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## GlycoLite™ and helps to reduce body weight: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

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### Abstract

Following an application from analyze & realize GmbH submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Ireland, 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 GlycoLite™. The Panel considers that the food, an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) which is the subject of the health claim, is sufficiently characterised. The claimed effect proposed by the applicant is 'helps to reduce body weight'. The proposed target population is 'overweight people from the age of 18 years who want to lose or manage their weight'. The Panel considers that a reduction in body weight is a beneficial physiological effect for overweight individuals. Two human intervention studies, carried out in the same centres and by the same research group, showed an effect of 3 g of GlycoLite™ on body weight when consumed daily for 12 weeks in the context of an energy restricted diet. The results have not been replicated in a different setting. One study of short duration and methodological limitations showed an effect of GlycoLite™ on body weight when eating *ad libitum*. No evidence for a plausible mechanism by which GlycoLite™ could exert a reduction in body weight *in vivo* in humans has been provided. The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) and a reduction of body weight either under energy restriction or when eating *ad libitum*.

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**Keywords:** GlycoLite, white kidney bean extract,  $\alpha$ -amylase inhibitor, body weight, weight loss, health claim

**Requestor:** Competent Authority of Ireland following an application by analyze & realize GmbH

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## Summary

Following an application from analyze & realize GmbH, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Ireland, 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 GlycoLite™ and helps to reduce body weight.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.

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 and the guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations.

The food proposed by the applicant as the subject of the health claim is GlycoLite™, an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its  $\alpha$ -amylase inhibitory activity (i.e. at least 3,000  $\alpha$ -amylase inhibiting units (AAIU)/g). The Panel notes that, based on the information provided regarding batch-to-batch analysis, the  $\alpha$ -amylase inhibitory activity of GlycoLite™ is two to three times higher than the minimum activity required in the product specification. The Panel also notes that no information has been provided in relation to the  $\alpha$ -amylase inhibitory activity of the aqueous extracts from white kidney bean used in the intervention studies submitted for the scientific substantiation of the claim, claimed by the applicant to comply with the specifications provided for GlycoLite™. The Panel considers, however, that the food, an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant is 'helps to reduce body weight'. The proposed target population is 'overweight people from the age of 18 years who want to lose or manage their weight'. The Panel considers that a reduction in body weight is a beneficial physiological effect for overweight individuals. Upon a request from EFSA, the applicant clarified that the effect can be achieved both under energy restriction and when eating *ad libitum*.

A total of six human intervention studies were evaluated in relation to this claim: three were performed under energy restriction and three were conducted when eating *ad libitum*.

The Panel considers that two human intervention studies performed under moderate energy restriction (20% reduction in energy intake) showed an effect of GlycoLite™ on the reduction of body weight. The Panel notes that these studies have been conducted in the same centres by the same research group and that the results have not been replicated in a different setting. The Panel considers that one human intervention study with methodological limitations conducted when eating *ad libitum* showed an effect of GlycoLite™ on the reduction of body weight.

The Panel considers that the results of one animal efficacy study cannot be used in support of an effect of GlycoLite™ on body weight *in vivo* in humans under the proposed conditions of use due to the methodological limitations of the study and the high dose of GlycoLite™ used.

The mechanistic studies submitted provide some evidence for a pancreatic  $\alpha$ -amylase inhibitory activity of GlycoLite™, which may induce a decrease in postprandial blood glucose responses when consumed in combination with meals containing high amounts of digestible carbohydrates. However, no evidence has been provided for a mechanism by which a partial inhibition of the  $\alpha$ -amylase activity could lead to a reduction in body weight in free-living humans. The Panel considers that no evidence has been provided for a plausible mechanism by which GlycoLite™ could exert a reduction in body weight *in vivo* in humans.

In weighing the evidence, the Panel took into account that two human intervention studies showed an effect of 3 g of GlycoLite™ on body weight when consumed daily for 12 weeks in the context of an energy restricted diet, and that one human intervention study with methodological limitations performed when eating *ad libitum* showed an effect of 3 g GlycoLite™ consumed daily for about 8 weeks on the reduction of body weight. However, the Panel also took into account that the two studies conducted under energy restriction were not performed by different research groups and in different settings, that only one study of short duration and methodological limitations showed an effect of GlycoLite™ on body weight when eating *ad libitum*, and that no evidence for a plausible mechanism by which GlycoLite™ could exert a reduction in body weight *in vivo* in humans has been provided.

