

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to Slendesta® Potato Extract and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 19 24/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to Slendesta® Potato Extract 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 Kemin Foods LC, 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 Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Slendesta® Potato Extract and reduction of body weight. The food constituent, Slendesta® Potato Extract, that is the subject of the health claim is sufficiently characterised. The claimed effect, a reduction of body weight, is a beneficial physiological effect for overweight individuals. In weighing the evidence, the Panel took into account that all four human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of Slendesta® Potato Extract on the reduction of body weight. The Panel concludes that a cause and effect relationship has not been established between the consumption of Slendesta® Potato Extract and reduction of body weight.

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KEY WORDS

Slendesta®, potato extract, proteinase inhibitor, body weight, health claims.

¹ On request from the Competent Authority of Belgium following an application by Kemin Foods LC, Question No EFSA-Q-2012-00704, adopted on 24 January 2013.

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SUMMARY

Following an application from Kemin Foods LC, 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 Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Slendesta® Potato Extract 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 constituent that is the subject of the health claim is Slendesta® Potato Extract. The Panel considers that Slendesta® Potato Extract is sufficiently characterised.

The claimed effect proposed by the applicant is reduction of body weight. The target population proposed by the applicant is “overweight adults wishing to lose weight”. The Panel considers that a reduction of body weight is a beneficial physiological effect for overweight individuals.

The applicant provided six reports on four randomised controlled trials (RCTs), two reports on one open label, single-arm study, and one meta-analysis of four of these studies.

The human intervention studies provided lasted between 6 and 20 weeks and examined the effect on body weight of 30 mg and/or 15 mg of proteinase inhibitor 2 (PI2) from Slendesta® Potato Extract to be consumed in two capsules, each taken 30-60 minutes prior to the two major meals.

One of these studies was an open label, single-arm intervention (no control group). The Panel notes that this study was uncontrolled, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The remaining four human intervention studies provided used Satise® Satiety Aid (a food supplement containing Slendesta® Potato Extract as the only active ingredient) as a source of PI2, and magnesium stearate and microcrystalline cellulose as placebo. The number of subjects per group ranged from 20 to 81. Three of these studies were conducted as three-arm studies using doses of 0, 15 and 30 mg of PI2 per day, while one study used a 2x2 factorial design with 15 mg PI2 per day and dietary and lifestyle counselling as variables. In all but one study, in which daily calorie intake was restricted to 1,500 kcal per day, subjects consumed *ad libitum* diets. There was no effect of Slendesta® Potato Extract on reduction of body weight in any of these studies.

The applicant also presented a meta-analysis of four of the five studies presented. The study in which Slendesta® was consumed in the context of an energy restricted diet was not included in this meta-analysis. Upon request from EFSA to clarify why this study was excluded from the analysis, the applicant indicated that the purpose of the meta-analysis was to evaluate the effect of Slendesta® Potato Extract “without changes in lifestyle”. The Panel notes that the purpose of the meta-analysis as claimed by the applicant does not address the conditions of use proposed for the claim (i.e. the dietary and lifestyle conditions in which Slendesta® should be consumed in order to achieve the claimed effect are not specified). The Panel also notes that a study in which Slendesta® was administered together with dietary and lifestyle counselling was included in the meta-analysis, and therefore considers that the study selection is not appropriate to fulfil the purpose of this meta-analysis as claimed by the applicant. The Panel considers that no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claim.

The Panel also notes that in the absence of evidence for an effect of Slendesta® Potato Extract on the reduction of body weight, the data provided by the applicant with respect to potential mechanisms by

which Slendesta® Potato Extract could exert the claimed effect do not provide evidence for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that all four human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of Slendesta® Potato Extract on the reduction of body weight.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Slendesta® Potato Extract 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 26/06/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The application includes a request for the protection of proprietary data.
- On 09/07/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 23/08/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 31/08/2012.
- On 26/10/2012, 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 30/10/2012 and restarted on 14/11/2012, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 19/11/2012, EFSA received the requested information.
- During its meeting on 24/01/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to Slendesta® Potato Extract 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: Slendesta® Potato Extract and reduction of body weight.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Slendesta® Potato Extract, a positive assessment of its safety, nor a decision on whether

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.

Slendesta® Potato Extract 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: Kemin Foods, LC – Kemin Portuguesa A.A, LDA (“Kemin”), Campo Grande, 35, 8^o – D, 1700-087 Lisboa, Portugal.

