# Short-chain fructooligosaccharides from sucrose and maintenance of normal defecation: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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# Short-chain fructooligosaccharides from sucrose and maintenance of normal defecation: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

## EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

## Abstract

Following an application from Beghin-Meiji and Tereos Syral, 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 Panel) was asked to deliver an opinion on the scientific substantiation of a health claim related to short-chain fructooligosaccharides (scFOS) from sucrose and maintenance of normal defecation. The food constituent that is the subject of the health claim is scFOS from sucrose. The Panel considers that scFOS from sucrose is sufficiently characterised. The claimed effect proposed by the applicant is 'maintaining normal intestinal transit regularity by increasing stool frequency'. The target population proposed by the applicant is the general population. Upon a request from EFSA, the applicant confirmed that the proposed claimed effect refers to maintenance of normal defecation. The Panel considers that maintenance of normal defecation is a beneficial physiological effect. The Panel considers that one human intervention study did not show an effect of scFOS from sucrose at a dose of 5.7 g/day for 4 weeks on defecation frequency, consistency of stools or dry faecal mass and that in two other human intervention studies 10 g/day of scFOS increased faecal bulk, whereas higher amounts (12.5 g/day) consumed for shorter period did not. Although a number of studies provided some evidence that scFOS are fermented in the colon and increase bacterial mass and faecal bulk, the information provided does not demonstrate that the changes in short-chain fatty acids (SCFA) or bile acids induced by scFOS lead to significant changes in the frequency of stools. The Panel concludes that a cause and effect relationship has not been established between the consumption of scFOS from sucrose and maintenance of normal defecation under proposed conditions of use.



**Keywords:** short-chain fructooligosaccharides from sucrose, defecation, bowel function, constipation, health claim

**Requestor:** Competent Authority of France following an application by Beghin-Meiji and Tereos Syral.

**Question number:** EFSA-Q-2015-00377

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## Summary

Following an application from Beghin-Meiji and Tereos Syral 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 European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) was asked to deliver an opinion on the scientific substantiation of a health claim related to short-chain fructooligosaccharides (scFOS) from sucrose and maintenance of normal defecation.

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 general approach of the NDA Panel for the evaluation of health claim applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims.

The food constituent that is the subject of the health claim is short-chain fructooligosaccharides from sucrose. The Panel considers that the food constituent, scFOS from sucrose, is sufficiently characterised.

The claimed effect proposed by the applicant is 'maintaining normal intestinal transit regularity by increasing stool frequency'. The target population proposed by the applicant is 'general population'. Upon a request from EFSA, the applicant confirmed that the proposed claimed effect refers to maintenance of normal defecation.

The Panel considers that maintenance of normal defecation is a beneficial physiological effect.

A total of 17 human studies, 11 animal studies and 6 *in vitro* studies have been identified by the applicant as being pertinent to the health claim.

In weighing the evidence, the Panel took into account that one human intervention study from which conclusions could be drawn did not show an effect of scFOS from sucrose consumed at a dose of 5.7 g/day for 4 weeks on defecation frequency, consistency of stools or dry faecal mass, and that in two other human intervention studies 10 g/day of scFOS consumed for 5 weeks increased faecal bulk, whereas higher amounts (12.5 g/day) consumed for shorter period of time (12 days) did not. The Panel also took into account that, although a number of animal efficacy studies and mechanistic studies provided some evidence that scFOS are fermented in the colon by the gut microbiota and increase bacterial mass and faecal bulk, the information provided by those studies does not demonstrate that the changes in short-chain fatty acids (SCFA) or bile acids which may be induced by scFOS lead to significant changes in the frequency of stools.

On the basis of data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of scFOS from sucrose and maintenance of normal defecation under proposed conditions of use.

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# 1. Introduction

## 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006[1] 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 in 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).

## 1.2. Interpretation of the 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: short-chain fructooligosaccharides (scFOS) from sucrose and maintenance of normal defecation.

