application by Vivatch, Question No EFSA-Q-2013-00087, adopted on 30 May 2013.

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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 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 Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included 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., 1.7x10⁸ CFU *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062), 4x10⁶ CFU of *Bifidobacterium longum* R0175 and 4x10⁶ CFU of *Lactobacillus helveticus* R0052. The Panel considers that Transitech[®] is sufficiently characterised.

The claimed effect proposed by the applicant is “helps to restore or to maintain a transit with regular stools with an efficacy maintained after the treatment” which was, after consultation with the applicant, amended by the applicant to “improves bowel function and durably regulates it”. The target population proposed by the applicant is the general population. The Panel considers that an improvement of bowel function which is maintained after cessation of consumption of the food is a beneficial physiological effect.

The applicant provided two unpublished human intervention studies for the scientific substantiation of the claim.

One of these studies did not investigate an effect of Transitech[®] on bowel function after cessation of exposure. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The other human intervention study evaluated the effects of daily consumption of Transitech[®] vs. placebo (50 subjects per group) over 10 days, after a seven-day run-in period, and followed by a 28-day observation period with no intervention, on stool frequency as the primary endpoint and colonic transit time as one of the secondary outcomes.

The average number of daily stools was statistically significantly different between the intervention and control group averaged over the 10 day intervention period (mean \pm SD: 0.95 \pm 0.49 (intervention) vs. 0.66 \pm 0.22 (control); $p < 0.001$). Also at day 10, total colonic transit time (mean hours \pm SD 33.79 \pm 28.19 (intervention) vs. 56.38 \pm 36.16 (control); $p = 0.01$) was statistically significantly shorter in the intervention group *versus* the placebo group.

Following the administration of the food or placebo from day 0 to day 10, the maintenance of the effect was evaluated during a 28-day follow-up period after cessation of consumption (i.e. day 11 to day 38). In this period, no statistically significant differences between groups with respect to stool frequency (daily average number of stools in the food and placebo group were 0.69 \pm 0.31 and 0.62 \pm 0.17, respectively; $p = 0.14$) were observed.

The Panel considers that this study does not show an effect of Transitech[®] on bowel function which is maintained after cessation of consumption of the food

In weighing the evidence, the Panel considers that the one study that investigated the claimed effect did not show an effect of Transitech[®] on bowel function which is maintained after cessation of consumption of the food.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

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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 22/01/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- The scientific evaluation procedure started on 13/02/2013.
- On 27/02/2013, 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. The clock was stopped on 05/03/2013 and restarted on 20/03/2013, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 21/03/2013, EFSA received the requested information (which was made available to EFSA in electronic format on 20/03/2013).
- During its meeting on 30/05/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

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: Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

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.

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.

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 (Alexandre et al., 2011, unpublished).

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* Uvaferm SC) 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, disturbed defecation and associated symptoms are very common issues in the general population. Consequently, helping to restore or to maintain a transit with regular stools (average of one stool per day in the general population) with an efficacy maintained after the treatment may be considered as beneficial for the general population.

Based on these hypotheses, the applicant states that 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 as well 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). This target population may be considered as the general population, both men and women, young and elderly, active and not active people. The applicant indicated that Transitech[®] can be used from the first signs of a decreased number of stools and suggested in order to obtain the claimed effect a daily consumption of two tablets per day, representing 453 mg of rhubarb, including 10 mg of anthracene derivatives to be taken over 10 days. According to the applicant, this product is not advised to children below 12 years, to pregnant and breast-feeding women; if the 10-day treatment period has no effect on defecation, medical advice is needed.

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., 1.7×10^8 CFU *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062), 4×10^6 CFU of *Bifidobacterium longum* R0175 and 4×10^6 CFU of *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.

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 Depository 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 NDA Panel, 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 NDA Panel, 2012), where it was concluded that the strain *L. helveticus* CNCM I-1722 was sufficiently characterised.

Data on the identification and characterisation of *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062) at species and strain level, by using genotypic (sequencing analysis of the D2 domain of 26S rDNA and RAPD) methods, were provided. The Panel considers that *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062) is sufficiently characterised.

The applicant indicated that the constituents in Transitech[®] responsible for the claimed effect are hydroxyanthracene derivatives derived from *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, and fructo-oligosaccharides derived from *Althaea officinalis* L. and *Cynara scolymus* L. The applicant also indicated that other ingredients in Transitech[®] are added in order to prevent bloating, flatulence and spasms.

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

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is “helps to restore or to maintain a transit with regular stools with an efficacy maintained after the treatment”.

Upon a request from EFSA to clarify if the claimed effect is related to an improvement in bowel function rather than transit time, the applicant indicated that the claimed effect could be changed into “improves bowel function and durably regulates it”. The applicant defined a sustained effect as an effect maintained for 28 days after cessation of consumption of the food. The target population proposed by the applicant is the general population.

