Polydextrose 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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Abstract

Following an application from Tate & Lyle PLC submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, 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 polydextrose 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 food constituent that is the subject of the health claim is 'polydextrose'. The Panel considers that polydextrose is sufficiently characterised. The claimed effect proposed by the applicant is 'improved bowel function by increasing stool bulk'. The target population proposed by the applicant is 'the general population'. The Panel considers that maintenance of normal defecation is a beneficial physiological effect. In weighing the evidence, the Panel took into account that, out of the three human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim, one study showed an effect at doses of 20 g/day when polydextrose was given for 10 days, whereas two studies in which polydextrose was administered at doses of 21 and 18 g/day for longer periods of time did not show an effect. The Panel also took into account that the evidence provided for the mechanisms by which polydextrose could contribute to the maintenance of normal defecation *in vivo* in humans is weak. The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and maintenance of normal defecation.

Keywords: polydextrose, bowel function, constipation, normal defecation, health claims

Requestor: Competent Authority of the United Kingdom following an application by Tate & Lyle PLC, United Kingdom

Question number: EFSA-Q-2015-00550

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Summary

Following an application from Tate & Lyle PLC submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the United Kingdom, the European Food Safety Authority (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 polydextrose 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 13.5 and 14 health claims and the guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms.

The food constituent that is the subject of the health claim is 'polydextrose'. The Panel considers that polydextrose is sufficiently characterised.

The claimed effect proposed by the applicant is 'improved bowel function by increasing stool bulk'. The target population proposed by the applicant is 'the general population'. The Panel considers that maintenance of normal defecation is a beneficial physiological effect.

A claim submitted under the Article 13(1) procedure on polydextrose and changes in bowel function was evaluated by the Panel with an unfavourable opinion on the basis of the poor methodological quality of the human intervention studies which were submitted for substantiation. In addition to these, the applicant has provided three other human intervention studies which have investigated the effects of polydextrose on different outcome variables related to the claimed effect and three *in vitro* studies as being pertinent to the claim.

In weighing the evidence, the Panel took into account that, out of the three human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim, one study showed an effect at doses of 20 g/day when polydextrose was given for 10 days, whereas two studies in which polydextrose was administered at doses of 21 and 18 g/day for longer periods of time (3–4 weeks) did not show an effect of the intervention on the maintenance of normal defecation. The Panel also took into account that the evidence provided for the mechanisms by which polydextrose could contribute to the maintenance of normal defecation *in vivo* in humans under the proposed conditions of use is weak.

On the basis of data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and maintenance of normal defecation.

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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 the 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: polydextrose and maintenance of normal defecation.

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

2.1.1. Information provided by the applicant

2.1.1.1. Food constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the claim is polydextrose. Polydextrose is a randomly bonded, water-soluble, low-calorie non-starch polysaccharide, used primarily as a bulking agent and texturiser in foods. It is a highly branched dextrose polymer and has a broad molecular weight (mw) range (162–20,000) with 90% of the molecules being between 504 and 5,000 mw. Polydextrose is non-sweet, and has been used as a low-calorie bulking agent and soluble fibre ingredient in many food products worldwide for over 25 years. In most countries, polydextrose is usually declared as a dietary fibre.

2.1.1.2. Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to the improvement of bowel function by increasing faecal bulk.

[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.

2.1.1.3. Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'Polydextrose contributes to an improved bowel function by increasing stool bulk'.

2.1.1.4. Specific conditions of use as proposed by the applicant

According to the applicant, the claimed effect is based on a daily ingestion of 18 g polydextrose, which can be consumed over several portions per day. Appropriate conditions reflecting the overall science would include foods that carry the nutrition claim 'high in fibre' or wording reflecting the same meaning, which would be in line with similar approved claims. The target population proposed by the applicant is the general population.

2.1.2. Data provided by the applicant

The applicant provided a health claim application on polydextrose and maintenance of normal defecation 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, 2016a), it is the responsibility of the applicant to provide the totality of the available evidence.

