

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

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

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Vivitech, 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 hydroxyanthracene derivatives and improvement of bowel function. An improvement of bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools is a beneficial physiological effect, provided that it does not result in diarrhoea. The Panel notes that the effect of hydroxyanthracene derivatives from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, from the bark of *Rhamnus frangula* L., from the bark of *Rhamnus purshianus* D.C. and from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids on the short-term alleviation of occasional constipation is well established. The Panel concludes that a cause and effect relationship has been established between consumption of hydroxyanthracene derivatives and improvement of bowel function.

© European Food Safety Authority, 2013

#### KEY WORDS

Transitech<sup>®</sup>, hydroxyanthracene derivatives, bowel function, health claims

<sup>1</sup> On request from the Competent Authority of France following an application by Vivitech, Question No EFSA-Q-2013-00650, adopted on 09 October 2013.

<sup>2</sup> 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](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2013;11(10):3412, 12 pp. doi:10.2903/j.efsa.2013.3412

Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

## 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 hydroxyanthracene derivatives and improvement of bowel function.

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<sup>®</sup>, 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.,  $1.7 \times 10^8$  CFU *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062),  $4 \times 10^6$  CFU *Bifidobacterium longum* R0175 and  $4 \times 10^6$  CFU *Lactobacillus helveticus* R0052.

The Panel considers that the food, Transitech<sup>®</sup>, which is the subject of the claim, is sufficiently characterised.

The claimed effect as proposed by the applicant is “improves bowel function”. The target population proposed by the applicant is the “general population experiencing disturbed defecation”.

The Panel considers that an improvement of bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools is a beneficial physiological effect, provided that it does not result in diarrhoea.

The applicant provided two unpublished randomised controlled trials as pertinent to the claim.

One study had considerable methodological limitations, and no conclusions could be drawn from this study for the scientific substantiation of the claim.

The second study was a randomised, placebo-controlled, double-blind study of parallel design which evaluated the effects of a daily consumption of Transitech<sup>®</sup> vs. placebo over 10 days on stool frequency as the primary endpoint. Secondary outcomes included colonic transit time, stool size, stool consistency and bloating. The average number of daily stools was significantly higher in the intervention group compared to the control group, averaged over the 10 day intervention, and colonic transit time was significantly shorter in the intervention group than in the placebo group. Diarrhoea occurred in two subjects in the intervention group and one in the control group.

The Panel notes the established effect of hydroxyanthracene derivatives from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, but also from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, from the bark of *Rhamnus frangula* L., from the bark of *Rhamnus purshianus* D.C. and from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids, on the short-term alleviation of occasional constipation, at the proposed conditions of use (i.e. 10 mg per day), and the established mechanism by which hydroxyanthracene derivatives exert an effect on bowel function (i.e. stimulation of colonic motility, inhibition of absorption of water and electrolytes, and stimulation of secretion of water and electrolytes into the lumen of the colon resulting in enhanced concentrations of fluid and electrolytes in the lumen of the colon).

The Panel also notes that the available evidence does not establish that any of the other food constituents in Transitech<sup>®</sup> exert an effect on bowel function. The Panel also notes that in the absence of a group consuming hydroxyanthracene derivatives alone in the studies submitted by the applicant, no conclusions can be drawn on whether Transitech<sup>®</sup> exerts an effect on bowel function over and above an effect of hydroxyanthracene derivatives. The available evidence also does not establish that the combination of food constituents in Transitech<sup>®</sup> would lead to a lower incidence of abdominal pain and passage of liquid stools which may be caused by the consumption of hydroxyanthracene derivatives, as claimed by the applicant.

In weighing the evidence, the Panel took into account the established effect of hydroxyanthracene derivatives on bowel function, and that the mechanism by which hydroxyanthracene derivatives exert the effect is known. The Panel also took into account that the evidence provided by the applicant did not establish that any of the other food constituents in Transitech<sup>®</sup> exert an effect on bowel function over and above the effect of hydroxyanthracene derivatives, or lead to a lower incidence of untoward effects of hydroxyanthracene derivatives.

