

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to “native chicory inulin” and maintenance of normal defecation by increasing stool frequency 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 BENEEO-Orafti S.A., submitted pursuant to Article 13.5 of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 “native chicory inulin” and maintenance of normal defecation by increasing stool frequency. The food constituent that is a subject of a claim is “native chicory inulin”. The Panel considers that “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean DP  $\geq 9$ , is sufficiently characterised in relation to the claimed effect. The Panel considers that maintenance of normal defecation by increasing stool frequency (provided that it does not result in diarrhoea) is a beneficial physiological effect. Six studies involving 86 subjects consistently showed that consumption of “native chicory inulin” at an amount of at least 12 g/day increases stool frequency. The Panel also notes the plausible mechanisms by which inulin and inulin-type fructans in “native chicory inulin” could exert the claimed effect. The Panel concludes that a cause and effect relationship has been established between the consumption of “native chicory inulin” and maintenance of normal defecation by increasing stool frequency. The following wording reflects the scientific evidence: “Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”. In order to obtain the claimed effect, 12 g of “native chicory inulin” should be consumed daily.

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#### KEY WORDS

inulin, chicory, bowel function, constipation, health claim

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<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)

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## SUMMARY

Following an application from BENEIO-Orafti, submitted pursuant to Article 13.5 of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, 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 “native chicory inulin” and maintenance of normal defecation by increasing stool frequency.

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 constituent that is the subject of the health claim is “native chicory inulin”. The Panel considers that “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean DP  $\geq$  9, is sufficiently characterised in relation to the claimed effect.

The claimed effect proposed by the applicant is “improves bowel function”. The target population proposed by the applicant is the general population. The Panel considers that maintenance of normal defecation by increasing stool frequency (provided that it does not result in diarrhoea) is a beneficial physiological effect.

Six out of eight human studies provided reported an increase in stool frequency with the consumption of “native chicory inulins” or chicory inulin. In these studies, the doses of “native chicory inulin” used ranged from 12 to 40 g/day and the dose of chicory inulin, which was used in one study, was 15 g/day. In two studies (three arms), administration of chicory inulin at doses from 5 to 8 g/day did not affect stool frequency. No adverse effects have been reported in any of these studies.

In weighing the evidence, the Panel took into account that six studies involving 86 subjects consistently showed that consumption of at least 12 g/day “native chicory inulin” increases stool frequency. The Panel also notes the plausible mechanisms by which inulin and inulin-type fructans in “native chicory inulin” could exert the claimed effect.

On the basis of data presented, the Panel concludes that a cause and effect relationship has been established between the consumption of “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean DP  $\geq$  9, and maintenance of normal defecation by increasing stool frequency. The Panel could have reached the conclusion that “native chicory inulin” contributes to the maintenance of normal defecation by increasing stool frequency without the study identified as proprietary by the applicant. However, this study was used to establish the conditions of use for this claim.

The following wording reflects the scientific evidence: “Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”. In order to obtain the claimed effect, 12 g “native chicory inulin” should be consumed daily. The target population is the general population.

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## 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 06/06/2014.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 02/07/2014.
- On 08/07/2014, 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 11/07/2014, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 25/07/2014, EFSA received the applicant’s reply and the clock was restarted.
- On 15/10/2014, 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 23/10/2014, in compliance with Art. 18(3) of Regulation (EC) No 1924/2006.
- On 04/11/2014, EFSA received the applicant’s reply and the clock was restarted.
- During its meeting on 11/12/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to “native chicory inulin” and maintenance of normal defecation by increasing stool frequency.

## 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 “native chicory inulin” and maintenance of normal defecation by increasing stool frequency.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of “native chicory inulin”, a positive assessment of its safety, nor a decision on whether “native chicory inulin” 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.

<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.

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:** BENE0-Orafti S.A., Rue L. Maréchal 1, B-4360 Oreye, Belgium.

The application contains a request for the protection of proprietary data for unpublished Schulz et al. (2012) study report in accordance with Article 21 of Regulation (EC) No 1924/2006.

### Food constituent as stated by the applicant

According to the applicant, the food for which this health claim is made is Orafti®Inulin. At the request of EFSA the applicant clarified that “chicory inulin” constitutes the subject of the health claim.