2.2. Methodologies

The general approach of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) for the evaluation of health claims applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016a).

The scientific requirements for health claims related to the immune system, the gastrointestinal (GI) tract and defence against pathogenic microorganisms are outlined in a specific EFSA guidance (EFSA NDA Panel 2016b).

3. Assessment

3.1. Characterisation of the food constituent

The food constituent which is the subject of the health claim is polydextrose.

Polydextrose is produced by the polycondensation of glucose in the presence of sorbitol and citric acid under vacuum at high temperatures (Radosta et al., 1992). Polydextrose is highly branched, with a degree of polymerisation between 2 and 110 (on average approximately 12 glucose units), and with an average mw of ~ 2,000 Da (Allingham, 1982; Murray, 1988). All possible linkages with the glycosidic carbon of glucose are present: α- and β-1,2; 1,3; 1,4; and 1,6; with the 1,6 linkage predominating (Auerbach et al., 2007). Polydextrose is highly soluble in water (80 g/100 g at 25°C), leading to a low viscosity solution (Allingham, 1982; Auerbach et al., 2007). Besides the polymer, polydextrose consists of small amounts of the starting materials glucose, sorbitol and citric acid, as well as levoglucosan and hydroxymethylfurfural, formed by caramelisation during the polycondensation process. Polydextrose is used primarily in the food industry as a stabiliser, thickening agent, humectant and carrier (E 1200).

Polydextrose is available in granular (fine or regular) and liquid forms. Upon a request from EFSA, the applicant specified that the content of sugars (mono- and disaccharides) in 100 g of the product is 3.2 g. Information about the manufacturing process, stability and variability between batches was provided in the application. Polydextrose can be measured in foods by established methods.

The Panel considers that polydextrose is sufficiently characterised.

3.2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is 'improved bowel function by increasing stool bulk'. The target population proposed by the applicant is 'the general population'.

EFSA informed the applicant that, in the context of the information provided in the application and of the human studies submitted for substantiation of the claim, the proposed claimed effect refers to the maintenance of normal defecation (in the context of constipation), as outlined in the updated

guidance on the scientific requirements for health claims related to gut and immune function (EFSA NDA Panel, 2016b).

The 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 interrelated (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 the 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, Centre for Agriculture and Biosciences (CAB) abstracts, Sci Finder and Science Direct databases with the use of the following key words: polydextrose AND (gut OR intestine OR bowel OR feces OR faecal bulk OR faeces OR transit) AND (human* OR adult*) NOT (baby OR babies OR child* OR infant* OR toddler*). Papers written in English or French were included.

A claim submitted under the Article 13(1) procedure on polydextrose and changes in bowel function was evaluated by the Panel with an unfavourable opinion on the basis of the poor methodological quality of the human intervention studies which were submitted for substantiation (Tomlin and Read, 1988; Endo et al., 1991; Achour et al., 1994; Jie et al., 2000). In addition to these, the applicant has provided three other human intervention studies which have investigated the effects of polydextrose on different outcome variables related to the claimed effect (Timm et al., 2013; Vester Boler et al., 2011; Sarkkinen et al., 2014) and three *in vitro* studies as being pertinent to the claim.

