

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts 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}

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ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Cyprus, 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 a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and reduction of body weight. The Panel considers that the food constituent which is the subject of the health claim is sufficiently characterised. The claimed effect, reduction of body weight, is a beneficial physiological effect for overweight subjects. One human intervention study from which no conclusions could be drawn for the scientific substantiation of the claim was provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and a reduction in body weight.

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KEY WORDS

Paullinia cupana, guarana, green tea, *Camellia sinensis*, body weight, health claims

¹ On request from the Competent Authority of Cyprus following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00590, adopted on 28 November 2012.

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SUMMARY

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Cyprus, 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 a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts 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 food constituent that is the subject of the health claim is a combination of guarana and green tea extracts, which are respectively standardised by their content of caffeine and epigallocatechin-3-gallate. The Panel considers that the food constituent, a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts, which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant is “helps to burn fat”. The target population proposed by the applicant is overweight healthy adults in the general population. Upon EFSA’s request for clarification, the applicant stated that the claimed effect to be evaluated was “helps to improve weight loss”, and that “helps to burn fat” was meant for use in the wording for consumer communication. The Panel considers that a reduction of body weight is a beneficial physiological effect for overweight subjects.

One human intervention study, which was undertaken with a green tea extract, was identified by the applicant as pertinent to the health claim. EFSA noted that the food constituent used in this study was not complying with the characterisation of the food for which the claim was requested. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of a health claim on the combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and a reduction in 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 21/05/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 14/06/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 05/07/2012, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 11/07/2012.
- On 12/09/2012, 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 20/09/2012 and restarted on 05/10/2012, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- On 12/10/2012, EFSA received the requested information (which was made available to EFSA in electronic format on 03/10/2012).
- During its meeting on 28/11/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts 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: a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and reduction of body weight.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of guarana and green tea extracts, a positive assessment of its safety, nor a decision

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.

on whether a combination of guarana and green tea extracts 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: Nutrilinks Sarl, Chemin de Beau-rivage 7, Post code 96 CH-1000 Lausanne 21, Switzerland.

Food/constituent as stated by the applicant

According to the applicant, the food constituent that is the subject of the health claim is green tea extract (675 mg), including epigallocatechin-3-gallate, and guarana extract (125 mg), including caffeine.

Health relationship as claimed by the applicant

According to the applicant, the health claim is “helps to burn fat”. The applicant claims that a synergic action between guarana (rich in caffeine) and green tea (rich in epigallocatechin-3-gallate) extracts increases energy expenditure and fat oxidation, and thus may help to improve weight loss.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “helps to burn fat”.

Alternative wordings: “helps to burn calories from fat”, “helps to promote weight loss as a consequence of fat burning”.

Specific conditions of use as proposed by the applicant

According to the applicant, 675 mg of green tea extract and 125 mg of guarana extract should be consumed daily to obtain the claimed effect. The applicant has proposed overweight healthy adults in the general population as the target population.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is a combination of guarana and green tea extracts.

The water soluble dry powder extract of guarana, which is obtained by extraction from the seeds of *Paullinia cupana* Kunth with water, is standardised to contain at least 80 % of caffeine by the addition of “natural” caffeine in an extract/caffeine ratio of 1:6.7.

The water soluble dry powder extract of green tea, which is obtained by extraction from the leaves of *Camellia sinensis* (L.) Kuntze with water, is standardised to contain at least 80 % of catechins of which 50 % is epigallocatechin-3-gallate (EGCG). According to the control specifications provided by the applicant, the green tea extract contains negligible amounts of caffeine (<1 %).

EGCG and caffeine can be measured in foods by established methods.

The combination of the dry powder extracts is proposed to be used in food supplements, with no reference to any specific formulation, in a quantity of 125 mg of guarana and 675 mg of green tea extracts per serving.

Information pertaining to the manufacturing process, control specifications (by HPLC), batch-to-batch variability and stability tests has been provided by the applicant.

Upon EFSA's request for clarification, the applicant confirmed that the food constituent that was the subject of this application was the combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts described above, rather than a combination of caffeine and EGCG from any source.

The Panel considers that the food constituent, a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts, 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 "helps to burn fat". The target population proposed by the applicant is overweight healthy adults in the general population.

Upon EFSA's request for clarification, the applicant stated that the claimed effect to be evaluated was "helps to improve weight loss", and that "helps to burn fat" was meant for use in the wording for consumer communication.

Weight loss can be interpreted as the achievement of a normal body weight in previously overweight subjects. Even a moderate weight loss without achieving a normal body weight in this population subgroup is considered a beneficial physiological effect.

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

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed/Medline, Science Direct, Google Scholar, IBIDS, Scopus, Scirus and Google using the search terms [(“caffeine” OR “Guarana extract”) AND (“catechine” OR “green tea extract” OR “EGCG”)] AND (“fat oxidation” OR “energy expenditure”) to identify human intervention studies performed with a combination of catechin and caffeine at doses of 270 mg and 100 mg or lower, respectively, with body weight as an outcome. The time span covered by the search was not indicated. The Panel notes the limitations of the literature search performed.

The applicant identified one human intervention study as pertinent to the health claim (Auvichayapat et al., 2008). In a request for clarification sent to the applicant, EFSA noted that the food constituent used in this study (i.e. a green tea extract) was not complying with the characterisation of the food for which the claim was requested. The applicant argued that the amounts of caffeine and EGCG provided by the green tea extract used in the study (i.e. 86 mg and 100 mg daily, respectively) were “similar” to those provided by the combination of guarana and green tea extracts (100 mg of caffeine and 270 mg of EGCG) for which the claim was made. However, the applicant confirmed for the second time that the claim was being requested for the combination of guarana and green tea extracts, and not for a combination of caffeine and EGCG from any source. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of a health claim on the combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts.

The Panel notes that no studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and a reduction in body weight.

CONCLUSIONS

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

- The food constituent, a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “helps to burn fat”. The target population proposed by the applicant is overweight healthy adults in the general population. Reduction of body weight is a beneficial physiological effect for overweight subjects.
- A cause and effect relationship has not been established between the consumption of a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and a reduction in body weight.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of *Paullinia cupana* Kunth (guarana) and *Camellia sinensis* (L.) Kuntze (green tea) extracts and reduction of body weight pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0353_CY). May 2012. Submitted by Nutrilinks Sarl.

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GLOSSARY/ABBREVIATIONS

| | |
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| EGCG | Epigallocatechin-3-gallate |
| HPLC | High-performance liquid chromatography |