

ADOPTED: 7 May 2021

doi: 10.2903/j.efsa.2021.6641

## Green kiwifruit (lat. *Actinidia deliciosa* var. Hayward) and maintenance of normal defecation: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA),  
Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst,  
John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle,  
Androniki Naska, Carmen Pelaez, Kristina Pentieva, Frank Thies, Sophia Tsabouri,  
Marco Vinceti, Jean-Louis Bresson and Alfonso Siani

### Abstract

Following an application from Zespri International Limited, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to green kiwifruit (lat. *Actinidia deliciosa* var. Hayward) 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 proposed by the applicant as the subject of the health claim is green kiwifruit. The Panel considers that green kiwifruit (*Actinidia deliciosa* var. Hayward) is sufficiently characterised. The claimed effect proposed by the applicant is 'maintenance of normal defecation'. Maintenance of normal defecation is a beneficial physiological effect provided that it does not result in diarrhoea. All human intervention studies submitted had different limitations and could not be used on their own for the scientific substantiation of the claim. However, the results of six pertinent human intervention studies are consistent with respect to an effect of consuming daily between two and four green kiwifruits var. Hayward on an increase in stool frequency. Two out of four studies in which a validated instrument was used to assess stool consistency showed an effect also on stool consistency. There is evidence for a plausible mechanism by which kiwifruit could exert an effect on normal defecation. The consumption of kiwifruit in the studies did not result in diarrhoea. A cause and effect relationship has been established between the consumption of green kiwifruit (*Actinidia deliciosa* var. Hayward) and maintenance of normal defecation. The following wordings reflect the scientific evidence: 'consumption of kiwifruit contributes to the maintenance of normal defecation'. In order to obtain the claimed effect, two large green kiwifruits (i.e. around 200 g of kiwi flesh) should be consumed.

© 2021 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

**Keywords:** kiwifruit, *Actinidia deliciosa*, defecation, health claim

**Requestor:** Competent Authority of Belgium following an application by Zespri International Limited.

**Question number:** EFSA-Q-2020-000562

**Correspondence:** [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

**Panel members:** Dominique Turck, Jacqueline Castenmiller, Stefaan De Henauw, Karen Ildico Hirsch-Ernst, John Kearney, Helle Katrine Knutsen, Alexandre Maciuk, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Carmen Pelaez, Kristina Pentieva, Alfonso Siani, Frank Thies, Sophia Tsabouri and Marco Vinceti.

**Declarations of interest:** The declarations of interest of all scientific experts active in EFSA's work are available at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

**Acknowledgements:** EFSA wishes to acknowledge the contribution of WG on Claims: Jean-Louis Bresson, Stefaan de Henauw, Alfonso Siani and Frank Thies to this opinion.

**Suggested citation:** EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), Turck D, Castenmiller J, De Henauw S, Hirsch-Ernst KI, Kearney J, Knutsen HK, Maciuk A, Mangelsdorf I, McArdle HJ, Naska A, Pelaez C, Pentieva K, Thies F, Tsabouri S, Vinceti M, Bresson J-L and Siani A, 2021. Opinion of the scientific panel on green kiwifruit (lat. *Actinidia deliciosa* var. Hayward) and maintenance of normal defecation: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2021;19(6):6641, 12 pp. <https://doi.org/10.2903/j.efsa.2021.6641>

**ISSN:** 1831-4732

© 2021 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.



## Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the requestor.....	4
1.2. Interpretation of the Terms of Reference.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Characterisation of the food/constituent.....	5
3.2. Relevance of the claimed effect to human health.....	6
3.3. Scientific substantiation of the claimed effect.....	6
4. Panel comments on the proposed wording.....	9
5. Conditions and possible restrictions of use.....	10
Conclusions.....	10
Documentation as provided to EFSA.....	10
Steps taken by EFSA.....	10
References.....	10
Abbreviations.....	11

## 1. Introduction

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

Regulation (EC) No 1924/2006 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 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: green kiwifruit and maintenance of normal defecation.

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

## 2. Data and methodologies

### 2.1. Data

#### Information provided by the applicant

##### Food/constituent as stated by the applicant

According to the applicant, the food for which the health claim is made is 'green kiwifruit (*Actinidia deliciosa* (var. Hayward))'.

##### Health relationship as claimed by the applicant

According to the applicant, the health effect is related to 'reduces gastrointestinal discomfort by the normalization of bowel habit and a reduction in sensations associated with discomfort'. Following a dialogue with EFSA and taking into account the proposed health relationship, the applicant agreed on the claimed effect: 'maintenance of normal defecation'.