3.3.1. Human efficacy studies

Vester Boler et al. (2011) compared the effect of snacks containing either polydextrose (21 g/day), soluble corn fibre (21 g/day) or no fibre (control) on several GI outcomes in 25 young healthy men (mean age 27.5 ± 4.3 years). The study was designed as a randomised, double-blind, placebo-controlled, crossover study consisting of three consecutive periods lasting 21 days (no wash-out). The study foods were snack bars made of rice crisps, each containing approximately 7 g of either polydextrose or soluble corn fibre or no fibre (control). The participants were asked to consume three bars daily. The three crossover intervention periods were assigned in a randomised order. Faeces were collected during the last 5 days of each study period. The outcomes measured included wet and dry stool weight, defecation frequency, stool consistency and ease of stool passage, among others (e.g. faecal composition and chemistry, symptoms of GI discomfort). A total of 21 subjects completed the study and entered data analysis (three did not initiate the study for reasons unrelated to the study and one was removed by the investigators based on predefined stopping rules). Data were analysed using the mixed models procedure of SAS. The fixed effect of treatment was tested considering period and subject as random effects. Total dietary fibre was used as a covariate. Differences among treatments were determined using a Fisher-protected least significant difference with a Tukey adjustment.

The macronutrient composition of the background diet did not differ significantly between periods. Mean daily fibre intake (excluding the supplemental fibres) was between 14.4 and 14.8 g/day and was not significantly different between periods. Faecal dry weight was significantly higher during the polydextrose period than during the placebo period (184.8 vs 155.9 g, pooled standard error of the mean (SEM) = 11.81, p = 0.02), while no significant differences between the polydextrose and placebo periods were reported for wet stool weight, frequency of defecations, stool consistency or subjective feeling of ease of stool passage. The Panel considers that this study does not show an effect of polydextrose on the maintenance of normal defecation when consumed at doses of 21 g/day for 3 weeks.

In a randomised, double-blind, placebo-controlled, crossover study of similar design, Timm et al. (2013) investigated the effects of polydextrose (20 g/day), soluble corn fibre (20 g/day) and low-fibre control (no added fibre) on several GI outcomes. The study consisted of three intervention periods lasting 10 days each, with 2-week wash-out periods in between. Participants (n = 36, 18 females, mean age 25.8 ± 9.1 years) were screened to be on low-fibre (< 15 g/day) background diets and

were asked to maintain such diets throughout the study. In addition, they were instructed to consume one packet of cereal and one muffin (with either polydextrose, soluble corn fibre or no added fibre) each day during the study periods. The three crossover intervention periods were assigned in a randomised order. Food records were collected for 3 days during each period. Participants recorded the time and date of each defecation and evaluated stool consistency using the Bristol stool scale. On day 6 of each period, participants swallowed 20 radio-opaque marker (ROM) pellets and collected their faeces for the five remaining days. They also kept a 5-day bowel movement diary where time and date of each movement were recorded, and collected all faecal samples. Whole gut transit time (WGTT) was investigated by X-raying each faecal sample to observe the passage of the ROM pellets. The 80% transit time method was used to calculate WGTT. GI comfort was assessed using a self-reported questionnaire. All participants completed the study and entered data analysis. Treatments were compared using mixed-effects linear models with treatment and visit as fixed effects and with a random intercept for each participant to model correlation between repeated measurements from the same participant. For each outcome, equal carry-over and treatment–visit interaction were checked by the mixed-effects models. Differences of least square means were used to determine differences among treatments.

During the polydextrose period, the frequency of defecations and wet stool weight were significantly higher compared to the low-fibre control period (5.5 ± 2.3 vs 4.4 ± 2.1/5 days, $p = 0.0005$; and 830 ± 443 g vs 623 ± 342 g, $p = 0.0007$, respectively). The consistency of stools during the polydextrose period was also softer compared to the control period (4.67 vs 3.86, $p = 0.002$). WGTT did not differ significantly between periods. The Panel notes the short duration of the intervention (10 days). The study products were well tolerated and no differences among the treatment periods for the bowel habit quality-of-life question were observed. The Panel considers that this short-term study shows an effect of polydextrose on the maintenance of normal defecation when consumed at doses of 20 g/day for 10 days.