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

## 1.3. Additional information

A claim on fructooligosaccharides from sucrose and changes in bowel function has already been assessed by the Panel with unfavourable outcome (EFSA NDA Panel, 2011a).

# 2. Data and Methodologies

### 2.1.1. Data

### 2.1.2. Information provided by the applicant

**Food constituent as stated by the applicant**

According to the applicant, the food that is the subject of the claim is scFOS obtained from sucrose being the combination of 1-kestose (glucose–fructose–fructose (GF2)) (37 ± 6%), nystose (glucose–fructose–fructose–fructose (GF3)) (53 ± 6%) and 1F-β-fructofuranosyl nystose (glucose–fructose–fructose–fructose–fructose (GF4)) (10 ± 6%). GF2, GF3 and GF4 are formed by a sucrose (glucose–fructose) molecule linked to, respectively, one, two or three fructose units by β 2-1 glycosidic bounds to the fructose unit of sucrose.

[1] 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.

### Health relationship as claimed by the applicant

According to the applicant, the claimed effect concerns maintaining normal intestinal transit regularity by increasing stool frequency.

The outcome measure used to assess the health effect on humans with no known structural abnormalities or infections or metabolic causes is the change in stool number between the end of consumption of scFOS from sucrose and baseline, compared to the consumption of a placebo product.

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

The applicant has proposed the following wording for the health claim: 'maintain normal intestinal regularity' or 'maintain intestinal regularity by increasing the frequency of bowel movements' or 'contributes to normal intestinal regularity or normal bowel function'.

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

The applicant has proposed an intake of 4.6 g of dry matter (DM) of the constituent scFOS from sucrose per day. The target population proposed by the applicant is the general population.

### Data provided by the applicant

The applicant provided a health claim application on scFOS from sucrose and maintenance of normal defecations pursuant to Article 13.5 of Regulation 1924/2006. The application was presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2011b).

As outlined in the EFSA General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011c), it is the responsibility of the applicant to provide the totality of the available evidence.

### 2.1.3. Methodologies

The general approach of the NDA Panel for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (EFSA NDA Panel, 2011c).

The scientific requirements for health claims related to gut and immune function are outlined in a specific EFSA guidance (EFSA NDA Panel, 2011d).

## 3. Assessment

### 3.1. Characterisation of the food constituent

The food which is the subject of the health claim is 'scFOS obtained from sucrose'.

Fructooligosaccharides (FOS) obtained from sucrose are prepared by enzymatic elongation of sucrose and consist of a mixture of kestose (GF2), nystose (GF3) and fructosylnystose (GF4), with an average degree of polymerisation (DPav) of 3.6, and are sometimes referred to as scFOS. They differ from natural fructans by degree of polymerisation (DP) (only 10% of native chicory inulins have a DP between 2 and 5 (Roberfroid, 2007) and from oligofructoses prepared by inulin hydrolysis (DP from 2 to 7, DPav 4) by the systematic presence of a glucose moiety.

ScFOS are offered as a powder and in liquid forms. Information about manufacturing process, stability and variability between batches was provided in the application. ScFOS can be measured in foods by established methods.

The Panel considers that the claim applies to scFOS from sucrose consisting of the combination of 1-kestose (GF2) (37 ± 6%), nystose (GF3) (53 ± 6%) and 1F-β-fructofuranosyl nystose (GF4) (10 ± 6%).

The Panel considers that the food constituent, scFOS from sucrose, is sufficiently characterised.

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

The claimed effect proposed by the applicant is 'maintaining normal intestinal transit regularity by increasing stool frequency'. The target population proposed by the applicant is 'general population'.

Upon a request from EFSA, the applicant confirmed that the proposed claimed effect refers to maintenance of normal defecation.

Maintenance of normal defecation may be assessed by a number of outcome variables which could provide information about the function and eventually about the underlying mechanism of action, some of which may be inter-related (e.g. frequency of defecations, stool consistency, sensation of complete/incomplete evacuation, faecal bulk, transit time). Although reduced stool frequency and consistency are among the signs/symptoms of functional constipation, changes in transit time and faecal bulk may or may not contribute to the maintenance of normal defecation in the context of constipation.