On the basis of the data presented the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) and a reduction of body weight either under energy restriction or when eating *ad libitum*.

## Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	5
1.1. Background and Terms of Reference as provided by the requestor.....	5
1.2. Interpretation of the Terms of Reference.....	5
2. Data and methodologies.....	5
2.1. Data.....	5
2.2. Methodologies.....	6
3. Assessment.....	6
3.1. Characterisation of the food/constituent.....	6
3.2. Relevance of the claimed effect to human health.....	7
3.3. Scientific substantiation of the claimed effect.....	7
4. Conclusions.....	12
Steps taken by EFSA.....	13
References.....	13
Abbreviations.....	14

## 1. Introduction

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

Regulation (EC) No 1924/2006<sup>1</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

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

### 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: GlycoLite™ and reduction in body weight.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of GlycoLite™, a positive assessment of its safety, nor a decision on whether GlycoLite™ 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 'GlycoLite™ - a proprietary standardized aqueous extract from white kidney bean (*Phaseolus vulgaris*)'.

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

According to the applicant, the claimed effect relates to: 'helps to reduce body weight in overweight or obese people'.

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

The applicant claims that 'α-amylase inhibitor isoform 1 (α-AI1), contained in GlycoLite™ inhibits pancreatic α-amylase. 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'.

<sup>1</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

## Specific conditions of use as proposed by the applicant

According to the applicant, the target population for the intended health claim is 'general population that wants to lose or manage their weight'. The applicant has proposed an intake of 1 g GlycoLite™ three times daily, approximately 30 min before main meals.

## Data provided by the applicant

Health claim application on GlycoLite™ and helps to reduce body weight pursuant to Article 13.5 of Regulation 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.<sup>2</sup>

As outlined in the General guidance for stakeholders on health claim applications,<sup>3</sup> 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 claims applications is outlined in the EFSA general guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016).

The scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations are outlined in a specific EFSA guidance (EFSA NDA Panel, 2012).

The application contains data claimed as confidential: manufacturing process; Chong (2012 unpublished study protocol), all parts not mentioned in the corresponding publication by Grube et al., (2014); Bothe (2018; unpublished study report); in vitro ProDigest (study report).

The application contains data claimed as proprietary: details related to the manufacturing process and batch-to-batch comparisons, nutritional profile of the final product, unpublished Chong study (Chong, 2012), unpublished Bothe (2018) study, unpublished ProDigest (2018) in vitro study.

## 3. Assessment

### 3.1. Characterisation of the food/constituent

The food proposed by the applicant as the subject of the health claim is GlycoLite™, an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its  $\alpha$ -amylase inhibitory activity (i.e. at least 3,000  $\alpha$ -amylase inhibiting units (AAIU)/g).

The  $\alpha$ -amylase inhibitor was indicated to be  $\alpha$ -amylase inhibitor isoform 1 ( $\alpha$ -AI1), 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). GlycoLite™ is derived from whole dried seeds of the Great Northern white kidney bean from United States.

A non-confidential summary of the manufacturing process has been provided. After grinding the whole, dried white kidney beans, ground beans are extracted with water and filtered. To obtain a concentrated bean extract, the filtrate is subjected to heat exchange. The extract is then encapsulated and later blended. Various sieving and magnetic separation steps in order to remove large size impurities and metal particles are implemented.

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 proximal duodenum, so that its inhibitory activity on pancreatic  $\alpha$ -amylase would be higher than that of other white kidney bean aqueous extracts (data claimed as confidential by the applicant).

The extract (an off-white to beige homogeneous powder) and products made thereof (i.e. extract plus excipients) have been marketed under the brand names of Glycosanol™ and Phase2™, among others. The applicant states that GlycoLite™ is used in the application as a generic name for all commercial products containing GlycoLite™ as the active ingredient. The applicant also claims that all the studies provided for the scientific substantiation of the claim (human intervention studies and

<sup>2</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), Turck D, Bresson J-L, Burlingame B, Dean T, Fairweather-Tait S, Heinonen M, Hirsch-Ernst KI, Mangelsdorf I, McArdle HJ, Naska A, Neuhauser-Berthold M, Nowicka G, Pentieva K, Sanz Y, Sjodin A, Stern M, Tome D, Van Loveren H, Vinceti M, Willatts P, Martin A, Strain JJ, Heng L, Valtueña Martínez S and Siani A, 2017. Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 2). EFSA Journal 2017;15(1):4680, 31 pp. <https://doi.org/10.2903/j.efsa.2017.4680>

<sup>3</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. 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>

mechanistic studies) have been conducted with aqueous extracts from white kidney bean complying with the specifications provided for GlycoLite™ in the present application. Therefore, for clarity reasons, GlycoLite™ is mentioned in this opinion as the food/constituent being assessed in all the studies described in Section 3.3.