In a randomised, double-blind, placebo-controlled, crossover study, Sarkkinen et al. (2014, unpublished, claimed as proprietary by the applicant) investigated the effect of polydextrose (18 g/day) compared to placebo (no polydextrose) in mildly constipated subjects (3–5 defecations/week). The study was divided into four periods: a 2-week run-in period, two 4-week intervention periods and a 6- to 8-week wash-out period between the intervention periods. During the intervention periods, subjects consumed two sachets of a drink mixture and three biscuits (one portion) daily providing 18 g of polydextrose or the same products containing no polydextrose. The two crossover intervention periods were assigned in a randomised order. Treatment compliance was set to $> 80\%$ product consumption. Faeces were collected by subjects at home, during four consecutive days, starting not earlier than the 21st day and not later than the 24th day of each intervention period, and before the measurement of total colonic transit time (CTT), which started the last day of faeces collection. CTT was measured using a ROM technique. Participants ingested two capsules (10 pellets each) at 24-h intervals for three consecutive days. One simple abdominal radiograph (one projection) was taken at the supine position 24 h after the ingestion of the last pellets. Stool consistency was assessed by subjects using the Bristol Stool Form scale during seven consecutive days at the run-in period, both interventions and the wash-out period. Participants also assessed the ease of stool passage at the end of the each intervention period. The primary outcome of the study was faecal wet weight, the variable which was used for sample size calculations. A sample size of 50 subjects was planned in order to be able to detect a difference of 20 g in mean daily stool bulk between the treatment periods with a probability of 80% at α level of 0.05. A total of 73 subjects were randomised to ensure that at least 50 subjects would have completed the study. Secondary outcomes included frequency of bowel movements, stool consistency, CTT and subjective scoring of GI tolerance. Intention-to-treat (ITT) analysis included all randomised subjects completing the study and the PP analysis included all randomised subjects completing the study as planned (i.e. without significantly violating the inclusion/exclusion criteria or other aspects of the protocol considered to potentially affect the study efficacy). The Panel notes that analysis of completers rather than an actual ITT was applied. The general linear model for the repeated measures was used in the crossover analyses of the primary outcome. As a significant (and unexplained) carry-over effect was found when analysing the primary outcome, the results of the second treatment period were no longer considered. Data from the first period was analysed as a randomised double-blind placebo-controlled parallel study. Differences between the study groups were analysed using the Student's *t*-test and the Wilcoxon rank sum test. It was estimated that for a sample size of 26 subjects per group (completers) and using an estimated standard deviation of 50 g for the stool

bulk, the study would be able to detect a difference of 38.5 g in mean daily stool bulk between the study groups with a probability of 80% at α-level of 0.05.

Ten subjects dropped out of the study and another 10 subjects were withdrawn from the study. One subject was excluded from the completers analysis (n = 52; 26 in the polydextrose and placebo groups) for suspected GI illness during the study. Another subject not consuming the study products as planned was excluded from the PP analyses (n = 51; 25 in the placebo group).

Mean faecal wet weight (g/4 days) was significantly higher in the polydextrose than in the placebo group (mean ± SD: 406.7 ± 210.1 vs 286.0 ± 167.0 g, p = 0.047, Wilcoxon). Mean faecal dry weight (g/4 days) was also significantly higher in the polydextrose group (mean ± SD: 110.4 ± 47.1 vs 84.7 ± 46.4 g, p = 0.045, Wilcoxon). In completers, only wet faecal weigh was significantly higher in the polydextrose group (406.7 ± 210.1 vs 296.7 ± 172.5 g) and only using a *t*-test for the analysis (p = 0.044) but not when using the Wilcoxon test (p = 0.075). Frequency of defecations, stool consistency, self-reported ease of stool passage and CTT were not statistically different between the groups in the PP or completers analyses. The Panel considers that this study does not show an effect of polydextrose when consumed at doses of 18 g/day for 28 days on the maintenance of normal defecation.