### Health relationship as claimed by the applicant

According to the applicant, the claimed effect refers to the ability of the fully fermentable dietary fibre Orafti®Inulin to increase the frequency of bowel movements and thus to improve bowel function. The frequency of bowel movements is used as primary outcome measure to assess the claimed effect of an improved bowel function. Secondary outcome measures comprise the assessment of stool bulk, stool consistency and transit time. Inulin resists hydrolysis and absorption in the human small intestine, but reaches the large intestine essentially complete, where it is fermented to short-chain fatty acids, lactate and gases by colonic bacteria. This is accompanied by an increase in bacterial cell mass and a higher water content of digesta. In this way Orafti®Inulin leads to softer stools and facilitated excretion as well as to an enhanced propulsion of colonic contents via chemical and mechanical stimulation of the peristaltic reflex and hence an increase in the frequency of bowel movements.

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

The applicant has proposed the following wordings for the health claim: “Orafti®Inulin improves bowel function”. Alternative wordings: “Orafti®Inulin improves bowel movements”, “Orafti®Inulin contributes to more frequent bowel movements”, “Orafti®Inulin improves/contributes to/maintains normal bowel movements”, “Orafti®Inulin contributes to/maintains a normal bowel function”, “Orafti®Inulin contributes to/maintains a normal digestive function”, “Orafti®Inulin improves/contributes to/maintains regularity”, “Orafti®Inulin improves/contributes to/maintains bowel regularity”.

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

The applicant has proposed an amount of 12 g Orafti®Inulin daily. The target population proposed is the general population.

## ASSESSMENT

### 1. Characterisation of the food constituent

The applicant initially stated that the food constituent that is the subject of the health claim is “Orafti®Inulin”. In response to the EFSA’s request for clarification, the applicant explained that “chicory inulin” is the food constituent that is the subject of the health claim.

Chemically, inulin is a linear  $\beta(2\rightarrow1)$ -fructan with a degree of polymerisation (DP) > 9 which typically has a terminal  $\alpha$ -glucose (EFSA NDA Panel, 2010).

Chicory (*Chicorium intybus*) root is one of the plants with the highest concentration of inulin. “Native chicory inulin” is extracted as a non-fractionated mixture of monosaccharides, disaccharides, oligosaccharides (inulin-type fructans, DP 3 – 9) and non-starch polysaccharides (inulin, DP > 9). Influencing factors for chain length distribution are growth conditions and harvest time as well as process technology.

From the information provided, including the human studies submitted for the scientific substantiation of the claim, the Panel notes that this claim relates to “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, oligosaccharides (inulin-type fructans) and polysaccharides (inulin) extracted from fresh chicory roots characterised by its mean DP (> 9).

The Panel considers that the food constituent “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean DP  $\geq$  9, is sufficiently characterised in relation to the claimed effect.

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

The claimed effect proposed by the applicant is “improves bowel function”. The target population proposed by the applicant is the general population. At the request of EFSA the applicant clarified that the claimed effect is “improves bowel function by increasing stool frequency”.

Constipation is associated with less frequent defecations (i.e. bowel movements, e.g. fewer than three per week, reduced faecal bulk and harder stools), which lead to gastrointestinal discomfort and may contribute to diseases, such as diverticular disease. More frequent defecations, i.e. bowel movements (e.g. through a reduction in transit time, increased faecal bulk, and softer stools) may contribute to the maintenance of normal defecation, provided that they do not result in diarrhoea.

The Panel considers that maintenance of normal defecation by increasing stool frequency (provided that it does not result in diarrhoea) is a beneficial physiological effect.

## 3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Caplus, Embase, Medline, and Biosis databases using the following search terms: prebiotic or fructan or fructans or FOS or fructooligosaccharide or fructo-oligosaccharide or oligo-fructose or inulin or inulin-type fructans or oligofructose and bowel habit or bowel regularity or bowel function or bowel motor function or bowel movement or large bowel function or stool regularity or stool frequency or stool consistency or soft stool or stool weight or stool bulk or gut function or gastrointestinal function or constipation or transit or faecal weight or faecal bulk or faeces. No limits were given with respect to dates, languages and population subgroups. A manual search was also carried out.

Ten human intervention studies were provided on the effects of “native chicory inulins” or chicory inulin on stool frequency. One study was available only as a poster abstract (Isakov et al., 2013). The Panel considers that sufficient information was not provided for that study to allow a scientific evaluation. Another study was performed with “native chicory inulin” with a mean DP < 9 (Brighenti et al., 1999). The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Six of the remaining eight human studies provided reported an increase in stool frequency with the consumption of “native chicory inulins” (mean DP > 9) (Gibson et al., 1995; Kleesen et al., 1997; Gråsten et al., 2003; Kleesen et al., 2007; Schulz et al., 2012 claimed as proprietary by the applicant) or chicory inulin (DP > 9) (Den Hond et al., 2000). In these studies, the doses of “native chicory inulin” used ranged from 12 to 40 g/day and the dose of chicory inulin was 15 g/day. In two studies (three arms), administration of doses from 5 to 8 g/day did not affect stool frequency (Bouhnik et al., 2007; Kolida et al., 2007). No adverse effects were reported in any of the studies mentioned above. The mean DP of the “native chicory inulin” used in these studies was 9–11.

