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EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to a combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bicoloured” spinach and “blu savoy” cabbage and maintenance of normal blood LDL-cholesterol concentration 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 combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood LDL-cholesterol concentration 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 Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, 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 Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood cholesterol concentration. The food that is the subject of the health claim, a combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” spinach (*Spinacia oleracea* L.) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.), is sufficiently characterised. The claimed effect, maintenance of normal blood LDL-cholesterol concentration, is a beneficial physiological effect. No human intervention 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 consumption of a combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood LDL-cholesterol concentration.

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KEY WORDS

black cabbage, Swiss chard, spinach, cabbage, cholesterol, LDL-cholesterol, health claims

¹ On request from the Competent Authority of Italy following an application by Italsur s.r.l., Question No EFSA-Q-2013-00576, adopted on 09 October 2013.

² Panel members: Carlo Agostoni, Roberto Berni Canani, Susan Fairweather-Tait, Marina Heinonen, Hannu Korhonen, Sébastien La Vieille, Rosangela Marchelli, Ambroise Martin, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Sean (J.J.) Strain, Inge Tetens, Daniel Tomé, Dominique Turck and Hans Verhagen. Correspondence: nda@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from Italsur s.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, 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 Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood cholesterol concentration.

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.

The food that is the subject of the health claim is a combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.) (## %), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.) (## %), “bi-coloured” spinach (*Spinacia oleracea* L.) (## %) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.) (## %). The Panel considers that a combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage, which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant is “maintenance of normal blood cholesterol concentration”. The target population proposed by the applicant is the general population. The Panel considers that maintenance of normal blood LDL-cholesterol concentration is a beneficial physiological effect.

The applicant identified one unpublished human study, seven published human intervention studies and four human observational studies as being pertinent to the claim.

All 11 published human studies did not use or refer to the food which is the subject of the claim. The applicant also referred to 19 reviews, seven guidelines, and eight animal and five *in vitro* studies, none of which contained data on the food which is the subject of the claim. The Panel notes that none of these studies can be used for the scientific substantiation of the claim.

Only one human intervention study (Bacchetti and Ferretti, unpublished, claimed as proprietary) was performed with the combination of the four vegetables which is the subject of the claim. This study was an open label single-arm intervention in which 38 healthy volunteers (23 females, mean age 41 ± 14 years) consumed daily for 14 days a portion (i.e. 300 g) of the food. The Panel considers that no conclusions can be drawn from this uncontrolled (single arm) study for the scientific substantiation of the claim.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between consumption of the combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” red and yellow spinach (*Spinacia oleracea* L.) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.) and maintenance of normal blood LDL-cholesterol concentration.

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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 11/06/2013.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- The scientific evaluation procedure started on 17/07/2013.
- During its meeting on 09/10/2013, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and maintenance of normal blood LDL-cholesterol concentration.

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 Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage and maintenance of normal blood LDL-cholesterol concentration.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage, a positive assessment of its safety, nor a decision on whether a combination of Tuscan black cabbage, "tri-coloured" Swiss chard, "bi-coloured" spinach and "blu savoy" cabbage 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.

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.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Italsur s.r.l., C. da Pianura Vomano, 64024 – Notaresco, Teramo, Italy.

The application includes a request for the protection of proprietary data for one unpublished study (Bacchetti and Ferretti, unpublished) in accordance with Article 21 of Regulation (EC) No 1924/2006.

Food as stated by the applicant

According to the applicant, the food is “Black cabbage mix”, which is a frozen mix containing: Tuscan black cabbage (*Brassica Oleracea botrytis* L. or Nero di Toscana or Black Palm Tree), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” spinach (*Spinacia oleracea* L.) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.).

Health relationship as claimed by the applicant

According to the applicant, the claimed effect is maintaining normal blood cholesterol concentration. This effect is related to their peculiar chemical composition. This vegetable mix “Black cabbage mix” is a source of essential nutrients such as vitamins and minerals and contains several compounds such as plant fibres and phytonutrients (polyphenols, phytosterols, carotenoids) which play regulatory roles of metabolism and cellular functions. All these bioactive compounds could act synergically on the cholesterol lowering effect.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: “maintains normal blood cholesterol concentration”.