The Panel considers that maintenance of normal defecation is a beneficial physiological effect.

## 3.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed database and Journal@rchive database with the use of the following key words: ("fructooligosaccharide(s)" OR "fructo-oligosaccharide(s)" OR "neosugar" OR "actilight" OR "nutraflora" OR "scFOS" AND ("stool frequency" OR "stool consistency" OR "soft stool" OR "stool weight" OR "stool bulk" OR " stool regularity" OR "f(a)ecal weight" OR "f(a)ecal mass" OR "f(a)ecal bulk" OR " f(a)ecal excretion" OR "bowel function" OR "bowel habit(s)" OR "bowel regularity" OR "bowel motor function(s)" OR "bowel movement(s)" OR "transit" OR "constipation" OR "def(a)ecation" OR "gut function" OR "colonic motility".

A total of 17 human studies, 11 animal studies and 6 *in vitro* studies have been identified by the applicant as being pertinent to the health claim.

### 3.3.1. Efficacy studies

#### Efficacy studies in humans

Ten human intervention studies in adult subjects which investigated the effect of scFOS from sucrose on one or more outcomes related to defecation were submitted for the substantiation of the claim.

The Panel notes that three of the human intervention studies provided (Kameoka et al., 1986; Tokunaga et al., 1993; Bouhnik et al., 2007) were one-arm, open-label studies. The Panel also notes that another human intervention study investigated the effect of scFOS from sucrose given once only (Respondek et al. 2014). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

Tominaga et al. (1999) studied the effect of scFOS from sucrose (3 g/day given for 2 weeks) vs placebo (sucrose) in healthy female volunteers (n = 34, mean age 20 years) in a single-blind, placebo-controlled, sequential (2 weeks scFOS from sucrose, 2 weeks wash-out period, 2 weeks placebo period) study. The results were presented separately for three groups of subjects according to their defecation frequency before the intervention: 'normal' (> 5 defecations/week, n = 12), 'lower' (> 3, and ≤ 5 defecations/week, n = 9) and 'lowest' (≤ 3 defecations/week, n = 13). The Panel notes that no *a priori* stratification for subgroup analysis was reported, and that the overall results for the intervention with respect to defecation frequency were not provided. The Panel considers that no conclusions can be drawn from this study for the scientific evaluation of the claim.

Bouhnik et al. (2004) investigated the effect of different doses of scFOS from sucrose (2.5, 5, 7.5 and 10 g/day) given for 7 days to healthy volunteers on Bifidobacteria counts in faeces compared to placebo (50% sucrose and 50% maltodextrin). Frequency of defecations was a secondary outcome, but the results of the study for this variable were not reported in the publication. The Panel considers that no conclusions can be drawn from this study for the scientific evaluation of the claim.

In a randomised four-arm, double-blind, placebo-controlled, parallel study conducted on healthy subjects (n = 68, 42 women, mean age 25 years) with normal frequency of defecations (1.4 bowel

movements per day on average), Swanson et al. (2002a) investigated the effect of sucrose, scFOS from sucrose, sucrose + *Lactobacillus acidophilus,* and scFOS from sucrose + *Lactobacillus acidophilus* consumed at doses of 5.7 g/day for 4 weeks on several aspects of intestinal function, including frequency of defecations, stool consistency, faecal dry mass and the chemical content of faeces. Subjects recorded frequency of defecations and stool consistency (assessed with a 5-point scale) in a diary. Fresh faecal samples were collected 3 times during the study: at the end of the baseline period and after 2 and 4 weeks of intervention. A total of 62 subjects completed the study. No significant changes in frequency of defecations (1.41 ± 0.12 vs 1.28 ± 0.11 defecations/day), consistency score (2.45 ± 0.12 vs 2.52 ± 0.12) and stool dry mass (26.82 ± 2.38 vs 24.65 ± 0.63 g/day) between the group consuming scFOS from sucrose (n = 15, 10 females) and the control group consuming sucrose (n = 15, 8 females) were found at the end of the 4-week intervention period. The Panel considers that this study does not show an effect of scFOS from sucrose consumed at doses of 5.7 g/day for 4 weeks on defecation frequency, consistency of stools or dry faecal mass.