##### Mechanism by which the food/constituent could exert the claimed effect as proposed by the applicant

The applicant claims that the putative mechanisms by which kiwifruit exerts the claimed effect are related to: altered intestinal motility (due to the presence of fibre and actinidin), changes in intestinal permeability and mucus secretion (due to fibre, kissper (a kiwifruit peptide), phenolics and raphides), altered faecal properties (due to fibre), and altered microbiota (due to fibre, phenolics and raphides).

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

The applicant originally proposed the following wording for the health claim: 'Regular consumption of green kiwifruit contributes to gastrointestinal comfort' or 'regular consumption of green kiwifruit reduces gastrointestinal discomfort'. Following a dialogue with EFSA and taking into account the

proposed health relationship, the applicant agreed on the following wording: 'Regular consumption of green kiwifruit maintains normal defecation'.

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

According to the applicant, the target population for the intended health claim is the general population. The daily consumption of two green kiwifruits is recommended.

### Data provided by the applicant

The health claim application on green kiwifruit and maintenance of normal defecation pursuant to Article 13.5 of Regulation (EC) No 1924/2006, 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.

As outlined in the General guidance for stakeholders on health claim applications (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 NDA Panel for the evaluation of health claim 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 tract and defence against pathogenic microorganisms are outlined in a specific EFSA guidance (EFSA NDA Panel, 2016b).

The application does not contain data claimed as confidential and data claimed as proprietary.

## 3. Assessment

The approach used by the NDA Panel for the evaluation of health claims is explained in the General scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016a). In assessing each specific food/health relationship, which forms the basis of a health claim, the NDA Panel considers the following key criteria:

- i) the food/constituent is defined and characterised;
- ii) the claimed effect is based on the essentiality of a nutrient; OR the claimed effect is defined and is a beneficial physiological effect for the target population and can be measured *in vivo* in humans;
- iii) a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Each of these three criteria needs to be assessed by the NDA Panel with a favourable outcome for a claim to be substantiated. In addition, an unfavourable outcome of the assessment of questions (i) and/or (ii) precludes the scientific assessment of question (iii).

### 3.1. Characterisation of the food/constituent

The food/constituent proposed by the applicant as the subject of the health claim is 'green kiwifruit (*Actinidia deliciosa* var. Hayward)'.

Nutrient composition for green kiwifruit, as presented in the United States Department of Agriculture (USDA database, 2019) National Nutrient Database for Standard Reference (released April 2018, revised April 2019) was provided. According to this database, 100 g of edible raw green kiwifruit flesh contains 1.14 g protein, 14.7 g carbohydrates (including 9.0 g sugars), 0.52 g fat and 3.0 g dietary fibre and provides 61 kcal (255 kJ) of energy. As a fresh fruit, the composition of kiwifruit varies slightly as a function of maturity, growing region, local climatic factors and horticultural practices (Taylor et al., 2003 unpublished). The kiwifruits supplied in the studies described in Section 3.3 had a weight of between 120 and 150 g, corresponding to 90 and 115 g of raw flesh.

The variety Hayward is the main green kiwifruit variety currently available on the market. This was also the variety that was used in all the human intervention studies described in Section 3.3.

Only the internal flesh of green kiwifruit is consumed, not the outer peel/skin.

Details related to the harvesting process and stability information were provided in the application.

The Panel considers that green kiwifruit (*Actinidia deliciosa* var. *Hayward*), which is the subject of the health claim, is sufficiently characterised.

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

The claimed effect as agreed with the applicant is 'maintenance of normal defecation'. The proposed target population is the general population.

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. stool frequency, stool consistency, sensation of complete/incomplete evacuation, faecal bulk, transit time). It is considered a beneficial physiological effect provided it does not result in diarrhoea (EFSA NDA Panel, 2016b).

The Panel considers that maintenance of normal defecation is a beneficial physiological effect provided that it does not result in diarrhoea.

