



**EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) , 2014 .
Scientific Opinion on the substantiation of a health claim related to a standardised
aqueous extract from white kidney bean (Phaseolus vulgaris L.) and reduction of
body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006**

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from InQpharm Europe Ltd, 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 a standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight. The Panel considers that the food is sufficiently characterised. A reduction in body weight is a beneficial physiological effect for overweight individuals. The applicant identified a total of four human intervention studies which investigated the effects of the aqueous extract from white kidney bean on body weight as being pertinent to the claim. No conclusions could be drawn from two of these four studies. In weighing the evidence, the Panel took into account that one human intervention study showed an effect of the standardised aqueous extract from white kidney bean in reducing body weight when consumed for 12 weeks, that the reduction in body weight was mostly through a reduction in body fat and that the effect of the standardised aqueous extract from white kidney bean on body weight was supported by a second study of shorter duration. However, the Panel also took into account that the first study was at risk of bias, that the supportive study suffered from methodological limitations and that no evidence was provided for a mechanism by which the standardised aqueous extract from white kidney bean could exert the claimed effect. The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

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KEY WORDS

white kidney bean extract, α -amylase inhibitor, body weight, weight loss, health claims

¹ On request from the Competent Authority of the United Kingdom following an application by InQpharm Europe Ltd, Question No EFSA-Q-2013-00973, adopted on 25 June 2014.

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SUMMARY

Following an application from InQpharm Europe Ltd, 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 a standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.

The food that is the subject of the health claim is an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised to its content of α -amylase inhibitor. The extract and tablets made thereof are marketed under the brand names Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™ and Starchlite™. The Panel considers that the food, an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its α -amylase inhibitory activity (Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™, Starchlite™), which is the subject of the health claim, is sufficiently characterised in relation to its *in vitro* α -amylase inhibitory activity.

The claimed effect is “helps to reduce body weight”. The target population proposed by the applicant is “the general population that wants to lose or manage their weight”. The Panel considers that a reduction in body weight is a beneficial physiological effect for overweight individuals.

The applicant identified a total of four human intervention studies, which investigated the effects of the aqueous extract from white kidney bean on body weight, as being pertinent to the claim.

Two double-blind, randomised, placebo-controlled, parallel intervention studies that assessed the effects of the aqueous extract from white kidney bean on body weight, body fat and waist and hip circumferences, and on subjective ratings of hunger, appetite and “energy level”, were claimed by the authors to be underpowered with respect to differences in body weight changes between the intervention and control groups based on post-hoc power calculations. None of the studies reported an effect of the aqueous extract from white kidney bean on any of the outcome measures considered. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a randomised, placebo-controlled, two-centre parallel study that was planned to be double-blind, 124 subjects were randomised to consume the aqueous extract from white kidney bean (n = 62; mean body weight 85.0 kg) or a placebo (n = 62; mean body weight 85.9 kg) daily for 12 weeks. The subjects were instructed to ingest either the aqueous extract from white kidney bean (3 g per day) or a placebo 30 minutes before their main meals. The primary outcome of the study was differences in body weight changes between study groups at week 12. Changes in waist and hip circumferences and in body fat and fat-free mass were assessed *inter alia* as secondary outcomes. One subject dropped out of the study. The Mann-Whitney U-test was used for between-group comparisons. An interim analysis with un-blinding took place after 50 % of the subjects had finished the study, in order to check whether sample size calculations were correct. Results were provided for the intention-to-treat (ITT; n = 123) population and for the per protocol (PP; n = 117) population. Considering the ITT population, at week 12 the subjects in the group who had consumed the kidney bean extract lost significantly more weight than subjects in the placebo group (results in mean \pm standard deviation (SD): -2.91 kg \pm 2.63 vs. -0.92 kg \pm 2.00; p < 0.001). This change was mostly attributed to a loss of body fat. Statistically significant differences were also reported for changes in waist circumference and hip circumference. There were no statistically significant differences between the groups for changes in fat-free mass. Energy intake and physical activity levels were not significantly different between the groups at any time point. Analysis of the PP population showed similar results on weight loss. Sensitivity analyses confirmed the results of the primary analysis. The Panel notes that this

study, which had a risk of bias through un-blinding, showed a decrease in body weight after consumption of the food for 12 weeks.