The Panel notes that three human intervention studies were performed both in healthy and constipated populations, using similar daily dose of polydextrose (from 18 to 21 g), with the sample size from 21 to 36 subjects and with the mean age of participants from 25 to 48 years. The Panel notes that two of these studies, with the intervention period of 21 and 28 days, did not show an effect of polydextrose on the maintenance of normal defecation (Vester Boler et al., 2011; Sarkkinen et al., 2014), while the third, short-term study with the intervention period lasting 10 days, showed an effect of polydextrose on maintenance of normal defecation (Timm et al., 2013).

In the previous opinion on polydextrose and changes in bowel function (EFSA NDA Panel, 2011a), the Panel evaluated four human intervention studies, which, in isolation, could not be used for the scientific substantiation of the claim owing to their methodological limitations. The Panel, however, will consider whether these studies could support an effect of polydextrose on the maintenance of normal defecation in the light of the additional evidence provided by the applicant.

Endo et al. (1991), in a single-arm, sequential, non-randomised intervention study, evaluated faecal weight in eight healthy volunteers (six male) given a low-cholesterol diet, a high-cholesterol diet and a high-cholesterol diet supplemented with polydextrose (15 g/day) for two consecutive weeks each. Other outcome variables related to the maintenance of normal defecation were not assessed. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a single-arm, sequential study in seven male volunteers on a controlled diet, (Achour et al., 1994) subjects consumed no polydextrose and a controlled diet for the first 8 days, 30 g/day of polydextrose and a controlled diet from days 9 to 16, and 30 g/day of polydextrose eating ad libitum from days 17 to 38. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Tomlin and Read (1988) investigated the effect of polydextrose consumed in addition to the usual diet on WGTT, stool mass, stool frequency and stool consistency in a group of 12 healthy male volunteers in a randomised, single-blind, three-arm, crossover study. After a 10-day run-in period, subjects received 30 g/day of polydextrose, 7 g/day of psyllium, and a mixture of polydextrose and psyllium (30 and 2 g/day, respectively) for 10 days each with a one-week wash-out period in between. The statistical significance of differences between the three intervention periods and the run-in period was tested by the Wilcoxon's matched-pairs signed ranks test. The Panel notes that the statistical analysis is not appropriate for the study design. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a randomised, placebo-controlled, double-blind, four-arm, parallel study, the effect of polydextrose (0, 4, 8 or 12 g/day given for 28 days) added to the usual diet on the frequency of defecation and on faecal wet and dry weight was investigated in 120 healthy volunteers (66 men; 30 subjects per group) (Jie et al., 2000). Analysis of variance (ANOVA) and the Dunnett's multiple (pair-wise) comparisons procedure was used to assess differences between the polydextrose groups and placebo. The Panel notes that the overall effect (with the use of ANOVA) was not reported in the paper, that comparisons were not made among the different polydextrose groups and that no formal dose–response analysis was presented, despite the study design. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that, out of the three human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim, one study showed an effect at doses of 20 g/day when polydextrose was given for 10 days (Timm et al., 2013), whereas two studies in which polydextrose was administered at doses of 21 (Vester Boler et al., 2011) and 18 g/day (Sarkkinen et al., 2014, unpublished, claimed as proprietary) for longer periods of time (3–4 weeks) did not show an effect of the intervention on the maintenance of normal defecation.

3.3.2. Mechanism by which the food constituent could exert the claimed effect

According to the applicant, polydextrose exerts the claimed effect by reaching the colon undigested, where it is slowly and only partially fermented by the colonic bacteria. About half of the polydextrose ingested would be excreted intact with the faeces, which would contribute to increased faecal mass per se and exert a mild osmotic effect. Colonic fermentation of polydextrose would, in addition, increase bacterial mass and the production of short-chain fatty acids (SCFA), which may promote peristalsis and increase faecal bulk.

Three *in vitro* studies provided by the applicant show partial fermentation of polydextrose in artificial models of the human colon, as well as an increased production of SCFA (Solomons and Rosenthal, 1985; Arrigoni et al., 1999; Mäkivuokko et al., 2005). A metabolic study in humans using labelled polydextrose also showed that about 50% of the ingested polydextrose is fermented in the colon (Figdor and Bianchine, 1983).