### 3.3. Scientific substantiation of the claimed effect

The applicant performed three literature searches (October 2013, January 2018 and July 2020) in Web of Knowledge, Web of Science, Current Contents Connect, Medline, PubMed, Sci-Finder Scholar, EBSCO, Science Direct, Google Scholar, ProQuest Science & Technology, Scopus, Scirus, Index New Zealand, Discover, Worldcat.org, Patentscope, European Patent Scope, NZ Patent Office, USA Patent & Trademark Office, International Clinical Trials Registry, and Zespri International Ltd – Internal Reports with the following key words: "kiwi\*", "actin\*", "kiwifruit\*", "Actinidia", "actinidin", "Chinese gooseberry", "bowel", "comfort", "laxati\*", "constipat\*", "regular\*", "gastro\*", "gut", "stool", "pain", "frequency", "transit", "health", "quality of life", "intestine\*", and "digest\*".

The applicant identified 18 human intervention studies (14 published and 4 unpublished) and one systematic review of human intervention studies (Lister and Drummond, 2014, unpublished) as being pertinent to the claim.

The study by Hill (2002) was submitted as a short report, the study by Hiele (2010), unpublished) as a PowerPoint presentation, and the study by Weir (2010) was reported as US Patent application only. All these references did not contain sufficient information for the scientific evaluation of the study. Six studies were performed with foods other than fresh green kiwifruits. These included the study by Udani and Bloom (2013), Ansell et al. (2015), Feng et al. (2015) and Kindleysides et al. (2015) performed with powdered extract from kiwifruit, by Uebaba et al. (2009) carried out with fresh kiwifruit freeze-dried juice, and by Weir et al. (2018) with freeze-dried green kiwifruit extract. Three studies (Chan et al., 2007; Ohsawa et al., 2010; Cunillera et al., 2015) were single arm, uncontrolled studies and the article by Chang et al. (2010) described a two-arm (kiwifruit vs control) non-randomised study with inconsistent reporting of results between tables and figures. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The systematic review by Lister and Drummond (2014, unpublished) covered 12 human intervention trials of which 11 trials were also submitted separately by the applicant. The only study that was not present in the application received by EFSA (Marzo and Cunillera, 2013, unpublished) was a one-arm uncontrolled study from which no conclusion can be drawn for the scientific evaluation of the claim. Therefore, this review was not considered further in the scientific evaluation of the claim.

Six human intervention studies reported in five publications (Rush et al., 2002; Wilkinson-Smith et al. 2019; Caballero et al., 2020; Drummond et al., 2020 unpublished study report; Chey et al., 2021) were evaluated by the Panel for the scientific substantiation of the claim. All of them were conducted with green kiwifruit var. Hayward. The Panel notes that all these human intervention studies submitted had different limitations (e.g. short duration, studies not specifically designed to evaluate outcomes related to normal defecation, small sample sizes, shortcomings in the statistical analyses, a cross-over study in which a carry-over effect could not be excluded) and could not be used on their own for the scientific substantiation of the claim.

The six pertinent human intervention studies are described below in terms of study population (healthy or constipated) in the order of decreasing sample size.

#### Studies in healthy individuals

Rush et al. (2002) reported on two randomised cross-over studies with a similar study design on stool frequency, stool bulk and stool consistency without specifying a primary outcome. In the first study, 48 healthy individuals (30 females) with an age between 18 and 50 years were included. Study periods in study 1 lasted six weeks. In the second study, 42 healthy volunteers (25 women) > 60 years of age were recruited, of whom 38 completed the study, including seven that took laxatives regularly.

Study periods in study 2 lasted 3 weeks. One green kiwifruit per 30 kg body weight per day (i.e. 2 or 3 kiwifruits daily depending on body weight) was used in one period of the studies. In the other period, the participants consumed their habitual diet without kiwifruit. There was no wash-out period. The participants were trained to keep a defecation diary. The diary was collected and checked with the participants each week. Stool consistency had to be rated in the diary on a 4-point scale (runny, soft, medium and hard). There was no information on the validation of this scale. Therefore, the results for stool consistency have not been further considered. Even though the study was a cross-over study, it was analysed as parallel study using the independent *t*-test to compare changes from baseline between kiwifruit and no kiwifruit consumption. Results are presented in the paper by period for each of the two sequences separately.

For study 1, data for each period were presented for the first and second 3 weeks of the period. No single value for the entire period was reported. In the kiwifruit period, daily stool frequency for participants in sequence 1 (kiwifruit second) was (mean  $\pm$  SEM)  $1.29 \pm 0.03$  (first three weeks) and  $1.29 \pm 0.03$  (second three weeks) and  $1.33 \pm 0.03$  and  $1.40 \pm 0.04$  in sequence 2 (kiwifruit first), respectively. Without kiwifruit, daily stool frequency in sequence 1 was  $1.26 \pm 0.03$  and  $1.18 \pm 0.04$  and for those in sequence 2  $1.30 \pm 0.04$  and  $1.26 \pm 0.04$ .