The application includes a request for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006 (Dana, 2005a, unpublished; Dana, 2005b, unpublished; Hu et al., 2004a, unpublished; Hu et al., 2004b, unpublished; Hu et al., 2004c, unpublished, 2004d, unpublished; Hu et al., 2004e, unpublished; Hu et al., 2005a, unpublished; Hu et al., 2005b, unpublished; Hu et al., 2005c, unpublished; Hu et al., 2010, unpublished; Hu et al., 2011, unpublished; Roberts and Maci, 2012, unpublished; Rogers, 2010, unpublished, 2012, unpublished).

Food/constituent as stated by the applicant

According to the applicant, the food which is the subject of the health claim is Slendesta® Potato Extract (Slendesta®), which is a patented, standardised potato extract produced through extraction of conventional potato (*Solanum tuberosum* L.) tubers. The active component of Slendesta® is proteinase inhibitor 2 (PI2), a natural constituent of potato, which is provided in a 5 % concentration in Slendesta®.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to a reduction of body weight in overweight individuals.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “Slendesta® contributes to the reduction of body weight in overweight individuals”.

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is healthy overweight adults wishing to lose weight. The applicant has proposed a daily intake of 30 mg of PI2 provided by Slendesta®, taken approximately one hour before the two largest meals.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is Slendesta® Potato Extract.

Slendesta® Potato Extract is a powdered food and food supplement ingredient extracted following a patented extraction procedure from whole, raw potato (*Solanum tuberosum* L.) tubers, and is standardised to contain a minimum of 5 % of proteinase inhibitor 2 (PI2) by weight. Besides PI2, Slendesta® Potato Extract also contains other proteinase inhibitors, such as carboxypeptidase inhibitor (CPI) and chymotrypsin inhibitor (PI1). Larger potato proteins, such as patatin, are selectively removed during the manufacturing process. Trypsin inhibition activity ranged between 0.93 and 1.36 mg trypsin/mg PI2 in 12 batches of Slendesta® Potato Extract analysed. Proteinase inhibitors and proteinase inhibition activity can be analysed in foods by established methods.

Information pertaining to the specifications of Slendesta® Potato Extract, the manufacturing process, the batch-to-batch variability and the stability has been provided by the applicant.

The Panel considers that the food constituent, Slendesta® Potato Extract, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect proposed by the applicant is reduction of body weight. The target population proposed by the applicant is “overweight adults wishing to lose weight”.

Weight loss in overweight subjects even without the achievement of a normal body weight is considered to be a beneficial physiological effect.

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

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and Scopus up to January 2012. The following key words were used: (“proteinase inhibitor” OR “protease inhibitor”) AND (“potato”) AND (“weight” OR “cholecystokinin” OR “satiety”). In addition, manual searches were performed. The inclusion criteria for selecting pertinent publications were human intervention studies on body weight using potato extracts.

Human intervention studies on weight loss using potato extracts providing 30 mg PI2 per day were considered by the applicant as directly pertinent to the claim. Human intervention studies on weight loss with doses other than 30 mg PI2 per day, or human intervention studies on satiety and food intake were considered by the applicant as supportive evidence.

Through the literature search performed, the applicant did not identify any published human intervention studies which investigated the effect of protease inhibitors on body weight.

The applicant provided six reports on four randomised controlled trials (RCTs) (Hu et al., 2004a, unpublished; Hu et al., 2004b, unpublished; Hu et al., 2004c, unpublished; Hu et al., 2005a, unpublished; Hu et al., 2010, unpublished; Rogers, 2012, unpublished, all claimed as proprietary by the applicant), two reports on one open label, single-arm study (Dana, 2005a, unpublished; Dana, 2005b, unpublished, claimed as proprietary by the applicant), and one meta-analysis of four of these studies (Hu et al., 2005b, unpublished, claimed as proprietary by the applicant).

The human intervention studies provided lasted between 6 and 20 weeks and examined the effect on body weight of 30 mg and/or 15 mg of PI2 from Slendesta® Potato Extract to be consumed in two capsules each taken 30-60 minutes prior to the two major meals.

One of these studies (Dana, 2005a, unpublished; Dana, 2005b, unpublished) was a single-arm intervention (no control group) in 28 overweight or obese subjects (23 female) in which changes in body weight in response to a supplementation with Slendesta® Potato Extract (30 mg PI2 per day) for up to 20 weeks were assessed. The Panel notes that this study was uncontrolled, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The remaining human intervention studies provided used Satise® Satiety Aid (a food supplement containing Slendesta® Potato Extract as the only active ingredient) as a source of PI2, and magnesium stearate and microcrystalline cellulose as placebo. The Panel notes the short duration of all but one of these studies (Hu et al., 2005a, unpublished) which had a duration of 12 weeks.