In a double-blind, randomised, placebo-controlled trial, 101 subjects recruited in Hangzhou, China, were randomised to receive 1 000 mg of the aqueous extract from white kidney bean (n = 51, mean body weight 79.2 kg) or a placebo (n = 50, mean body weight 81.3 kg), taken three times per day (before each meal) for 60 days. Body weight and waist and hip circumferences were measured at baseline and on days 30 and 60 of the study. Differences in changes in body weight between the two study groups were analysed by t-test, which did not take into account the repeated measures design of the study. At day 60, the subjects in the kidney bean extract group had lost significantly more weight than the subjects in the placebo group (mean \pm standard error of the mean (SEM): $-1.9 \text{ kg} \pm 0.15$ vs. $-0.4 \text{ kg} \pm 0.13$; $p < 0.001$). Significant findings were also reported for changes in waist circumference. The Panel considers that this study, which had methodological limitations, showed a reduction in body weight after consumption of the food for about eight weeks.

The applicant claims that the standardised aqueous extract from white kidney bean could exert the claimed effect by (i) inhibiting pancreatic α -amylase activity *in vivo*, which would reduce digestion of starch and thereby absorption of dietary complex glycaemic carbohydrates; (ii) delaying gastric emptying; and (iii) reducing feelings of hunger. The Panel notes that no evidence was provided for a mechanism by which the standardised aqueous extract from white kidney bean could exert the claimed effect *in vivo* in humans.

In weighing the evidence, the Panel took into account that one human intervention study showed an effect of the standardised aqueous extract from white kidney bean in reducing body weight when consumed for 12 weeks, that the reduction in body weight was mostly through a reduction in body fat, and that the effect of the standardised aqueous extract from white kidney bean on body weight was supported by a second study of shorter duration. However, the Panel also took into account that the first study was at risk of bias, that the supportive study suffered from methodological limitations and that no evidence was provided for a mechanism by which the standardised aqueous extract from white kidney bean could exert the claimed effect.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

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BACKGROUND

Regulation (EC) No 1924/2006⁴ harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 02/12/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application included a request for the protection of proprietary data.
- On 23/01/2014, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 28/01/2014, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 30/01/2014.
- On 06/03/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 17/03/2014 and was restarted on 01/04/2014, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 02/04/2014, EFSA received the requested information (which was made available to EFSA in electronic format on 31/03/2014).
- During its meeting on 25/06/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

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: standardised aqueous extract (Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™, Starchlite™) from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

⁴ 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.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of the standardised aqueous extract from white kidney bean, a positive assessment of its safety or a decision on whether the standardised aqueous extract from white kidney bean 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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: InQpharm Europe Ltd, Invision House, Wilbury Way, Hitchin, Hertfordshire SG4 0TY, United Kingdom.

The application includes a request for the protection of proprietary data for two unpublished study reports (Chong, 2012; Chong and Beah, 2013), in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food/constituent as stated by the applicant

According to the applicant, the food that is the subject of the health claim is PhaseLite™, which is a proprietary standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.).

The applicant indicated that PhaseLite™ is contained in/ marketed as Glucosanol™, Glycolite™, Phase 2[®], PhaseLite™ and Starchlite™.

Health relationship as claimed by the applicant

According to the applicant, the consumption of PhaseLite™ helps to reduce body weight in overweight or obese people. The mechanism proposed by the applicant is the inhibition of pancreatic α -amylase by α -amylase inhibitor isoform 1 (α -AII), contained in PhaseLite™. This inhibition would lead to a reduction in starch digestion and absorption, delayed gastric emptying and a lower sense of hunger, overall resulting in reduced body weight.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Helps to reduce body weight".