The  $\alpha$ -amylase activity is determined by using a spectrophotometric method according to Foo and Bais (1998) and Lorenz et al. (1999). The  $\alpha$ -amylase inhibiting activity of GlycoLite™ is calculated as the ratio of activity of an amylase standard solution with and without GlycoLite™. The Panel notes that, based on the information provided regarding the batch-to-batch analysis (claimed as confidential by the applicant), the  $\alpha$ -amylase inhibitory activity of GlycoLite™ is two to three times higher than the minimum activity required in the product specification (i.e. at least 3,000 AAU/g). The Panel also notes that no information has been provided in relation to the  $\alpha$ -amylase inhibitory activity of the aqueous extracts from white kidney bean used in the intervention studies submitted for the scientific substantiation of the claim, claimed by the applicant to comply with the specifications provided for GlycoLite™ (Section 3.3). The Panel considers, however, that GlycoLite™ is sufficiently characterised based on the manufacturing process and its *in vitro*  $\alpha$ -amylase inhibitory activity as measured in the batch-to-batch analysis.

The Panel considers that the food, an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) which is the subject of the health claim, is sufficiently characterised.

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

The claimed effect proposed by the applicant is 'helps to reduce body weight'. The proposed target population is 'overweight people from the age of 18 years who want to lose or manage their weight'.

The scientific evidence for the substantiation of health claims on the reduction of body weight can be obtained from human intervention studies showing a reduction in body weight which could not be attributed to a reduction in lean body mass/body water. The conditions in which the effect on body fat/body weight is achieved need to be specified (e.g. under energy-restriction, eating *ad libitum*, etc). Evidence for a sustained effect with continuous consumption of the food/constituent over, for example, about 12 weeks, should also be provided (EFSA NDA Panel, 2012).

Upon a request from EFSA, the applicant clarified that the effect can be achieved both under energy restriction and eating *ad libitum*.

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

### 3.3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed using the following key words: 'white kidney bean extract OR phaseolus vulgaris AND weight loss OR body weight'. The search was restricted to studies written in English. Other studies were identified via the applicant's internal database.

In 2014, the Panel assessed a claim on '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. The Panel concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of the standardised aqueous extract from white kidney bean (*P. vulgaris* L.) and reduction of body weight (EFSA NDA Panel, 2014).

#### **Human intervention studies**

The applicant identified three human intervention studies (Grube et al., 2014; Wu et al., 2010; Bothe, 2018, unpublished study report) and one meta-analysis of human intervention studies (Udani et al., 2018) as being pertinent to the claim.

The meta-analysis includes 11 human intervention studies on the effect of GlycoLite™, either alone or in combination with other food/constituents, on body weight (Udani et al., 2018). Three studies were conducted with GlycoLite™ in combination with other foods/constituents and do not allow conclusions on the effect of GlycoLite™ alone on body weight (Thom, 2000; Celleno et al., 2007; Yamada et al., 2007, unpublished), while three other studies were uncontrolled, single-arm studies (Asano et al., unpublished; Koike et al., 2005; Osorio and Land Gamboa, 2005, unpublished). The Panel considers that no conclusions can be drawn from these six studies for the scientific substantiation of the claim. However, three of the studies included in this meta-analysis were considered pertinent to the claim (Rothacker, 2003, unpublished; Udani et al., 2004; Udani and Singh, 2007).

Considering the applicant's clarification upon EFSA's request that the effect can be achieved both under energy restriction and when eating *ad libitum*, a total of six human intervention studies were evaluated in relation to this claim: three were performed under energy restriction (Udani and Singh, 2007; Grube et al., 2014; Bothe, 2018, unpublished) and three were conducted when eating *ad libitum* (Rothacker, 2003; Udani et al., 2004; Wu et al., 2010).

### Human intervention studies performed under energy restriction

Two human intervention studies (Grube et al., 2014, also submitted in the previous application as Chong, 2012, unpublished study report; and Udani and Singh, 2007) have already been assessed by the Panel in the previous opinion (EFSA NDA Panel, 2014).