The Panel concludes that a cause and effect relationship has been established between consumption of hydroxyanthracene derivatives and improvement of bowel function.

The Panel considers that the following wording reflects the scientific evidence: “Hydroxyanthracene derivatives improve bowel function”.

The Panel considers that in order to bear the claim, a product should provide 10 mg hydroxyanthracene derivatives per day either from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, and/or from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, and/or from the bark of *Rhamnus frangula* L and/or from the bark of *Rhamnus purshianus* D.C. and/or from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids. The target population is adults.

In relation to the restrictions of use, the Panel notes that stimulant laxatives should not be consumed continually for periods longer than one to two weeks. The use of stimulant laxatives for more than two weeks requires medical supervision. Long-term use of stimulant laxatives should be avoided owing to the danger of electrolyte imbalance, impaired function of the intestine, and dependence on laxatives. Stimulant laxatives should only be used if an effect on bowel function cannot be achieved by a change of diet or the administration of bulk forming agents.

## TABLE OF CONTENTS

Abstract .....	1
Summary .....	2
Table of contents .....	4
Background .....	5
Terms of reference .....	5
EFSA Disclaimer.....	5
Information provided by the applicant .....	6
Assessment .....	6
1. Characterisation of the food/constituent .....	6
2. Relevance of the claimed effect to human health.....	7
3. Scientific substantiation of the claimed effect .....	7
4. Panel’s comments on the proposed wording .....	9
5. Conditions and restrictions of use .....	9
Conclusions .....	10
Documentation provided to EFSA .....	10
References .....	10
Abbreviations .....	12

## BACKGROUND

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, 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 02/07/2013.
- 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 18/07/2013.
- During its meeting on 09/10/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function.

## 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: hydroxyanthracene derivatives and improvement of bowel function.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of hydroxyanthracene derivatives, a positive assessment of its safety, nor a decision on whether hydroxyanthracene derivatives are, or are 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.

---

<sup>4</sup> 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.

## 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<sup>®</sup>". Transitech<sup>®</sup> 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. Re-establishing a normal and regular defecation (average of one stool per day in the general population) presents, according to the applicant, a psychological interest since it relieves from the gastro-intestinal symptoms and helps the subject to feel better.

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

The following wording is proposed by the applicant: "Improves bowel function".

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

According to the applicant, the recommended daily amount for this product is two pills per day, representing 453 mg of rhubarb, including 10 mg of "anthracene" derivatives. The supplementation should be taken over 10 days. The target population is the general population experiencing disturbed defecation.

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food that is the subject of the health claim is Transitech<sup>®</sup>, 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<sup>8</sup> CFU *Saccharomyces cerevisiae* UVAFERM SC (LYCC 6062), 4x10<sup>6</sup> CFU *Bifidobacterium longum* R0175 and 4x10<sup>6</sup> CFU *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<sup>®</sup>. The applicant also provided a certificate of analysis of the hydroxyanthracene derivative and cynarine

content of one batch of Transitech<sup>®</sup>. 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<sup>®</sup> 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<sup>®</sup> are added in order to prevent bloating, flatulence and spasms.

The Panel considers that the food, Transitech<sup>®</sup>, which is the subject of the claim, is sufficiently characterised.

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

The claimed effect as proposed by the applicant is “improves bowel function”. The target population proposed by the applicant is the “general population experiencing disturbed defecation”.

The Panel considers that an improvement of bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools is a beneficial physiological effect, provided that it does not result in diarrhoea.

## 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<sup>®</sup>, and exclusion criteria were studies in patients with gastro-intestinal 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<sup>®</sup>.

The study by Guillou and Chesne (2000, unpublished) was a double-blind RCT with a cross-over design in 33 women (baseline characteristics not given), of whom only 15 completed both study periods and were included in the analysis. Each product (Transitech® or placebo (lactose)) was tested for two eight-day periods with a seven day wash-out period in between. Statistical analysis was carried out using the paired t-test.