Specific conditions of use as proposed by the applicant

The applicant has proposed an intake of 1 g PhaseLite™ three times daily, approximately 30 minutes before main meals. The proposed target population is the "general population that wants to lose or manage their weight".

ASSESSMENT

1. Characterisation of the food/constituent

The food that is the subject of the health claim is an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised to its content of α -amylase inhibitor (i.e. at least 3 000 α -amylase inhibiting units (AAIU)/g).

The α -amylase inhibitor was indicated to be α -amylase inhibitor isoform 1 (α -AII), which is the most widely distributed of the isoforms and is found in most of the common bean cultivars grown worldwide (Obiro et al., 2008).

An overview of the manufacturing process and information on the stability and batch-to-batch analyses were provided.

The applicant claims that the specific manufacturing process (confidential information) results in an increased stability of the extract in acidic conditions (such as those prevailing in the stomach and duodenum), so that its inhibitory activity on pancreatic α -amylase would be different from that of other (generic) white kidney bean aqueous extracts, as suggested by the maintenance of the α -amylase inhibitory activity of the extract *in vitro* after being exposed to acidic conditions mimicking those of the gastrointestinal tract, as compared to other extracts.

The extract (an off-white to beige homogeneous powder) and tablets made thereof (i.e. extract plus excipients) are marketed under the brand names Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™ and Starchlite™.

The Panel considers that the food, an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its α -amylase inhibitory activity (Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™, Starchlite™), which is the subject of the health claim, is sufficiently characterised in relation to its *in vitro* α -amylase inhibitory activity.

2. Relevance of the claimed effect to human health

The claimed effect is “helps to reduce body weight”. The target population proposed by the applicant is “the general population that wants to lose or manage their weight”.

A reduction in body weight is considered a beneficial physiological effect for adults with an excess body weight, if body fat is reduced (EFSA NDA Panel, 2012).

The Panel considers that a reduction in body weight is a beneficial physiological effect for overweight individuals.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in Medline, using the search terms “standardized extract from white kidney bean (*Phaseolus vulgaris*)”, “Phase 2®[®]”, “weight management”, “weight loss”, “body weight”, “ α -amylase inhibitor from white kidney beans”, “human”, “study” and “trial”. The search was limited to publications in the English language. Studies were included if they were of “sound design” (i.e. randomised controlled trials) and were concerned with weight loss in overweight and obese subjects or supported the mode of action (mechanism) of PhaseLite™, Phase 2®[®], Starchlite™, Glucosanol™ or Glycolite™. Studies focusing on aspects other than weight management/loss, studies using raw kidney bean preparations or bean varieties other than white kidney bean and studies using combinations of α -amylase inhibitor plus lectins or other food ingredients (e.g. vitamins and minerals) were excluded.

Human intervention studies

The applicant identified a total of four human intervention studies which investigated the effects of an aqueous extract from white kidney bean (complying with the specifications indicated in section 1) on body weight as being pertinent to the claim (Udani et al., 2004; Udani and Singh, 2007; Wu et al., 2010; Chong, 2012, unpublished study report, claimed as proprietary by the applicant, and published by Grube et al., 2013).

Two double-blind, randomised, placebo-controlled, parallel intervention studies (Udani et al., 2004; Udani and Singh, 2007) that assessed the effects of the aqueous extract from white kidney bean on body weight, body fat and waist and hip circumferences, and on subjective ratings of hunger, appetite and “energy level”, were claimed by the authors to be underpowered with respect to differences in body weight changes between the intervention and control groups based on post-hoc power calculations. The study by Udani et al. (2004) randomised 39 adult subjects to consume either

1 500 mg of the aqueous extract from white kidney bean (n = 20) or placebo (n = 19) twice daily for eight weeks. The second study (Udani and Singh, 2007) randomised 25 adult subjects to consume either 1 000 mg of the aqueous extract from white kidney bean (n = 13) or placebo (n = 12) twice daily for four weeks. Neither of the studies reported an effect of the aqueous extract from white kidney bean on any of the outcome measures considered. The Panel notes that these studies were claimed by the authors to be underpowered to assess changes in body weight. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