Udani and Singh (2007) reported on a 4-week parallel study conducted in a small number of subjects (13 and 12 individuals in the intervention and control groups, respectively) which provided 2 g of GlycoLite™ daily. No statistically significant differences in body weight changes between groups were observed. The Panel noted that this study of short duration was claimed by the authors to be underpowered to assess changes in body weight based on post hoc power calculations and considered that no conclusions could be drawn for the scientific substantiation of the claim.

In the randomised, placebo-controlled, two-centre parallel study by Grube et al. (2014), 124 subjects were randomised to consume an aqueous extract from white kidney bean, 3 g/day in three doses of 1 g taken about 30 min before the main meals (n = 62) or a placebo (n = 62) daily for 12 weeks. An interim analysis with unblinding for the assessors took place after 50 % of the subjects had finished the study, in order to check whether sample size calculations were correct. Subjects in the intervention group lost significantly more weight than subjects in the placebo group (mean ± SD: -2.91 kg ± 2.63 vs. -0.92 kg ± 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. The Panel noted that this study, which had a risk of bias through unblinding, showed a decrease in body weight after consumption of 3 g/day GlycoLite™ for 12 weeks (EFSA NDA Panel, 2014).

The new study provided by the applicant (Bothe, 2018, unpublished study report, claimed as proprietary) was a randomised, two-arm, parallel, double-blind, two-centre study which investigated the effects of consuming 3 g/day of GlycoLite™ for 12 weeks on body weight as compared to placebo in a group of adult outpatients.

Men and women 18–65 years old and body mass index (BMI) between 25 and 34.9 kg/m<sup>2</sup>, with stable body weight (< 5% self-reported weight change in the last 3 months) who wished to lose weight were enrolled in the study. Upon a request from EFSA, the applicant clarified that the study was conducted in two centres: the office of a general practitioner and a research centre. The Panel notes that this trial used the same centres which were involved in the study by Grube et al. (2014). The participants were recruited by public advertisement and from the general practitioner patients' database.

Participants underwent a run-in period of 2 weeks, followed by the intervention lasting 12 weeks. They visited the centre five times: a screening visit, an inclusion visit (baseline), two control visits after 4 and 8 weeks and a final visit after 12 weeks.

At baseline, they were randomly assigned to one of three groups: (a) high-dose GlycoLite™, (b) low-dose GlycoLite™ or (c) placebo. During the 12-week intervention period, the subjects were asked to consume two capsules 30 min before each of the three main meals (breakfast, lunch and dinner/supper) with a glass of water (150 mL), for a total of 6 capsules daily. Each capsule contained either 500 mg of GlycoLite™ (high dose, 3 g/day), 350 mg of GlycoLite™ (low dose, 2.1 g/day) or microcrystalline cellulose (placebo).

Block randomisation was used, stratified according to gender and BMI at baseline, per centre. The randomisation ratio was 2:1:2 (high-dose GlycoLite™: low-dose GlycoLite™: placebo). The authors clarified that the low-dose GlycoLite™ group was included for exploratory reasons. For the purpose of this opinion, only the results related to the high-dose GlycoLite™ group vs placebo are discussed. The Panel notes that subjects were independently randomised in the two centres with a similar number of subjects, gender distribution and treatment allocation between the two centres.

The primary outcome was difference in weight change (in kg) at week 12 from baseline between the high-dose GlycoLite™ and the placebo groups. Based on the results of the study by Grube et al. (2014), sample size (36 subjects per arm) was calculated assuming a reduction of body weight of 3.5% in the high-dose GlycoLite™ group, with  $\alpha = 0.05$  and a power of 90%, accounting for a drop-out rate of 20%.



A number of secondary outcomes were assessed at weeks 4, 8 and 12 of the intervention, including body weight as % change, the proportion of subjects who lost at least 3% and at least 5% of baseline body weight; fat mass (in kg and as % body weight) and fat-free mass assessed by bioelectrical impedance analysis (BIA); BMI, waist circumference, hip circumference, waist-to-hip-ratio and thigh circumference. The blood lipid profile, haemoglobin A1c (HbA1c), general well-being using the 12-Item Short Form Health Survey (SF-12), a global evaluation of benefit by the subjects (4-point categorical scale) and a global evaluation of benefit by the investigators (4-point categorical scale) were assessed after 12 weeks.