In the randomised, double-blind, placebo-controlled, two-centre parallel study by Hu et al. (2005a, unpublished), 240 overweight or obese subjects (196 female, mean age 47.1 ± 9.4 years, BMI $>25 \text{ kg/m}^2$) eating *ad-libitum* were randomised to consume daily placebo capsules (n=80) or identical capsules providing either 30 mg PI2 (n=79) or 15 mg PI2 (n=81) for 12 weeks. Body weight was measured at baseline and weeks 4, 8 and 12 of the study. A total of 196 subjects completed the study (64 in the 30 mg PI2 group, 62 in the 15 mg PI2 group, and 70 in the placebo group). Reasons for drop-outs were reported.

Data were analysed using two different models in SAS PROC MIXED assuming a compound symmetry covariance structure. Model 1 analysed absolute change in weight with treatment, time and centre as fixed factors including all subjects with at least one visit following baseline. Model 2 analysed body weight at different time points with time and treatment as fixed factors including all subjects as randomised and accommodated in the model through the covariance structure. Using model 1, a statistically significant treatment x centre interaction was observed. However, no significant treatment x time interaction with respect to changes in body weight was found between groups over the 12 weeks of the study. Adding centre as a factor in the model did not change the result. No significant treatment x time interaction was observed using model 2 either. The applicant also presented sub-group analyses in non-obese subjects (n=135) (Hu et al., 2010, unpublished) and in non-obese subjects in the 30 mg dose group (n=not reported), both overall and separately by centre (Rogers, 2012, unpublished). Upon a request from EFSA for clarification, the applicant indicated that these sub-group analyses were not pre-planned, and that no interaction analysis which could justify these sub-group analyses was carried out between body weight at baseline and treatment effects. The Panel considers that no conclusions can be drawn from these sub-group analyses for the scientific substantiation of the claim. The Panel notes that this study does not show an effect of Slendesta® Potato Extract on the reduction of body weight.

In the randomised, double-blind, placebo-controlled study by Hu et al. (2004c, unpublished), 93 overweight or obese women (mean age 41.1 ± 14 years, BMI $>25 \text{ kg/m}^2$) were randomised to consume daily placebo capsules or identical capsules providing either 30 mg or 15 mg PI2 (31 subjects per group) in conjunction with an energy restricted diet (1,500 kcal/day). Physical activity was encouraged.

Twenty-six subjects dropped out of the study (reasons for drop-outs were provided by the applicant upon a request from EFSA). Body weight was measured at baseline and at each week throughout the study, and was analysed by a mixed model for repeated measures using SAS PROC MIXED with treatment and time as fixed factors. The analysis was carried out in the population of completers (n=20 in the 30 mg group, n=24 in the 15 mg group, n=23 in the placebo group). Treatment x time interaction with respect to changes in body weight between groups was not statistically significant. The Panel considers that this study does not show an effect of Slendesta® Potato Extract on the reduction of body weight.

In the randomised, double-blind, placebo-controlled study by Hu et al. (2004a, unpublished), 96 overweight or obese women (mean age: 45.2 ± 8.9 years, BMI $>25 \text{ kg/m}^2$) eating *ad libitum* were randomised to consume daily placebo capsules or identical capsules providing either 30 mg or 15 mg PI2 (32 subjects per group) for six weeks.

Nine subjects dropped-out of the study (reasons for drop-outs were provided by the applicant upon a request from EFSA). Body weight was measured at baseline and at weeks 2, 4, and 6 of the study, and was analysed by a mixed model for repeated measures using SAS PROC MIXED with treatment and time as fixed factors. Analysis was carried out in the population of completers (n=29 in the 30 mg group, n=28 in the 15 mg group, n=26 in the placebo group). No statistically significant treatment x time interaction between groups was observed. The Panel considers that this study does not show an effect of Slendesta® Potato Extract on the reduction of body weight.

In the randomised, double-blind, eight-week, placebo-controlled, 2x2 factorial design study by Hu et al. (2004b, unpublished), 92 overweight or obese women (mean age: 37.7 ± 10.6 , BMI $>25 \text{ kg/m}^2$) eating *ad-libitum* were randomised to four groups: 15 mg PI2 (n=23), 15 mg PI2 with counselling (i.e. dietary and lifestyle education and psychological support, n=23), placebo only (n=23) or placebo with counselling (n=23).