In a randomised, placebo-controlled, two-centre parallel study which was planned to be double-blind, (Chong, 2012, unpublished study report, claimed as proprietary by the applicant; Grube et al., 2013) 124 subjects (91 female, 32 male; mean age 46 ± 10.1 years) were randomised to consume the aqueous extract from white kidney bean (n = 62; mean body weight 85.0 ± 11.3 kg) or a placebo (inert tablet excipients; n = 62; mean body weight 85.9 ± 10.1 kg) daily for 12 weeks. Inclusion criteria were body mass index (BMI) between 25 and 35 kg/m² and a stable body weight three months prior to the study. Randomisation was stratified to ensure equal distribution of overweight and obese subjects (cut-off at BMI ≥ 30 kg/m²) between the study groups. The subjects were instructed to ingest six tablets per day of either the aqueous extract from white kidney bean (500 mg/tablet; 3 g per day) or placebo, i.e. two tablets three times per day 30 minutes before their main meals (breakfast, lunch and dinner). In addition, all subjects were instructed to maintain a “mildly hypo-caloric” diet (energy deficit of 500 kcal per day) providing approximately 40 % of energy from “starchy” foods. Participants were also encouraged to gradually increase their physical activity. The 12-week study period was preceded by a 2-week run-in period during which subjects consumed the placebo. Energy intakes and physical activity levels (using the International Physical Activity Questionnaire (IPAQ)) of all subjects were assessed at all study visits, based on the subjects’ diaries (subjects recorded daily energy intakes and weekly physical activities).

The primary outcome of the study was differences in body weight changes between study groups at week 12. Based on the results of previous studies, and assuming a drop-out rate of 20 %, 62 subjects per group were needed to detect changes in body weight with a power of 80 % (at a significance level of 5 %), assuming an effect size of 0.6. Changes in waist and hip circumferences, and in body fat and fat-free mass (calculated from bioelectrical impedance analysis measurements), were assessed *inter alia* as secondary outcomes. Measurements were taken at the start of the run-in phase (week -2), at the beginning of the intervention (i.e. baseline, week 0) and at weeks 4, 8 and 12. One subject (from the placebo group) dropped out of the study (reasons not provided). The Mann-Whitney U-test was used for between-group comparisons. An interim analysis with un-blinding took place after 50 % of the subjects had finished the study, in order to check whether sample size calculations were correct. No adjustment of sample size was found to be necessary in this interim analysis. Results were provided for the intention-to-treat (ITT) population (n = 123), i.e. all the randomised subjects without the one drop-out, and for the per protocol (PP) population (n = 117), i.e. subjects with at least 80 % compliance (which led to the exclusion of six subjects, four from the placebo group and two from the kidney bean extract group). Considering the ITT population, at week 12 the subjects in the group who had consumed the kidney bean extract had lost significantly more weight than subjects in the placebo group (results in mean \pm SD: -2.91 kg \pm 2.63 vs. -0.92 kg \pm 2.00; $p < 0.001$). This change was mostly attributed to a loss of body fat (kidney bean extract: -2.23 kg \pm 2.16; placebo: -0.65 kg \pm 2.33; $p < 0.001$). Statistically significant differences were also reported for changes in waist circumference (kidney bean extract: -2.50 cm \pm 2.25; placebo: -0.90 cm \pm 2.13; $p < 0.001$) and hip circumference (kidney bean extract: -2.34 cm \pm 2.13; placebo: -0.84 cm \pm 1.42; $p < 0.001$). There were no statistically significant differences between the groups for changes in fat-free mass. Energy intake and physical activity levels were not significantly different between the groups at any time point. Analysis of the PP population showed similar results for weight loss (kidney bean extract: -3.01 kg \pm 2.59; placebo: -0.95 kg \pm 2.05; $p < 0.001$).