In study 2, kiwifruit consumption led to daily stool frequency of  $1.43 (\pm 0.11)$  in sequence 1 (kiwifruit second) and in sequence 2 (kiwifruit first)  $1.24 (\pm 0.11)$ , while without kiwifruit stool frequency was  $1.17 \pm 0.07$  and  $1.24 \pm 0.09$  for individuals in sequences 1 and 2, respectively.

The Panel notes that these cross-over studies, in which a primary outcome was not specified, were analysed as parallel studies. Therefore, the results of the statistical analyses are not interpretable.

Wilkinson-Smith et al. (2019) performed a randomised, cross-over study that evaluated the effect of consumption of green kiwifruits vs an energy-matched control drink containing maltodextrin on colonic transit time (longitudinal relaxation time was the primary outcome of the study), stool frequency, stool consistency and abdominal symptoms. Sixteen healthy adults (six females, range 21–33 years) were recruited. Two kiwifruits twice daily (i.e. four fruits a day) or the control drink were consumed for three days. Stool frequency was documented in a questionnaire and assessed on the days of consumption of test products plus one day. Stool consistency was evaluated using the Bristol stool scale and transit time by an MRI technique. Statistical comparisons were performed by the Wilcoxon signed-rank test (kiwifruit compared to control) without correction for multiple testing. Fourteen participants completed the study. Daily stool frequency was significantly higher during the kiwifruit period compared with the control period ( $1.46 \pm 0.66$  vs  $1.14 \pm 0.46$  stools per day;  $p = 0.034$ ). Stools during the kiwifruit period were also softer ( $p = 0.011$ ). Whole gut transit time was not affected.

The Panel notes that this study with a small sample size and a short duration was not designed to investigate changes in defecation and that the number of kiwifruits consumed in the study was twice the amount proposed in the conditions of use.

Caballero et al. (2020) carried out a two-period cross-over, randomised, single-blind study to evaluate the effect of consumption of a low-flatulogenic diet (excluding legumes, vegetables, garlic, onion, cucumber, nuts, cereals, whole-meal bread, and fizzy drinks) plus green kiwifruit in comparison to a low flatulogenic diet alone on intestinal gas production (primary outcome), stool frequency, stool consistency and abdominal symptoms. Eleven healthy individuals (8 women; age range 18–23 years) were recruited and all completed the study. Two two-week periods were compared: a period on the low-flatulogenic diet (without kiwifruits) and a period in which two green kiwifruits per day were consumed while being on the same low-flatulogenic diet. Stool frequency was assessed by using a diary in which participants recorded the number of daily bowel movements and stool consistency by the Bristol stool scale. Comparisons of normally distributed data were performed by the Student *t*-test for paired data. Non-parametric data were compared using the Wilcoxon signed-rank test. Intake of kiwifruits was associated with more frequent bowel movements per day (mean  $\pm$  SE:  $1.8 \pm 0.1$  vs  $1.5 \pm 0.1$  off-kiwifruit;  $p = 0.001$ ). The consumption of kiwifruits did not lead to diarrhoea. The results were not corrected for multiple testing. There was no effect on stool consistency.

The Panel notes that this study with a small sample size and a short duration was not designed to investigate changes in defecation.

The Panel notes that weekly differences in changes from baseline in stool frequency between periods (as calculated by EFSA) ranged between around 0.5 and 2 stools per week in favour of green kiwifruit in the four studies that investigated the outcome in healthy individuals. In the studies that used the validated Bristol stool scale to assess stool consistency, the consumption of kiwifruit led to softer stools in one study, in which, however, four kiwifruits per day were consumed. This was not the

case in the study in which two kiwifruits per day were used, but which also had a considerably smaller sample size ( $n = 8$  as compared to  $n = 14$ ).