In a randomised, double-blind, placebo-controlled parallel study, Benamouzig (2015, unpublished study report) investigated the effect of scFOS from sucrose (Actilight® 4.6 g/day) vs placebo (maltodextrin) on the change in the frequency of defecations per week throughout a 6-week intervention period in adult subjects meeting Rome III criteria for functional constipation (n = 150, mean age 32.8 years, 119 females). The secondary outcomes included changes in stool consistency, gastrointestinal discomfort, total and segmental colonic transit time, and changes in microbiota in faecal samples. The sample size was calculated assuming a 30% difference in the weekly number of bowel movements between groups (n = 128 subjects). A total 150 of subjects were recruited to increase the power from 79.6% to 86.7%. The study consisted of three consecutive periods: 1-week run-in period, 6-week intervention period and 2-week follow-up period. The frequency of defecations was assessed by using a daily questionnaire which also included questions related to stool consistency (Bristol scale), and type and intensity of gastrointestinal symptoms (vomiting, nausea, bloating, borborygmus, flatulence, abdominal pain and diarrhoea). Three questionnaires were filled out by the participants in the run-in period and at the end of the intervention: the hospital anxiety and depression scale (HADS), the functional digestive disorders quality of life (FDDQOL), and a 3-day 24-hour record of food intake. Total and segmental colonic transit time was measured by using radio-opaque markers technique. Changes in faecal microbiota and changes of SCFA content were assessed in stool samples collected before and at the end of the intervention for 50% of the subjects.

The per-protocol (PP) population consisted of 128 subjects who completed the study (n = 60 in the treatment group and n = 68 in the placebo group). There were 15 drop-outs in the treatment group and 7 drop-outs in the placebo group, respectively. Upon a request from EFSA, the applicant specified that most drop-outs in the intervention group (n = 10) were related to inadequate compliance and that the higher drop-out rate could not be attributed to the appearance of adverse effects. The Panel notes that a higher number of drop-outs in the intervention group (15 vs 7) may be related to the treatment.

The results of the study were presented as means and standard deviations (SDs) for the PP and intention-to-treat (ITT) populations. Regarding the weekly frequency of defecations, between-group differences at week 6 and between-group differences in changes between week 6 and run-in were assessed.

The baseline number of defecations/week was not significantly different between the two groups: 2.90 ± 1.56 and 3.10 ± 1.70 for the scFOS and placebo groups, respectively (p = 0.60). In the PP analysis, the number of defecations per week at week 6 was not significantly different between groups 5.24 ± 2.79 and 4.42 ± 2.26 for the scFOS and placebo groups, respectively; p = 0.06), whereas the increase in the weekly frequency of defecations form the run-in period to week 6 was significantly higher in the scFOS group (+2.37 ± 2.92) compared to the placebo group (+1.36 ± 2.36; p = 0.03) using the Mann–Whitney test for independent samples. No differences were observed between groups in the ITT analyses with respect to the weekly frequency of defecations, neither at week 6 (5.04 ± 2.7 in scFOS group and 4.49 ± 2.23 in placebo group) or as changes from the run-in period (+2.14 ± 2.8 for scFOS group and +1.39 ± 2.33 for placebo group; p=0.06) using the same statistical analyses.

Upon a request by EFSA to comment about the reasons why only the last week of the intervention was used for the analysis of the results of the study, the applicant reported to have re-analysed the

data using a mixed effects linear model taking into account all intermediate weeks in the model. However, the applicant provided only the significance values for the PP and ITT populations. The Panel is, therefore, unable to evaluate the results of this analysis and to draw conclusions from it.