EFSA requested the applicant to clarify whether, and how, the repeated measures design of the study was taken into account in the analysis, and, if this was not the case, to provide a sensitivity analysis

taking into account the design of the study. In reply, the applicant provided two analyses: (i) a non-parametric multivariate analysis of longitudinal data (i.e. non-parametric multivariate analysis of variance (MANOVA) for repeated measures); and (ii) a non-parametric multivariate analysis of covariance for repeated measures (MANCOVA) with baseline data as covariate. For the MANCOVA, only data from subjects with complete observations were used (i.e. seven subjects were excluded). These sensitivity analyses confirmed the results of the primary analysis. The Panel notes that this study, which had a risk of bias through un-blinding, showed a decrease in body weight after consumption of the food for 12 weeks.

In a double-blind, randomised, placebo-controlled trial (Wu et al., 2010), 101 subjects recruited in Hangzhou, China, were randomised to receive 1 000 mg of the aqueous extract from white kidney bean ($n = 51$, 27 females; mean bodyweight $79.2 \text{ kg} \pm 1.6$ (SEM)) or a placebo (microcrystalline cellulose; $n = 50$, 19 females; mean bodyweight $81.3 \text{ kg} \pm 1.7$ (SEM)), taken 15 minutes before each meal (i.e. three times per day) for 60 days. Body weight and waist and hip circumferences were measured at baseline and at days 30 and 60 of the study. Body fat content was not assessed. No power calculations were performed. No information was provided on the subjects' physical activity or background diet. Differences in changes in body weight between the two study groups were analysed by t-test, which did not take into account the repeated measures design of the study. At day 60, the subjects in the kidney bean extract group had lost significantly more weight than the subjects in the placebo group ($-1.9 \text{ kg} \pm 0.15$ (SEM) vs. $-0.4 \text{ kg} \pm 0.13$ (SEM); $p < 0.001$). Significant findings were also reported for changes in waist circumference ($-1.9 \text{ cm} \pm 0.32$ (SEM) vs. $-0.4 \text{ cm} \pm 0.26$ (SEM); $p < 0.001$). The Panel considers that this study, which had methodological limitations, showed a reduction in body weight after consumption of the food for about eight weeks.

Mechanisms by which the food could exert the claimed effect

The applicant claims that the standardised aqueous extract from white kidney bean could exert the claimed effect by (i) inhibiting pancreatic α -amylase activity *in vivo*, which would reduce digestion of starch and thereby absorption of dietary complex glycaemic carbohydrates; (ii) delaying gastric emptying; and (iii) reducing feelings of hunger.

Out of the eight human intervention studies that were provided by the applicant in support of the mechanism by which the food could exert the claimed effect (Layer et al., 1985, 1986; Boivin et al., 1987; Jain et al., 1989, 1991; Udani, et al., 2009; Vinson et al., 2009), only three (Udani, et al., 2009; Vinson et al., 2009 – reporting on two studies) were conducted with a white kidney bean extract complying with the specifications mentioned in section 1. Those studies addressed the effects of the standardised aqueous extract from white kidney bean on the glycaemic index of foods or meals containing complex carbohydrates.

In a randomised, open-label, six-arm cross-over study (Udani, et al., 2009), glycaemic index testing was performed in 13 subjects who consumed 50 g of net carbohydrates in white bread with and without the addition of white kidney bean extract in capsule or powder form, each in dosages of 1 500 mg, 2 000 mg and 3 000 mg. No statistically significant effects were seen when the white kidney bean extract was provided in capsule form. With regards to the powder form, a significant reduction of glycaemic index (-20.23 or 34.11 %; $p = 0.023$) was seen after consumption of the highest dose, i.e. 3 000 mg, but not for the 1 500 mg and 2 000 mg doses. Vinson et al. (2009) reported on two randomised, double-blind, cross-over, single-dose studies. In the first study, 11 fasting subjects were given four slices of white bread and 42 g of margarine (610 kcal from 60.5 g carbohydrates, 36.5 g fat and 10.5 g protein) with or without 1 500 mg of the white kidney bean extract. Blood glucose concentrations were measured for two hours and the incremental areas under the curve (iAUC) were calculated from baseline to when the curves first returned to baseline. The iAUC was 66 % lower ($p < 0.05$) for the bean extract than for the control. The second study was carried out in seven subjects and included a full meal (630 kcal from 64 g carbohydrates, 29 g fat and 29 g protein) consumed after an overnight fast with and without 750 mg of the bean extract. There