### Studies in individuals with constipation

The study by Drummond et al. (2020 unpublished study report) was a randomised, single-blind (blinded to investigators and statisticians), two-period, cross-over study which compared the effect of consumption of kiwifruit (two kiwifruits per day) with psyllium (7.5 g/day) consumed for four weeks on stool frequency (Complete Spontaneous Bowel Movements (CSBM) was the primary outcome of the study), stool consistency and gastrointestinal discomfort. Both interventions (kiwifruit and psyllium) provided about 6 g/day of dietary fibre. The study was carried out in three research centres localised in New Zealand, Japan and Italy. Three groups of subjects (in total 172 participants (136 females, mean age  $\pm$  SD  $35.5 \pm 14.6$  years)) were recruited for the study: a) individuals with functional constipation according to ROME III criteria (FC;  $n = 52$ ), b) individuals with irritable bowel syndrome and constipation of mild or moderate severity according to ROME III criteria (IBS-C;  $n = 58$ ) and c) healthy controls (HC,  $n = 62$ ). The 16-week study period consisted of a 2-week run-in, two 4-week intervention periods with a 4-week washout in between and a 2-week follow-up period. Randomisation was stratified by the groups mentioned above in the centres in Japan and Italy, but not in New Zealand, and balanced within blocks of 4, with 10 blocks per stratum. Bowel movements were recorded daily by participants in a diary. Stool consistency was evaluated using the Bristol stool scale. Gastrointestinal transit times were determined using a wireless motility capsule device (in Italy and New Zealand) or radiopaque method (in Japan) in half of the participants. Statistical analyses were performed on an intention-to-treat (ITT) basis separately for each study group (HC, FC and IBS-C) and for the combined constipated group (FC + IBS-C), using a mixed model (Proc Mixed, SAS/STAT 14.1) with fixed effects for gender, intervention sequence, and treatment, using subject as random effect. For the present opinion, the results in the combined constipated group (FC + IBS-C) were considered. Using the method described by Shen and Lu (2006), a significant carry-over effect in the IBS-C group was observed showing that the increase in stool frequency was higher in the kiwifruit period that followed the psyllium period than in the kiwifruit period that preceded the psyllium period. However, no significant effect of sequence was observed in the mixed model. The treatment per time interaction in the mixed model using absolute weekly stool frequencies was not statistically significant (week 4: 5.49 (95% CI 4.81–6.18) vs 4.45 (3.81–5.08) stools per week for kiwifruit vs psyllium). In an analysis on weekly changes from baseline, using a repeated measures analysis of variance with centre, sequence, period and treatment as fixed effects and subject as random effect, a statistically significant increase in stool frequency was observed for kiwifruit as compared with psyllium (i.e. increase in 1.69 (95% CI 1.11–2.28 vs 0.90 (95% CI: 0.39–1.42) stools per week,  $p = 0.038$ ). The consumption of kiwifruits led to softer stools as compared with the consumption of psyllium ( $p = 0.011$ ) but did not cause diarrhoea. Gastrointestinal transit time was not different between periods.

The Panel notes that a possible carry-over effect from the psyllium into the kiwifruit period cannot be excluded and that the results were not consistent between the statistical analysis based on absolute values and the one based on changes from baseline.

In a parallel, three-arm study Chey et al. (2020) studied the effect of green kiwifruit ( $n = 30$ ; two kiwifruits per day), prunes ( $n = 26$ ; 100 g/day) and psyllium ( $n = 23$ ; 12 g/day) consumed for 4 weeks on a number of outcomes related to bowel function in 79 adults (69 females, median age 42.7 years) with functional constipation and with IBS-C according to ROME IV criteria. All three interventions contained 6 g/day of fibre. While the prunes and psyllium arms of the study were randomised, the kiwifruit arm was not. The primary endpoint was the proportion of patients in each group reporting an increase of  $\geq 1$  CSBM per week compared to baseline for at least 2 of 4 treatment weeks. Bowel movements were recorded daily by participants in a diary. Stool consistency was evaluated using the Bristol stool scale. Differences in the primary endpoint were assessed using chi squared tests and one sample test of binomial proportions were used to generate the upper and lower limits of the 95% CI. Differences in stool frequency for weeks 3 and 4 averaged were compared using ANOVA. One individual in the kiwifruit group, two in the prunes group and one in the psyllium group did not complete the study. The CSBM responder rate was 45% for the kiwi group (13/29; 95% CI (0.27, 0.63)), 64% for the psyllium group (14/22; 95% CI (0.44, 0.84)) and 67% for the prunes group (16/24; 95% CI (0.48, 0.86)), with no statistically significant differences between groups ( $p = 0.22$ ). There were no statistically significant differences between groups. Weekly CSBM increased significantly within groups, on average by 1.0 with the consumption of kiwifruit, by 1.7 on psyllium and by 2.7 on prunes. At week 4, average weekly stool frequency amounted to 2.3 on kiwifruit, 3.0 on psyllium and 4.1 on

prunes (read from graph). No between group comparisons are reported for the difference in stool frequency. There were no differences between groups with respect to stool consistency, even though a statistically significant improvement in stool consistency from baseline was reported for the kiwifruit and the prune groups, but not for the psyllium group.