Energy requirements for each subject were calculated based on BMI and reported physical activity level at screening. A diet plan was developed for each subject aiming at a 20% reduction in energy intake vs the calculated energy requirement. Throughout the study, subjects compiled 3-day food diaries weekly (2 week days and 1 weekend day). Their physical activity level was assessed at each visit using a global physical activity questionnaire. Subjects were classified as non-compliant when, based on the subjects' diaries, their energy intake deviated by more than 20% of the individual diet plan throughout the entire intervention period.

The primary outcome was analysed using the univariate exact nonparametric Wilcoxon–Mann–Whitney test for independent groups, followed by a corresponding univariate nonparametric covariance analysis with baseline as covariate. Generalised estimating equations (GEE) were used to account for potential confounders. Results for secondary outcomes were considered exploratory.

All analyses were performed for the full analysis set (FAS) population (subjects who had taken the study supplements at least once and had at least one post-baseline assessment for any measurement). Additionally, the analysis for the primary outcome and selected secondary outcomes was also carried out in the valid case analysis set (VCAS) population, which included all subjects in the FAS terminating the study without any major violation of the protocol.

A total of 112 subjects were screened and 90 subjects were randomised (36 high-dose GlycoLite™, 18 low-dose GlycoLite™, 36 placebo, mean age  $47.6 \pm 11.5$  years, mean BMI  $29.8 \pm 2.4$ , 60 female). Four subjects terminated the study prematurely and two took less than 80% of the capsules. Two subjects deviated beyond the target range of total energy intake (between 81.1% and 118.1%) and one failed to complete the food diary. All nine participants mentioned above were excluded from the VCAS population. FAS analysis was performed in the 90 participants randomised and VCAS analysis in 81 participants.

Body weights were similar between the study groups at baseline visit ( $84.71 \pm 12.49$  kg in the high-dose GlycoLite™ group and  $84.26 \pm 11.30$  kg in the placebo group).

At 12 weeks, body weight was reduced by  $4.48 \pm 1.56$  kg; (95% CI: 3.94–5.02) in the high-dose GlycoLite™ group compared to  $0.54 \pm 1.46$  kg (95% CI: 0.03–1.08) in the placebo group ( $p < 0.001$ ; FAS population). In the VCAS population, body weight was reduced by  $4.48 \pm 1.56$  kg (95% CI: 3.94–5.02) in the high-dose GlycoLite™ group compared to  $0.63 \pm 1.50$  kg (95% CI: 0.07–1.23) in the placebo group ( $p < 0.001$ ).

The GEE analyses of the high-dose GlycoLite™ vs the placebo group for the primary endpoint adjusted for baseline values showed a significant effect of GlycoLite™ on body weight independently of the potential confounders considered (physical activity level, energy intake, gender, centre, age, BMI).

Body fat mass was reduced by  $3.17 \pm 3.78$  kg in the high-dose GlycoLite™ group and by  $0.65 \pm 2.60$  kg in the placebo group ( $p = 0.002$ ). In the FAS population, fat free mass was reduced by  $1.42 \pm 3.49$  kg in the high-dose GlycoLite™ group while an increase of  $0.12 \pm 2.56$  kg was observed in the placebo group, after 12 weeks of intake ( $p = 0.027$ ).

In the FAS population, waist circumference was significantly more reduced ( $p < 0.001$ ) in the high-dose GlycoLite™ group ( $3.94 \pm 2.29$  cm) compared with the placebo group ( $1.00 \pm 1.89$  cm)

The Panel notes that bioelectrical impedance is not an appropriate method for assessing small changes in body fat mass in intervention studies (EFSA NDA Panel, 2012). However, the effect size on weight loss and changes in waist circumference overall suggests a relevant decrease in body fat mass.

In the FAS population, no significant differences in energy intake at different time points through the study (except for week 1) or physical activity level between the high-dose GlycoLite™ and placebo groups were observed.

The Panel considers that this study shows a reduction of body weight after consumption of 3 g of GlycoLite™ daily for 12 weeks in the context of an energy restricted diet.

The Panel considers that two human intervention studies performed under moderate energy restriction (20% reduction in energy intake) (Grube et al., 2014; Bothe, 2018 unpublished study report) showed an effect of GlycoLite™ on the reduction of body weight. The Panel notes that these

studies have been conducted in the same centres by the same research group and that the results have not been replicated in a different setting.

### Human intervention studies conducted when eating *ad libitum*

The applicant submitted three human intervention studies conducted when eating *ad libitum* (Rothacker, 2003; Udani et al., 2004; Wu et al., 2010), two of which (Udani et al., 2004; Wu et al., 2010) have already been assessed by the Panel in a previous opinion (EFSA NDA Panel, 2014).