were no significant differences in the iAUC between the meals consumed with or without the bean extract. The Panel considers that these studies do not provide evidence for an effect of the standardised aqueous extract from white kidney bean in reducing the activity of pancreatic α -amylase *in vivo* which would lead to a decrease in carbohydrate digestion and absorption under the conditions of use proposed by the applicant and tested in the efficacy studies provided (Chong, 2012, and Grube et al., 2013; Wu et al., 2010).

The Panel notes that no evidence was provided for an effect of the standardised aqueous extract from white kidney bean on the rate of gastric emptying.

Three studies (Udani et al., 2004; Udani and Singh, 2007; Chong, 2012, and Grube et al., 2013) out of four human intervention studies that addressed the effects of the standardised aqueous extract from white kidney bean on body weight also reported subjective ratings of satiety, hunger and the overall tolerability of the product. No significant differences between the intervention and control groups were reported in relation to these outcomes in any of the studies (Udani et al., 2004; Udani and Singh, 2007; Chong, 2012, and Grube et al., 2013). The Panel notes that the standardised aqueous extract from white kidney bean had no effect on subjective ratings of hunger or satiety.

Out of the three animal studies (Tormo et al., 2004, 2006; Harikumar et al., 2005), one study (Harikumar et al., 2005) was performed with a white kidney bean extract complying with the specifications mentioned in section 1. This study assessed the acute and sub-chronic toxicity, rather than the efficacy with respect to the claimed effect, of the white kidney bean extract in Wistar rats. The *in vitro* studies (Bowman, 1945; Marshall and Lauda, 1975; Bompard-Gilles et al., 1996; Le Berre-Anton et al., 1997, 2000) were concerned with purification, structural analysis and characterisation of binding properties of α -amylase inhibitor isolated from *Phaseolus vulgaris*. The Panel considers that no conclusions can be drawn from these studies with respect to the scientific substantiation of the claim.

The Panel notes that no evidence has been provided for a mechanism by which the standardised aqueous extract from white kidney bean could exert the claimed effect *in vivo* in humans.

In weighing the evidence, the Panel took into account that one human intervention study showed an effect of the standardised aqueous extract from white kidney bean in reducing body weight when consumed for 12 weeks, that the reduction in body weight was mostly through a reduction in body fat, and that the effect of the standardised aqueous extract from white kidney bean on body weight was supported by a second study of shorter duration. However, the Panel also took into account that the first study was at risk of bias, that the supportive study suffered from methodological limitations and that no evidence was provided for a mechanism by which the standardised aqueous extract from white kidney bean could exert the claimed effect.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

CONCLUSIONS

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

- The food, an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its α -amylase inhibitor activity (Glucosanol™, Glycolite™, Phase 2®[®], PhaseLite™, Starchlite™), which is the subject of the health claim, is sufficiently characterised.

- The claimed effect is “helps to reduce body weight”. The target population proposed by the applicant is “the general population that wants to lose or manage their weight”. A reduction in body weight is a beneficial physiological effect for overweight individuals.
- The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a standardised aqueous extract (Glucosanol™, Glycolite™, Phase 2® , PhaseLite™, Starchlite™) from white kidney bean (*Phaseolus vulgaris* L.) and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0403_UK). December 2013. Submitted by InQpharm Europe Ltd.

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ABBREVIATIONS

AAIU	α -amylase inhibiting units
iAUC	incremental area under the curve
ITT	intention to treat
MANOVA	multivariate analysis of variance
MANCOVA	multivariate analysis of covariance
PP	per protocol
SD	standard deviation
SEM	standard error of the mean