The Panel notes the high drop-out rate, that no information is available on whether stool frequency returned to baseline after the wash-out period, and the limitations of the paired t-test in the analysis of cross-over designs when potential carry-over or period effects cannot be excluded. 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 of 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 on stool frequency as the primary endpoint in subjects presenting with two to five stools per week. Secondary outcomes included colonic transit time, stool size, stool consistency and bloating.

One-hundred healthy adults with an average of  $0.56 \pm 0.21$  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 six to day ten. Segmental colonic transit times were assessed at day zero and day ten 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, and they were not considered in the analysis. Ten of the included subjects had a normal stool frequency with more than five stools per week. Data were averaged over time, and analysed using the unpaired 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 significantly higher in the intervention group compared to the control group, averaged over the 10 day intervention (mean  $\pm$  SD:  $0.95 \pm 0.49$  (intervention) vs.  $0.66 \pm 0.22$  (control);  $p < 0.001$ ) using ANCOVA. 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 significantly shorter in the intervention group than in the placebo group.

Diarrhoea occurred in two subjects in the intervention group and one in the control group.

The Panel considers that this study shows an effect of Transitech® on bowel function by a decrease in colonic transit time and an increase in stool frequency.

The Panel notes the established effect of hydroxyanthracene derivatives from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, but also from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, from the bark of *Rhamnus frangula* L., from the bark of *Rhamnus purshianus* D.C. and from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids, on the short-term alleviation of occasional constipation at the proposed conditions of use (i.e. 10 mg per day), and the established mechanism by which hydroxyanthracene derivatives exert an effect on bowel function (i.e. stimulation of colonic motility, inhibition of absorption of water and electrolytes, and stimulation of secretion of water and

electrolytes into the lumen of the colon resulting in enhanced concentrations of fluid and electrolytes in the lumen of the colon) (WHO, 1999, 2004; HMPC, 2006a, 2006b, 2006c, 2006d, 2007a, 2007b, 2008).

The Panel notes that the available evidence does not establish that any of the other food constituents in Transitech<sup>®</sup> exert an effect on bowel function. The Panel also notes that in the absence of a group consuming hydroxyanthracene derivatives alone in the studies submitted by the applicant, no conclusions can be drawn on whether Transitech<sup>®</sup> exerts an effect on bowel function over and above an effect of hydroxyanthracene derivatives. The available evidence also does not establish that the combination of food constituents in Transitech<sup>®</sup> would lead to a lower incidence of abdominal pain and passage of liquid stools which may be caused by the consumption of hydroxyanthracene derivatives (WHO, 1999, 2004; HMPC, 2006a, 2006b, 2006c, 2006d, 2007a, 2007b, 2008), as claimed by the applicant.

In weighing the evidence, the Panel took into account the established effect of hydroxyanthracene derivatives on bowel function, and that the mechanism by which hydroxyanthracene derivatives exert the effect is known. The Panel also took into account that the evidence provided by the applicant did not establish that any of the other food constituents in Transitech<sup>®</sup> exert an effect on bowel function over and above the effect of hydroxyanthracene derivatives, or lead to a lower incidence of untoward effects of hydroxyanthracene derivatives.

The Panel concludes that a cause and effect relationship has been established between consumption of hydroxyanthracene derivatives and improvement of bowel function.

On the basis of the published literature on hydroxyanthracene derivatives, the Panel could have reached its conclusions without the human intervention study claimed as proprietary by the applicant (Alexandre et al., 2011, unpublished).

#### **4. Panel's comments on the proposed wording**

The Panel considers that the following wording reflects the scientific evidence: "Hydroxyanthracene derivatives improve bowel function."

#### **5. Conditions and restrictions of use**

The Panel considers that in order to bear the claim, a product should provide 10 mg hydroxyanthracene derivatives per day either from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, and/or from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, and/or from the bark of *Rhamnus frangula* L and/or from the bark of *Rhmanus purshianus* D.C. and/or from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids. The target population is adults.