The Panel notes that this study was not randomised with respect to the kiwifruit intervention.

The Panel notes that in none of the studies described above diarrhoea was reported to have occurred in conjunction with kiwifruit consumption.

The Panel notes that in the two studies in constipated individuals in which the effect of green kiwifruit was investigated in comparison to a positive control (i.e. psyllium or prunes), the effect of consumption of green kiwifruit on stool frequency appeared to be at least similar to the effect of the positive control. In one study, the consumption of green kiwifruit led to softer stools than the consumption of psyllium, while in the other study no statistically significant differences were observed, even though significant improvement in stool consistency from baseline was reported for the kiwifruit and the prune groups, but not for the psyllium group.

The Panel considers that notwithstanding the methodological limitations of the studies, overall, the evidence derived from six studies suggests a favourable effect of the consumption of two green kiwifruits a day on an increase in stool frequency that ranges between around 0.5 to 2 extra stools per week in healthy individuals. When compared to a positive control (psyllium or prunes) in individuals with constipation, the effect on stool frequency appeared to be at least similar to the positive control. Two out of four studies in which a validated instrument was used to assess stool consistency also indicated an effect on stool consistency.

### Mechanism of action

The Panel notes that kiwifruit contains approximately 3% dietary fibre (USDA, 2019) comprised of one-third soluble fibre and two-thirds insoluble fibre. The soluble fibre fraction contains almost exclusively pectic polysaccharides, whereas the insoluble fibre is mostly cellulose and hemicellulose.

Insoluble components of dietary fibre are not broken down by microorganisms in the colon and are one determinant of faecal bulk, not only by their presence but also by retaining water within the cellular structure. The soluble components are metabolised by the microbiota and by this stimulate microbial growth which in turn impacts on faecal bulk (Cummings, 2001). It is established that an increased faecal mass promotes normal laxation (Gélinas, 2013; Korczak et al., 2017; Bharucha and Lacy, 2020) that is mediated by an increasing diameter of the lumen of the colon, thereby decreasing intraluminal pressure and allowing increased forward flow of the faeces (Gregory and Strong, 2005).

The Panel notes that the flesh of two large green kiwifruits (i.e. around 200 g of flesh) will provide around 6 g of dietary fibre.

The Panel considers that there is evidence for a plausible mechanism by which green kiwifruit exerts an effect on normal defecation.

### Weighing of the evidence

In weighing the evidence, the Panel took into account that the results of the six human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim, are consistent with respect to an effect of consuming daily between two and four green kiwifruits var. Hayward on an increase in stool frequency. The Panel also took into account that two out of four studies in which a validated instrument was used to assess stool consistency showed an effect also on stool consistency and that there is evidence for a plausible mechanism by which kiwifruit could exert an effect on normal defecation. Finally, the Panel also took into account that the consumption of kiwifruit in the studies did not result in diarrhoea.

The Panel concludes that a cause and effect relationship has been established between the consumption of green kiwifruit (*Actinidia deliciosa* var. *Hayward*) and maintenance of normal defecation. However, the scientific evidence does not establish that the effect of green kiwifruit on normal defecation is over and above what could be expected by its content in dietary fibre.

## 4. Panel comments on the proposed wording

The Panel considers that the following wordings reflect the scientific evidence: 'consumption of kiwifruit contributes to the maintenance of normal defecation'.

## 5. Conditions and possible restrictions of use

The Panel considers that in order to obtain the claimed effect, two large green kiwifruits (i.e. around 200 g of kiwi flesh)/day should be consumed. The target population is the general population.

### Conclusions

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

- The food/constituent, green kiwifruit (lat. *Actinidia deliciosa* var. Hayward), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is 'maintenance of normal defecation'. The target population proposed by the applicant is 'the general population'. Maintenance of normal defecation is a beneficial physiological effect provided that it does not result in diarrhoea.
- A cause and effect relationship has been established between the consumption of green kiwifruit (lat. *Actinidia deliciosa* var. Hayward) and maintenance of normal defecation.
- The following wording reflects the scientific evidence: 'consumption of kiwifruit contributes to the maintenance of normal defecation'.
- In order to obtain the claimed effect, two large green kiwifruits (i.e. around 200 g of kiwi flesh)/day should be consumed. The target population is the general population.