However, the Panel notes that in the human intervention studies provided by the applicant for the scientific substantiation of this claim, no effect of polydextrose on the composition of the gut microbiota (with the exception of decreasing number of *Clostridium perfringens*) (Endo et al., 1991), or a change in the bacterial profile with increased production of SCFA (Jie et al., 2000) were reported. In addition, consumption of 30 g/day of polydextrose did not significantly affect the bacterial mass (calculated as % faecal dry matter) in the only study which assessed this outcome (Achour et al., 1994), and which also showed no effect of polydextrose on wet or dry faecal weight. The Panel also notes that, in the human studies provided, polydextrose does not appear to affect transit time significantly, and that its effects on dry and wet faecal weight are inconsistent across studies: one study reported an increase in dry (but not wet) faecal weight at doses of 21 g/day (Vester Boler et al., 2011); one study reported an increase in wet faecal weight at doses of 20 g/day and did not report on dry faecal weight (Timm et al., 2013); one study showed no consistent effect on either dry or wet faecal weight at doses of 18 g/day (Sarkkinen et al., 2014; unpublished, claimed as proprietary); and two studies reported significant effects on faecal mass at 30 g/day (Tomlin and Read, 1988) and on dry and wet faecal weight at doses as low as 4 g/day (Jie et al., 2000).

The Panel considers that the experimental studies submitted by the applicant provide some evidence that polydextrose is partially fermented in the colon, increasing SCFA production. However, in human studies no evidence has been provided for an effect of polydextrose on bacterial mass, and the evidence provided for the bulking capacity of polydextrose through an osmotic effect is inconsistent. Therefore, the Panel considers that the evidence provided for the mechanisms by which polydextrose could contribute to the maintenance of normal defecation *in vivo* in humans under the proposed conditions of use is weak.

3.3.3. Weighing of the evidence

In weighing the evidence, the Panel took into account that, out of the three human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim, one study showed an effect at doses of 20 g/day when polydextrose was given for 10 days, whereas two studies in which polydextrose was administered at doses of 21 and 18 g/day for longer periods of time (3–4 weeks) did not show an effect of the intervention on the maintenance of normal defecation. The Panel also took into account that the evidence provided for the mechanisms by which polydextrose could contribute to the maintenance of normal defecation *in vivo* in humans under the proposed conditions of use is weak.

The Panel concludes that a cause and effect relationship has not been established between the consumption of polydextrose and maintenance of normal defecation.

4. Conclusions

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

- The food constituent, polydextrose, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'improved bowel function by increasing stool bulk'. The target population proposed by the applicant is general population. Maintenance of normal defecation is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of polydextrose and maintenance of normal defecation.

Documentation provided to EFSA

Health claim application on polydextrose and maintain normal defecation pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0440_UK). Submitted by Tate & Lyle PLC, 1 Kingsway, London WC2B 6AT, United Kingdom.

1) This application was received by EFSA on 28/9/2015.
2) 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.
3) The scientific evaluation procedure started on 12/11/2015.
4) On 24/11/2015, 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 3/12/2015 and was restarted on 18/12/2015, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
5) On 22/12/2015, EFSA received the applicant's reply.
6) On 19/1/2016, 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 28/1/2016 and was restarted on 2/2/2016, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
7) On 2/2/2016, EFSA received the applicant's reply.
8) During its meeting on 20/4/2016, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to polydextrose and maintenance of normal defecation.

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Abbreviations

ANOVA	analysis of variance
CAB	Centre for Agriculture and Biosciences
CTT	colonic transit time
GI	gastrointestinal
ITT	intention-to-treat
mw	molecular weight
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
PP	per protocol
ROM	radio-opaque marker
SCFA	short- chain fatty acids
SEM	standard error of the mean
WGTT	whole gut transit time