Thirteen subjects dropped-out of the study (reasons for drop-outs were provided by the applicant upon a request from EFSA). Body weight was measured at baseline and at weeks 2, 4, 6 and 8 of the study, and was analysed using a mixed model for repeated measures using SAS PROC MIXED with treatment and time as fixed factors. Analysis was carried out in the population of completers (n=17 in the PI2 group, n=20 in the PI2+counselling group, n=22 in the placebo group, n=20 in the placebo+counselling group). Treatment x time interaction with respect to changes in body weight between groups was not statistically significant. When counselling was added to the model, a significant treatment x counselling x time interaction was observed, resulting from an increase in body weight of the group receiving counselling and 15 mg PI2 per day relative to the other groups. The Panel considers that this study does not show an effect of Slendesta® Potato Extract on the reduction of body weight.

The Panel notes that none of the human intervention studies provided showed an effect of Slendesta® Potato Extract on the reduction of body weight.

The applicant also presented a meta-analysis (Hu et al., 2005b, unpublished) of the studies by Dana (2005a, unpublished), Hu et al. (2005a, unpublished), Hu et al. (2004a, unpublished) and Hu et al. (2004b, unpublished). The study by Hu et al. (2004c, unpublished), in which Slendesta® was consumed in the context of an energy restricted diet, was not included in the meta-analysis. Upon a request from EFSA to clarify why this study was excluded from the analysis, the applicant indicated that the purpose of the meta-analysis was to evaluate the effect of Slendesta® Potato Extract “without changes in lifestyle”. The Panel notes that the purpose of the meta-analysis as claimed by the applicant does not address the conditions of use proposed for the claim (i.e. the dietary and lifestyle conditions in which Slendesta® should be consumed in order to achieve the claimed effect are not specified) and therefore considers that no conclusions can be drawn from this meta-analysis for the scientific substantiation of the claim.

With respect to the possible mechanisms by which Slendesta® Potato Extract could exert the claimed effect, the applicant provided five published human intervention studies (Hill et al., 1990; Peikin et al., 1989; Peters et al., 2011; Spiegel et al., 1999; Vasselli et al., 1999) and four unpublished human intervention studies described in seven reports (Hu et al., 2004b, unpublished; Hu et al., 2004d, unpublished; Hu et al., 2004e, unpublished; Hu et al., 2005c, unpublished; Hu et al., 2011, unpublished; Roberts and Maci, 2012, unpublished; Rogers, 2010, unpublished, all claimed as proprietary by the applicant) on the effect of Slendesta® Potato Extract on subsequent appetite ratings and food/energy intake, as well as one systematic review (Vlachoianis et al., 2010) on different applications of PI2. The applicant also provided two human intervention studies investigating the effect of Slendesta® Potato Extract on gastric emptying (Schwartz et al., 1994) and post-prandial blood glucose concentrations (Schwartz et al., 1994; Spreadbury et al., 2003), and one animal study (Komarnytsky et al., 2011) which assessed the effect of a PI2 concentrate other than Slendesta® Potato Extract on food intake, gastric emptying, and post-prandial plasma blood glucose and cholecystokinin concentrations.

The Panel notes that in the absence of evidence for an effect of Slendesta® Potato Extract on the reduction of body weight, the data provided with respect to potential mechanisms by which Slendesta® Potato Extract could exert the claimed effect do not provide evidence for the scientific substantiation of the claim.

In weighing the evidence, the Panel took into account that all four human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of Slendesta® Potato Extract on the reduction of body weight.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Slendesta® Potato Extract and reduction of body weight.

CONCLUSIONS

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

- The food constituent, Slendesta® Potato Extract, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is reduction of body weight. The target population proposed by the applicant is “overweight adults wishing to lose weight”. A reduction of body weight is a beneficial physiological effect for overweight individuals.
- A cause and effect relationship has not been established between the consumption of Slendesta® Potato Extract and reduction of body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on Slendesta® Potato Extract and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0359_BE). August 2012. Submitted by Kemin Foods, LC.

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GLOSSARY AND ABBREVIATIONS

BMI	Body mass index
CPI	Carboxypeptidase inhibitor
PI	Proteinase inhibitor
RCT	Randomised controlled trial