No significant differences were found between groups at the end of the intervention with respect to the consistency of stools and the total colonic transit time in the ITT or the PP analysis.

The Panel notes that, in this study, the number of drop-outs in the intervention group was higher than in the control group (15 vs 7, respectively) and that the reasons for dropping-out may have been related to the intervention. In this context, the information provided does not ensure that the PP group is a random sample of the ITT group, and, therefore, the results for the PP group may be at high risk of bias. The Panel also notes that no effect of scFOS from sucrose on the weekly frequency of defecations, stool consistency or total colonic transit time has been reported for the ITT population. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The applicant also submitted two randomised, placebo-controlled, cross-over studies investigating the effect of scFOS from sucrose on stool mass and using sucrose as placebo. In the study by Tahiri et al. (2001), the effect of scFOS from sucrose (10 g/day for 5 weeks) was investigated in 11 postmenopausal women (mean age 59 years). The washout period was 3 weeks and stool mass was a secondary outcome. Wet stool mass (119.1 ± 39.1 vs 83.6 ± 28.0 g/day, $p < 0.05$) and dry stool mass (24.1 ± 5.3 vs 18.5 ± 4.4 g/day, $p < 0.05$) were significantly higher in the scFOS group compared to the placebo group. In contrast, in the study by Bouhnik et al. (1996) conducted in healthy volunteers (n = 20), the consumption of scFOS from sucrose (12.5 g/day for 12 days, with a 12-day washout period) had no significant effect on wet stool weight compared to sucrose. The Panel notes that the dose of scFOS from sucrose used in these studies is more than double the dose proposed by the applicant in the conditions of use, and that other outcomes which could provide information about the maintenance of normal defecation (e.g. stool frequency, stool consistency, sensation of complete/incomplete evacuation, transit time) were not assessed in these two studies. The Panel notes that, in these studies, 10 g/day of scFOS consumed for 5 weeks had an effect on faecal bulk, whereas higher amounts (12.5 g/day) consumed for shorter periods of time (12 days) did not.

### Animal efficacy studies

A significant increase in faecal bulk was observed in eight studies (Tokunaga et al., 1986; Younes et al., 1995; Sakaguchi et al., 1998; Le Blay et al., 2003; Tamura et al., 2006; Tanabe et al., 2006; Pan et al., 2009; Kaji et al., 2011) in rodents in which scFOS was 5% to 20% w/w of the feed, but not in one study in dogs in which scFOS in the feed was 1% w/w (Swanson et al., 2002b).

The effect on intestinal transit time was evaluated in two studies in rats. Transit time was reduced after scFOS consumption in one study (Tokunaga et al., 1986) but not in the other study (Sakaguchi et al., 1998).

The Panel notes that these studies provide evidence for an effect of high doses of scFOS from sucrose on faecal bulk in rodents.

### Mechanisms by which the food constituent could exert the claimed effect

According to the applicant, there are several mechanisms by which the intake of scFOS could maintain normal bowel function. The applicant claims that scFOS from sucrose increase bacterial cell mass in the colon which, in turn, leads to an increase in faecal bulk. The applicant also claims that scFOS are only slightly absorbed in the small intestine (around 4%) and most reach the large intestine where they are completely fermented (Molis et al., 1996), and that SCFA produced from the fermentation of scFOS, together with the changes induced in the composition of the microbiota and in the composition of bile acids, can modulate intestinal motility in humans.