### Documentation as provided to EFSA

Health claim application on 'green kiwifruit' and 'maintenance of normal defecation' pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0498\_BE). Submitted by Zespri International Limited, 400 Maunganui Road, Mt. Maunganui 3116, New Zealand.

### Steps taken by EFSA

- 1) This application was received by EFSA on 19/08/2020.
- 2) The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- 3) The scientific evaluation procedure started on 21/10/2020.
- 4) On 9/11/2020, 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 8/12/2020 and was restarted on 22/12/2020, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 5) On 26/01/2021, 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 13/02/2021 and was restarted on 27/02/2021, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 6) During its meeting on 7/05/2021, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to the consumption of green kiwifruit (lat. *Actinidia deliciosa* var. Hayward) and maintenance of normal defecation.

### References

- Ansell J, Butts CA, Paturi G, Eady SL, Wallace AJ, Hedderley D and Geary RB, 2015. Kiwifruit-derived supplements increase stool frequency in healthy adults: a randomized, double-blind, placebo-controlled study. *Nutritional Research*, 35, 401–408.
- Bharucha AE and Lacy BE, 2020. Mechanisms, evaluation, and management of chronic constipation. *Gastroenterology*, 158, 1232–1249.e3. <https://doi.org/10.1053/j.gastro.2019.12.034>
- Caballero N, Benslaiman B, Ansell J and Serra J, 2020. The effect of green kiwifruit on gas transit and tolerance in healthy humans. *Neurogastroenterology and Motility*, e13874. <https://doi.org/10.1111/nmo.13874>
- Chan AOO, Leung G, Tong T and Wong NYH, 2007. Increasing dietary fiber intake in terms of kiwifruit improves constipation in Chinese patients. *World Journal of Gastroenterology*, 13, 4771–4775.
- Chang CC, Lin YT, Lu YT, Liu YS and Liu JF, 2010. Kiwifruit improves bowel function in patients with irritable bowel syndrome with constipation. *Asia Pacific Journal of Clinical Nutrition*, 19, 451–457.
- Chey SW, Chey WD, Jackson K and Eswaran S, 2021. Exploratory comparative effectiveness trial of green kiwifruit, psyllium, or prunes in US patients with chronic constipation. *American Journal of Gastroenterology*. <https://doi.org/10.14309/ajg.0000000000001149>