The study by Wu et al. (2010) was a double-blind, randomised, placebo-controlled trial which showed a reduction in body weight after consumption of GlycoLite™ (3 g/day) for about 8 weeks (60 days). 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, subjects in the GlycoLite™ group (n = 51) had lost significantly more weight than subjects in the placebo group (n = 50) (mean ± SEM: -1.9 kg ± 0.15 vs. -0.4 kg ± 0.13; p < 0.001). Changes in waist circumference were also statistically significant (-1.9 cm ± 0.32 vs. -0.4 cm ± 0.26; p < 0.001). The Panel considered that this study, which had methodological limitations, showed a reduction in body weight after consumption of GlycoLite™ for about eight weeks.

In its previous opinion, the Panel also evaluated the study by Udani et al. (2004). The Panel considered that no conclusions could be drawn from this underpowered study of 8-week duration, which was conducted with 1.5 g of GlycoLite™ daily and included a small number of subjects (27 completers, 14 in the GlycoLite™ group and 13 in the placebo group, respectively), for the scientific substantiation of the claim.

The study by Rothacker, 2003 (unpublished) was a randomised, two-arm, parallel, double-blind, placebo-controlled study which investigated the effects of GlycoLite™ (3 g/day) for 12 weeks on body weight as compared to placebo.

The study aimed to recruit healthy men and women motivated to lose weight between 18 and 75 years of age and BMI between 24 and 32 kg/m<sup>2</sup>. Exclusion criteria included intake of over-the-counter diet or slimming aids, prescription medications other than birth control pills and serious illness. Participants were randomised (block randomisation) to GlycoLite™ or placebo and underwent a run-in period of 2 weeks, followed by the intervention lasting 12 weeks. They were advised to eat a balanced diet with moderate energy intake and encouraged to walk and exercise regularly. The Panel notes that the diet and physical activity of the participants during the study was not assessed.

The primary outcomes of the study were changes in body weight, body fat and lean body mass measured by BIA. Waist and hip circumferences were also measured. All measurements were performed at baseline and weeks 6, 8 and 12 of the intervention.

A two-tailed independent t-test was used to compare the results between the groups at each time-point. The Panel notes that multiple measurement points were not taken into account in the statistical analysis.

A total of 88 subjects (62 females and 26 males, mean age 33.2 ± 16.4 years, mean BMI 33.8 ± 9.8) were randomised. The Panel notes that mean BMI exceeded the upper limit of the inclusion criteria specified in the study protocol. The Panel also notes that baseline weight was significantly higher in the intervention group vs placebo (91.8 ± 25.8 vs 86.6 ± 24.1 kg, p = 0.039). The study reports on the 60 participants (34 in the intervention group and 26 in the placebo group) who completed the study.

The Panel considers that, owing to the methodological limitations of the study (groups not comparable in relation to body weight at baseline, subjects not meeting the inclusion criteria for enrolment, statistical analysis not appropriate for the study design), no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel considers that one human intervention study with methodological limitations (Wu et al., 2010) conducted when eating *ad libitum* showed an effect of GlycoLite™ on the reduction of body weight for about eight weeks.

### Animal efficacy study

Twenty-four six-week-old male Wistar rats were randomly assigned to three groups (8 rats each): normal diet, high-fat diet or high-fat diet containing 5% of GlycoLite™ (the content expressed as g/kg body weight (bw) not given) (Yang et al., 2014). After 5 weeks intervention, body weight gain was significantly lower in the group supplemented with GlycoLite™ compared with the high-fat group (p < 0.05). Body weight after intervention was 212.2 ± 21.6 g in the high-fat GlycoLite™ group vs

233.5 ± 26.5 g in the normal diet group and 285.3 ± 38.3 g in the high-fat group. A reduction of food intake was also reported in the high-fat GlycoLite™ group (21.6 ± 2.1 g/day) compared with the high-fat group (24.6 ± 2.3 g/day),  $p < 0.05$ . Feed efficacy (calculated as weight gain/food intake, %) was significantly lower in the high-fat GlycoLite™ and control groups compared with the high-fat group (9.9 ± 0.7% vs 9.6 ± 1.0% and 11.6 ± 1.3%, respectively). Between-group differences were assessed using independent t-tests.