In several human and animal studies, the consumption of scFOS increased the faecal concentration of Bifidobacteria, Lactobacilli and *Clostridium coccoides* (Hidaka et al., 1986; Stone-Dorshow and Levitt, 1987; Hosoya et al., 1988; Tokunaga et al., 1993; Bouhnik et al. 1996; Molis et al., 1996; Bouhnik et al., 1999; Le Blay et al., 2003; Bouhnik et al., 2004; Boutron-Ruault et al., 2005; Bouhnik et al., 2006; Tamura et al., 2006; Bouhnik et al., 2007; Pan et al., 2009; Respondek et al., 2013). Other studies

showed that consumption of scFOS increase SCFA excretion (Hosoya et al., 1988; Tokunaga et al., 1993; Younes et al., 1995; Le Blay et al., 2003; Tsukahara et al., 2003; Bouhnik et al., 2004; Boutron-Ruault et al., 2005; Tamura et al., 2006; Tanabe et al., 2006; Pan et al., 2009). An increase in Bifidobacteria and SCFA production has also been observed in *in vitro* studies where the faecal flora was incubated with scFOS (Luo et al., 1996; Probert and Gibson, 2002; Saulmier et al., 2008; Stewart et al., 2008; Hernot et al., 2009; Likotrafiti et al., 2014). In one study, changes in the composition of bile acids in the large intestine after consumption of scFOS were shown (Boutron-Ruault et al., 2005). The Panel notes that in another study this effect on bile acids was not found (Bouhnik et al., 2007).

The Panel considers that the above-mentioned studies provided some evidence that scFOS are fermented in the colon by the gut microbiota generating SCFAs, which may increase bacterial mass and thus faecal mass. The Panel considers, however, that the studies provided do not demonstrate that the magnitude of those changes induced by scFOS lead to significant changes in the frequency of defecations.

**Weighing of the evidence**

In weighing the evidence, the Panel took into account that one human intervention study from which conclusions could be drawn did not show an effect of scFOS from sucrose consumed at a dose of 5.7 g/day for 4 weeks on defecation frequency, consistency of stools or dry faecal mass, and that in two other human intervention studies 10 g/day of scFOS consumed for 5 weeks increased faecal bulk, whereas higher amounts (12.5 g/day) consumed for shorter period of time (12 days) did not. The Panel also took into account that, although a number of animal efficacy studies and mechanistic studies provided some evidence that scFOS are fermented in the colon by the gut microbiota and increase bacterial mass and faecal bulk, the information provided by those studies does not demonstrate that the changes in SCFA or bile acids which may be induced by scFOS lead to significant changes in the frequency of stools.

The Panel concludes that a cause and effect relationship has not been established between the consumption of scFOS from sucrose and maintenance of normal defecation under the proposed conditions of use.

# 4. Conclusions

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

- The food constituent, scFOS from sucrose, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'maintaining normal intestinal transit regularity by increasing stool frequency'. The target population proposed by the applicant is the general population. Maintenance of normal defecation is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of scFOS from sucrose and maintenance of normal defecation under the proposed conditions of use.

## Documentation provided to EFSA

1. Health claim application on short-chain fructooligosaccharides from sucrose and maintain normal intestinal regularity pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0436_FR). Submitted by Beghin Meiji, ZI et portuaire 67390 Marckolsheim, France and Tereos Syral, ZI et portuaire 67390 Marckolsheim, France.

2. This application was received by EFSA on 12/6/2015.

3. 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.

4. The scientific evaluation procedure started on 24/7/2015.

5. On 7/10/2015, 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 scientific evaluation was suspended on 15/10/2015 and was restarted on 30/10/2015, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.

6. On 29/10/2015, EFSA received the applicant's reply.

7. During its meeting on 11/12/2015, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to scFOS from sucrose and maintenance of normal defecation.

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## Abbreviations

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| DPav | average degree of polymerization |
| DM | dry matter |
| FDDQOL | functional digestive disorders quality of life |
| FOS | fructooligosaccharides |
| GF2 | glucose–fructose–fructose (kestose) |
| GF3 | glucose–fructose–fructose–fructose (nystose) |
| GF4 | glucose–fructose–fructose–fructose–fructose (1F-β-fructofuranosyl nystose) |
| HADS | hospital anxiety and depression scale |
| ITT | intention-to-treat |
| PP | per-protocol |
| SCFA | short-chain fatty acids |
| SD | standard deviation |
| scFOS | short-chain fructooligosaccharides |