The Panel considers that an improvement of bowel function which is maintained after cessation of consumption of the food is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in “PubMed” with the search terms [“rhubarb” OR “rheum palmatum” OR “rheum officinale” OR “sennosides” OR “senna” OR “artichoke” OR “yeast” OR “saccharomyces cerevisiae” OR “Bifidobacterium longum” OR “Lactobacillus helveticus”] AND [“constipation” OR “defecation” OR “transit time” OR “colonic motility”]. No limits were applied in the search. The time span which was covered by the search was not indicated. Inclusion criteria were clinical studies performed with Transitech[®] and exclusion criteria were studies in patients with gastrointestinal pathology. The Panel notes the limitations in the literature search performed.

The applicant indicated that no pertinent human study was identified through this literature search. The applicant provided two unpublished randomised controlled trials (RCTs) (Guillou and Chesne 2000; Alexandre et al. 2011) as pertinent to the claim. These two RCTs were performed with Transitech[®].

The study by Guillou and Chesne (2000, unpublished) did not investigate an effect of Transitech[®] on bowel function after cessation of exposure. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The study by Alexandre et al. (2011, unpublished, claimed as proprietary) was a randomised, placebo-controlled, double-blind study in parallel design which evaluated the effects of a daily consumption of Transitech[®] vs. placebo (sugar cane, magnesium stearate) over 10 days after a seven-day run-in period, and followed by a 28-day observation period, on stool frequency as the primary endpoint in subjects presenting with 2 to 5 stools per week. Secondary outcomes included colonic transit time, stool size, stool consistency and bloating.

One-hundred healthy adults with an average of 0.56 ± 0.21 daily stools were randomised in blocks of four to consume either two tablets of Transitech[®] ($n = 50$) or placebo ($n = 50$). The study was powered ($\beta = 0.1$) to detect a difference between groups at a significance level of 0.05 assuming a variation of 30 %, and 8 % loss to follow-up. Stool frequency, stool size, consistency and bloating (latter three evaluated on five-score scales) were recorded daily in self-administered questionnaires from day minus 6 to day 38. Segmental colonic transit times were assessed at day 0 and day 10 by abdominal X-rays using radiopaque markers. The Panel notes that no information was provided by the applicant on the validation of the scale used to assess stool consistency, stool size and bloating.

Subjects were instructed not to modify their eating habits. Six subjects (three per group) did not complete the study. No baseline data were available for these subjects who were not considered in the analysis. Ten of the included subjects presented with normal stool frequency with more than 5 stools per week. Data were averaged over time, and analysed using unpaired Student’s t-test to compare the difference in percent change from baseline in frequency of defecations between the intervention and control group, and using analysis of covariance (ANCOVA) with baseline measures as covariate for analysis of absolute values for all endpoints.

The average number of daily stools was statistically significantly different between the intervention and control group averaged over the 10 day intervention (mean \pm SD: 0.95 ± 0.49 (intervention) vs. 0.66 ± 0.22 (control); $p < 0.001$) using ANCOVA. Also at day 10, total colonic transit time (mean hours \pm SD 33.79 ± 28.19 (intervention) vs. 56.38 ± 36.16 (control); $p = 0.01$) was statistically significantly shorter in the intervention group versus the placebo group.

Following the administration of the food or placebo from day 0 to day 10, the maintenance of the effect was evaluated during a 28-day follow-up period after cessation of consumption (i.e. day 11 to day 38). In this period, no statistically significant differences between groups with respect to stool frequency (daily average number of stools in the food and placebo group were 0.69 ± 0.31 and 0.62 ± 0.17 , respectively; $p = 0.14$) were observed. The Panel notes that drop-outs and multiple

comparisons were not taken into account in the analysis, and notes the limitations in the reporting of the study.

The Panel considers that the study by Alexandre et al. (2011, unpublished) does not show an effect of Transitech[®] on bowel function which is maintained after cessation of consumption of the food.

In weighing the evidence, the Panel considers that the one study that investigated the claimed effect did not show an effect of Transitech[®] on bowel function which is maintained after cessation of consumption of the food.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

CONCLUSIONS

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

- The food constituent, Transitech[®], which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “helps to restore or to maintain a transit with regular stools with an efficacy maintained after the treatment” which was, after consultation with the applicant, amended by the applicant to “improves bowel function and durably regulates it”. The target population proposed by the applicant is the general population. An improvement of bowel function which is maintained after cessation of consumption of the food is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Transitech[®] and improvement of bowel function which is maintained after cessation of consumption of the food pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0375_FR). February 2013. Submitted by Vivatech.

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- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 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, 2012;10(8):2849, 18 pp. doi:10.2903/j.efsa.2012.2887.
- Guillou S and Chesne C, 2000, unpublished. Efficacy, organoleptic acceptability and tolerance of Transitech food supplement. Evaluation in women presenting intestinal laziness.

GLOSSARY AND ABBREVIATIONS

ANCOVA	Analysis of covariance
RAPD	Random amplification of polymorphic deoxyribonucleic acid
RCT	Randomised controlled trial
rDNA	Ribosomal deoxyribonucleic acid