The Panel notes that the statistical analysis used to compare differences between the groups is inadequate, and that the dose of white bean extract used in this animal study is high and not comparable to the dose used in the human studies provided. The Panel also notes that the reduction in body weight observed in the high-fat GlycoLite™ group could be explained by the differences in food intake observed between groups, which could be due to a lower palatability of the high-fat GlycoLite™ diet, and that the effect of GlycoLite™ on food intake was not observed in humans (Bothe, 2018). The applicant suggested that the difference in feed efficacy between the high-fat group and the high-fat GlycoLite™ indicates that a lower food intake is not the only reason that could explain the lower weight gain observed in the high-fat GlycoLite™ group vs the high-fat group. The Panel notes that the concept of feed efficacy is valid, but difficult to translate within the context of the human intervention studies considering the methodological limitations of this study and the high dose of GlycoLite™ used. The Panel considers that the results of this study cannot be used in support of an effect of GlycoLite™ on body weight *in vivo* in humans under the proposed conditions of use.

### **Mechanism of action**

The applicant claims that 'GlycoLite™ inhibits pancreatic  $\alpha$ -amylase activity, which in turn leads to a suppression of starch digestion, availability of carbohydrate-derived calories and food intake'. Other mechanisms proposed in the previous application (i.e. delaying gastric emptying and reducing feelings of hunger) are not considered in this opinion.

Preuss et al. (2007) performed single-dose studies on 96 rats and two pigs to investigate the ability of GlycoLite™ to inhibit the absorption of rice starch and sucrose. First, groups of nine Sprague–Dawley rats were gavaged with 2.0 mL of water alone (control) or with 0.5 g of GlycoLite™ 30 min prior to the sucrose/starch challenge. During the sucrose/starch challenge, rats were gavaged again with 2.0 mL of water alone or water containing 0.5 g GlycoLite™ plus 2 g rice starch, sucrose or combined rice starch and sucrose (2 g each). Plasma glucose was measured at baseline and every hour for 4 hours thereafter. GlycoLite™ reduced the blood glucose concentrations compared to control after the rice starch challenge over the first 2 h. The area under the curve for GlycoLite™ was 40% of the control after the rice starch challenge. After the sucrose challenge, blood glucose concentrations were significantly lower during the first 3 h in the GlycoLite™ group compared with the control. The area under the curve was 51% of the control after the sucrose challenge. A dose–response study was conducted, where groups of nine Sprague–Dawley rats were gavaged with water or water containing 1.0, 1.5 or 2.0 g of GlycoLite™, plus rice starch. Blood samples were obtained every hour for 2 h after the rice starch challenge. With increasing GlycoLite™ concentrations, circulating glucose concentrations decreased over the first two hours after rice starch challenge. A significant reduction in blood glucose concentrations was also observed after the starch and/or sucrose challenge in two Yorkshire pigs. The Panel notes that these studies provide some evidence that GlycoLite™ reduces postprandial blood glucose concentrations when consumed in combination with a carbohydrate-containing test meal.

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 a white kidney bean extract (claimed to be GlycoLite™ by the applicant). Blood glucose concentrations were measured over two hours and the incremental areas under the curve (iAUC) were calculated. The iAUC was 66% lower ( $p < 0.05$ ) when the meal was consumed with GlycoLite™. 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 GlycoLite™. There were no significant differences in the iAUC between the meals consumed with or without GlycoLite™.

The Panel notes that these studies support an effect of GlycoLite™ on postprandial blood glucose responses when consumed at doses of 1,500 mg per about 60 g of digestible carbohydrates, but not when consumed at doses of 750 mg.

The ProDigest study (2018, unpublished study report) evaluated the effect of GlycoLite™ on starch digestion (two doses tested: 4,500 and 9,000 AAIU which corresponded to 0.5 and 1 g/meal) *in vitro* in an artificial model of human gastrointestinal tract (Simulator of the Human Intestinal Microbial

Ecosystem – SHIME®) as compared to a negative control (no inhibitor added). A positive control (acarbose 0.1 g/meal) was used to validate the test setup. The stomach, small intestinal and proximal colon compartments of SHIME® were used. The upper gastrointestinal tract incubations were performed under fed conditions with an integrated dialysis approach to mimic the absorptive processes in the small intestine. Incubation conditions (pH profiles, incubation times) were optimised in order to resemble *in vivo* conditions in the different regions of the gastrointestinal tract. The incubation lasted 48 h. The aim of the study was to investigate how the test product potentially affected digestion of starch and subsequent absorption of glucose. The impact on microbial fermentation and production of microbial metabolites (acidification, gas production, short-chain fatty acids (SCFA), lactate and ammonium) was also evaluated. The Panel notes no information was provided regarding the statistical analyses performed.