In relation to the restrictions of use, the Panel notes that stimulant laxatives should not be consumed continually for periods longer than one to two weeks. The use of stimulant laxatives for more than two weeks requires medical supervision. Long-term use of stimulant laxatives should be avoided owing to the danger of electrolyte imbalance, impaired function of the intestine, and dependence on laxatives. Stimulant laxatives should only be used if an effect on bowel function cannot be achieved by a change of diet or the administration of bulk forming agents (WHO, 1999, 2004; HMPC, 2006a, 2006b, 2006c, 2006d, 2007a, 2007b, 2008).

## CONCLUSIONS

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

- The food constituent, Transitech<sup>®</sup>, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “improves bowel function”. The target population proposed by the applicant is “the general population experiencing disturbed defecation“. An improvement of bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools is a beneficial physiological effect, provided that it does not result in diarrhoea.
- A cause and effect relationship has been established between consumption of hydroxyanthracene derivatives and improvement of bowel function.
- The following wording reflects the scientific evidence: “Hydroxyanthracene derivatives improve bowel function”.
- In order to bear the claim, a product should provide 10 mg hydroxyanthracene derivatives per day either from the root and rhizome of *Rheum palmatum* L. and/or *Rheum officinale* Baillon and/or their hybrids, and/or from the leaves or fruits of *Cassia senna* L. and/or *Cassia angustifolia* Vahl, and/or from the bark of *Rhamnus frangula* L and/or from the bark of *Rhamnus purshianus* D.C. and/or from *Aloe barbadensis* Miller and/or various aloe species, mainly *Aloe ferox* Miller and its hybrids. The target population is adults.
- In relation to the restrictions of use, it is noted that stimulant laxatives should not be consumed continually for periods longer than one to two weeks. The use of stimulant laxatives for more than two weeks requires medical supervision. Long-term use of stimulant laxatives should be avoided owing to the danger of electrolyte imbalance, impaired function of the intestine, and dependence on laxatives. Stimulant laxatives should only be used if an effect on bowel function cannot be achieved by a change of diet or the administration of bulk forming agents.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on Transitech<sup>®</sup> and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0392\_FR). July 2013. Submitted by Vivitech.

## REFERENCES

- Alexandre V, Bouchoucha M, Levy V and Benamouzig R, 2011, unpublished. Randomized double-blind placebo-controlled trial to assess the efficacy of a food supplement on transit in participants presenting disturbed bowel movements and the persistence of such effect (claimed as proprietary).
- 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.2012.2849.
- Guillou S and Chesne C, 2000, unpublished. Efficacy, organoleptic acceptability and tolerance of Transitech food supplement. Evaluation in women presenting intestinal laziness.

- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2006a. Community Herbal Monograph on *Rhamnus frangula* L., cortex.
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2006b. Community Herbal Monograph on *Aloe barbadensis* Miller and on *Aloe* (various species, mainly *Aloe ferox* Miller and its hybrids).
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2006c. Community Herbal Monograph on *Cassia senna* L. and *Cassia angustifolia* Vahl, folium.
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2006d. Community Herbal Monograph on *Cassia senna* L. and *Cassia angustifolia* Vahl, fructus.
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2007a. Community Herbal Monograph on *Rheum palmatum* L. and *Rheum officinale* Baillon, radix.
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2007b. Community Herbal Monograph on *Rhamnus purshianus* D.C., cortex.
- HMPC (Committee on Herbal Medicinal Products of the European Medicines Agency), 2008. Assessment report for rhubarb (*Rhei radix*).
- WHO (World Health Organization), 1999. WHO Monographs on Selected Medicinal Plants - Volume 1.
- WHO (World Health Organization), 2004. WHO Monographs on Selected Medicinal Plants - Volume 2.

**ABBREVIATIONS**

ANCOVA	Analysis of covariance
CFU	Colony forming units
CNCM	Collection Nationale de Cultures de Microorganismes
RAPD	Random amplified polymorphic deoxyribonucleic acid
RCT	Randomised controlled trials
rDNA	Ribosomal deoxyribonucleic acid