The Panel notes that these human intervention studies are very heterogeneous regarding the dose of chicory inulin used, the form in which was administered (powder in sachets, in bakery products, breakfast cereals, chocolate drinks), the duration of the intervention (from one to four weeks), the sample size (4 to 44 subjects), the type of subjects recruited (healthy volunteers, subjects with

constipations), the age of participants (23 to 76 years) and the study settings (free-living individuals, hospitalised subjects, subjects in a metabolic room). The Panel also notes that stool frequency was only a secondary outcome in the majority of the studies, and that statistical comparisons between the intervention and control groups were not always reported. However, the Panel considers that, taken collectively, these studies provide evidence for an increase in stool frequency with the consumption of “native chicory inulin” at doses of 12g/day.

The applicant also provided six human studies showing the non-digestibility of inulin and inulin-type fructans in the small intestine and their fermentation in the colon, leading to an increase in total bacterial mass (Brighenti et al. 1995, Ellegård et al., 1997; Castiglia-Delavaud et al., 1998; Rumessen and Gudmand-Hoyer, 1998; Van Dokkum et al., 1999; Marteau et al., 2011). Seven studies in different animal species (dogs, cats, goats, rats, pigs) reported higher stool bulk and softer stools upon ingestion of “native chicory inulins” (Delzenne et al., 1995; Diez et al., 1998; Hesta et al., 2001; Kleesen et al., 2001; Pierce et al., 2005; Verlinden et al., 2006; Kara et al., 2012). The *in vitro* studies provided related to the production of short-chain fatty acids (SCFA) by bacterial degradation of inulin (Wang and Gibson, 1993; Rycroft et al., 2001; Timm et al., 2010).

The Panel notes that inulin and inulin-type fructans in “native chicory inulin” are non-digestible carbohydrates which could exert an effect on stool frequency by stimulating bacterial growth in the gut and by increasing bacterial cell mass and faecal bulk. The Panel also notes that mono- and disaccharides present in “native chicory inulin” in small amounts are unlikely to contribute to the claimed effect.

In weighing the evidence, the Panel took into account that six studies involving 86 subjects consistently showed that consumption of at least 12 g/day “native chicory inulin” increases stool frequency. The Panel also notes the plausible mechanisms by which inulin and inulin-type fructans in “native chicory inulin” could exert the claimed effect.

The Panel concludes that a cause and effect relationship has been established between the consumption of “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory with a mean DP  $\geq$  9, and maintenance of normal defecation by increasing stool frequency.

The Panel could have reached the conclusion that “native chicory inulin” contributes to the maintenance of normal defecation by increasing stool frequency without the data identified as proprietary by the applicant (Schulz et al., 2012, unpublished). However, this study (Schulz et al., 2012, unpublished) was used to establish the conditions of use for this claim.

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

The Panel considers that the following wording reflects the scientific evidence: “Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”.

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

The Panel considers that, in order to obtain the claimed effect, 12 g of “native chicory inulin” should be consumed daily. The target population is the general population.

### **CONCLUSIONS**

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

- The food product, “native chicory inulin”, a non-fractionated mixture of monosaccharides (< 10%), disaccharides, inulin-type fructans and inulin extracted from chicory, with a mean



DP  $\geq$  9, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

- The claimed effect is “improves bowel function by increasing stool frequency”. The target population as proposed by the applicant is the general population. Maintenance of normal defecation by increasing stool frequency (provided that it does not result in diarrhoea) is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of “native chicory inulin” and maintenance of normal defecation by increasing stool frequency.
- The following wording reflects the scientific evidence: “Chicory inulin contributes to maintenance of normal defecation by increasing stool frequency”.
- In order to obtain the claimed effect, 12 g of “native chicory inulin” should be consumed daily. The target population is the general population.

## DOCUMENTATION PROVIDED TO EFSA

Health claim application on “native chicory inulin” and maintenance of normal defecation by increasing stool frequency pursuant to Article 13.5 of Regulation (EC) No 1924/2006 (Claim serial No: 0416\_BE). June 2014. Submitted by BENE0-Orafti S.A.

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## ABBREVIATIONS

DP	degree of polymerisation
FOS	fructooligosaccharides
SCFA	short-chain fatty acids