Specific conditions of use as proposed by the applicant

The applicant has proposed a daily intake of a portion of 300 g of “Black cabbage mix” for two weeks. Consumption should be included in the normal daily diet as a side dish, and no specific time of consumption or accompanying meal or preparation is established. The target population is the general population.

ASSESSMENT

1. Characterisation of the food

The food that is the subject of the health claim is “Black cabbage mix”, which is a combination of four vegetables: Tuscan black cabbage (*Brassica Oleracea botrytis* L.) (## %), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.) (## %), “bi-coloured” red and yellow spinach (*Spinacia oleracea* L.) (## %) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.) (## %). One box contains 300 g of frozen vegetables.

The detailed nutritional composition of the combination of four vegetables was given. An overview of the manufacturing process was provided, together with stability data and information regarding batch-to-batch variability.

The Panel considers that a combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” red and yellow spinach (*Spinacia oleracea* L.), and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.), 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 refers to “maintaining normal blood cholesterol concentration”. The target population proposed by the applicant is the general population.

Low-density lipoproteins (LDL) carry cholesterol to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention > 160 mg/dL (> 4.1 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant performed a literature search in PubMed and Cochrane Library databases using the following key terms: “cholesterol”, “total cholesterol”, “low density lipoprotein”, “lipids”, “lipid metabolism”, “lipoprotein metabolism”, “cardiovascular disease” and “hypercholesterolemia” cross-referenced with “green vegetable”, “vegetable”, “green leafy vegetable”, “spinach”, “chard”, “chicory” and “black cabbage” with a time frame from 1966 to February 2013. A manual search was also performed.

The applicant identified one unpublished human study, seven published human intervention studies and four human observational studies as being pertinent to the claim.

All 11 published human studies did not use or refer to the food which is the subject of the claim. The applicant also referred to 19 reviews, seven guidelines, and eight animal and five *in vitro* studies, none of which contained data on the food which is the subject of the claim. The Panel notes that none of these studies can be used for the scientific substantiation of the claim.

Only one human intervention study (Bacchetti and Ferretti, unpublished, claimed as proprietary) was performed with the combination of the four vegetables which is the subject of the claim. This study was an open label single-arm intervention in which 38 healthy volunteers (23 females, mean age 41 ± 14 years) consumed daily for 14 days a portion (i.e. 300 g) of the food. The Panel considers that no conclusions can be drawn from this uncontrolled (single arm) study for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between consumption of a combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” red and yellow spinach (*Spinacia oleracea* L.) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.) and maintenance of normal blood LDL-cholesterol concentration.

CONCLUSIONS

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

- The food, a combination of Tuscan black cabbage (*Brassica Oleracea botrytis* L.), “tri-coloured” Swiss chard (*Beta vulgaris cicla* L.), “bi-coloured” red and yellow spinach (*Spinacia oleracea* L.) and “blu savoy” cabbage (*Brassica oleracea* convar. *capitata* var. *sabauda* L.), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is “maintenance of normal blood cholesterol concentration”. The target population as proposed by the applicant is the general population. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between consumption of a combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood LDL-cholesterol concentration.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of Tuscan black cabbage, “tri-coloured” Swiss chard, “bi-coloured” spinach and “blu savoy” cabbage and maintenance of normal blood LDL-cholesterol concentration pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0385_IT). July 2013. Submitted by Italsur s.r.l.

REFERENCES

Bacchetti T and Ferretti G, 2013. Effect of consumption of “Black cabbage mix” on lipid profile and lipid peroxidation: a short-term human intervention study (not published). Protocol No 211525. Polytechnic University of Marche (UNIVPM), Italy.

ABBREVIATIONS

LDL low-density lipoproteins