In the presence of a lower  $\alpha$ -amylase concentration, GlycoLite™ inhibited starch digestion as shown by a significant reduction in the amount of all products of starch digestion tested (glucose, maltose and maltotriose) compared with the control during both stomach and duodenal stages. GlycoLite™ did not significantly reduce the absorption through a dialysis membrane of any of the products of starch digestion. The Panel notes that the model used in this study is inadequate for assessing glucose absorption as the integrated dialysis approach used does not mimic the physiological mechanisms responsible for glucose absorption (i.e. facilitated and active transport system) *in vivo* in humans. Therefore, The Panel considers that no conclusions can be drawn from this study with regards to potential effects of GlycoLite™ on intestinal glucose absorption mechanisms.

In the previous opinion (EFSA NDA Panel, 2014), the Panel considered that no evidence was provided for a mechanism by which GlycoLite™ could exert the claimed effect. New data from the mechanistic studies submitted by the applicant provides some evidence for the pancreatic  $\alpha$ -amylase inhibitory activity of GlycoLite™, which may induce a decrease in postprandial blood glucose responses when consumed in combination with test meals containing high amounts of digestible carbohydrates. However, no evidence has been provided for a mechanism by which a partial inhibition of the  $\alpha$ -amylase activity could lead to a reduction in body weight in free-living humans.

The Panel considers that no evidence has been provided for a plausible mechanism by which GlycoLite™ could exert the claimed effect (a reduction in body weight) *in vivo* in humans.

### Weighing of the evidence

In weighing the evidence, the Panel took into account that two human intervention studies showed an effect of 3 g of GlycoLite™ on body weight when consumed daily for 12 weeks in the context of an energy restricted diet, and that one human intervention study with methodological limitations performed under no energy restriction showed an effect of 3 g GlycoLite™ consumed daily for about 8 weeks on the reduction of body weight. However, the Panel also took into account that the two studies conducted under energy restriction were not performed by different research groups and in different settings, that only one study of short duration with methodological limitations showed an effect of GlycoLite™ on body weight when eating *ad libitum*, and that no evidence for a plausible mechanism by which GlycoLite™ could exert a reduction in body weight *in vivo* in humans has been provided.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) and a reduction of body weight either under energy restriction or eating *ad libitum*.

## 4. Conclusions

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

- The food/constituent, an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'helps to reduce body weight'. The target population proposed by the applicant is 'overweight people from the age of 18 years who want to lose or manage their weight'. 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 an aqueous extract from white kidney bean (*P. vulgaris* L.) standardised by its *in vitro*  $\alpha$ -amylase inhibitory activity (GlycoLite™) and a reduction of body weight either under energy restriction or when eating *ad libitum*.

## Steps taken by EFSA

Health claim application on “an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its  $\alpha$ -amylase inhibitory activity (GlycoLite™) and reduction in body weight” pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0478\_NL). Submitted by analyze & realize GmbH on behalf of Omega Pharma Innovation & Development. A change of applicant was communicated to MS Ireland and EFSA on 4 April 2019. The new applicant is analyze & realize GmbH, Waldseeweg 6, 13467 Berlin, Germany.

- 1) This application was received by EFSA on 1/08/2018.
- 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 23/10/2018.
- 4) On 28/11/2018, 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 13/12/2018 and was restarted on 24/12/2018, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 5) During its meeting on 15/05/2019, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to an aqueous extract from white kidney bean (*Phaseolus vulgaris* L.) standardised by its  $\alpha$ -amylase inhibitory activity (GlycoLite™) and reduction in body weight.

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## Abbreviations

$\alpha$ -AI1	$\alpha$ -amylase inhibitor isoform 1
AAIU	$\alpha$ -amylase inhibiting units
BIA	Bioelectrical Impedance Analysis
BMI	Body Mass Index
bw	body weight
FAS	Full Analysis Set
GEE	Generalised Estimating Equations
HbA1c	haemoglobin A1c
iAUC	incremental Area Under the Curve
SCFA	short-chain fatty acid
SF-12	12-Item Short Form Health Survey
SHIME	Simulator of the Human Intestinal Microbial Ecosystem
VCAS	Valid Case Analysis Set