- Cummings J, 2001. The effect of dietary fiber on fecal weight and composition. In: Spiller G (ed.). CRC Handbook of Dietary Fiber in Human Nutrition. CRC Press, Boca Raton, Florida, USA. pp. 183–252.
- Cunillera O, Almeda J, Mascort JJ, Basora J and Marzo-Castillejo M and the Catalan kiwifruit Study Group, 2015. Improvement of functional constipation with kiwifruit intake in a Mediterranean patient population. An open, non-randomized pilot study. *Revista Española de Nutrición Humana y Dietética*, 19, 58–67.
- Drummond L, Geary R, Barbara G and Fukudo S, 2020 (unpublished). The effect of Zespri green kiwifruit (*Actinidia deliciosa* var. Hayward) on gastrointestinal comfort and function. A randomised, single blind, positively controlled, cross-over clinical intervention study. Unpublished study report, 20th July 2020.
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016a. General scientific guidance for stakeholders on health claim applications. *EFSA Journal* 2016;14(1):4367, 38 pp. <https://doi.org/10.2903/j.efsa.2016.4367>
- EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016b. Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms. *EFSA Journal* 2016;14(1):4369, 23 pp. <https://doi.org/10.2903/j.efsa.2016.4369>
- Feng C, Feng X, Zhu YW and Zhao X, 2015. Prophylactic effect of microencapsulated kiwi on constipation. *Science and Technology of Food Industry*, 15, 352–356 (In Chinese, English abstract).
- Gélinas P, 2013. Preventing constipation: a review of the laxative potential of food ingredients. *International Journal of Food Science and Technology*, 48, 445–467.
- Gregory MC and Strong MB, 2005. Diseases: manifestations and pathophysiology. In: Beringer P, DerMarderosian A, Felton L, Gelone S, Gennaro AR, Gupta PK, Hoover JE, Popovick NG and Reilly WJJ (eds.). *The science and practice of pharmacy*. Lippincott Williams & Wilkins, Philadelphia, 1108.
- Hiele M, 2010 unpublished. Effect of consumption of kiwifruit on constipation in adults Effect of consumption of kiwifruit on constipation in adults. Confidential Report to Zespri International Ltd.
- Hill J, 2002 (unpublished). The effect of Kiwi Crush on constipation in Aucklanders who have had Parkinson's disease for less than 10 years: a pilot study. University of Otago (presented as poster), Dunedin.
- Kindleysides S, Kuhn-Sherlock B, Yip W and Poppitt SD, 2015. Encapsulated green kiwifruit extract: a randomised controlled trial investigating alleviation of constipation in otherwise healthy adults. *Asia Pacific Journal of Clinical Nutrition*, 24, 421–429.
- Korczak R, Kamil A, Fleige L, Donovan SM and Slavin JL, 2017. Dietary fiber and digestive health in children. *Nutritional Review*, 75, 241–259. <https://doi.org/10.1093/nutrit/nuw068>
- Lister C and Drummond L, 2014 (unpublished). Health claim self-substantiation dossier. A systematic review to meet the requirements of FSANZ Standard 1.2.7.
- Marzo M and Cunillera O, 2013 (unpublished). Effect of consumption of kiwi fruit on constipation in adults in a Spanish population.
- Ohsawa H, Okawa M and Ebihara T, 2010. (unpublished). Effect of kiwifruit on defecation and skin condition in subjects prone to constipation. Confidential Report to Zespri International Ltd. (ZP210C01). Tokyo, Japan.
- Rush EC, Patel M, Plank LD and Ferguson LR, 2002. Kiwifruit promotes laxation in the elderly. *Asia Pacific Journal of Clinical Nutrition*, 11, 164–168.
- Shen D and Lu Z, 2006. Estimate carryover effect in clinical trial crossover designs. LexJansen, Paper PO16. Available online: <https://www.lexjansen.com/pharmasug/2006/Posters/PO16.pdf>.
- Taylor G, Athar N, Lister C and Koolard J, 2003 (unpublished study report). Nutritional assessment of overseasgrown Hort16A kiwifruit. Confidential Report, 796.
- Udani JK and Bloom DW, 2013. Effects of kivia powder on gut health in patients with occasional constipation: a randomized, double-blind, placebo-controlled study. *Nutrition Journal*, 12, 78–87.
- Uebaba K, Urata T, Suzuki N, Arai T, Strong JM, Oono S and Hayashi H, 2009. Mild laxative and QOL-improving effects of kiwi fruit extract in the elderly - an explanatory study on effectiveness and safety. *Japanese Journal of Complementary and Alternative Medicine (J-Stage)*, 6, 97–103.
- USDA (U.S. Department of Agriculture (USDA), 2019. FoodData Central. Available online: <https://fdc.nal.usda.gov/fdc-app.html/#?query=kiwifruit>
- Weir IE, 2010. United States Patent No. US2010/0143319. US Patent Office: United States Patent Application Publication.
- Weir I, Shu Q, Wei N, Wei C and Zhu Y, 2018. Efficacy of actinidin-containing kiwifruit extract Zyactinase on constipation: a randomised double-blinded placebo-controlled clinical trial. *Asia Pacific Journal of Clinical Nutrition*, 27, 564–571.
- Wilkinson-Smith V, Dellschaft N, Ansell J, Hoad C, Marciani L, Gowland P and Spiller R, 2019. Mechanisms underlying effects of kiwifruit on intestinal function shown by MRI in healthy volunteers. *Alimentary Pharmacology and Therapy*. <https://doi.org/10.1111/apt.15127>

## Abbreviations

ANOVA	analysis of variance
BSFS	Bristol Stool Form Scale
CI	confidential Interval

CSBM	Complete Spontaneous Bowel Movements
FC	Functional Constipation
GSR	Gastrointestinal Symptom Rating Scale
HC	healthy controls
IBS	irritable Bowel Syndrome
IBS-C	irritable Bowel Syndrome with constipation
ITT	Intention to treat
MRI	magnetic resonance imaging
NDA Panel	Panel on Nutrition, Novel Foods and Food Allergens
PP	Per protocol
QoL	quality of Life
SCFA	short-chain fatty acid
SE	standard error
SEM	standard error of mean
USDA	United States Department of Agriculture