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Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration: evaluation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA),
Dominique Turck, Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait,
Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle,
Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva,
Yolanda Sanz, Anders Sjödin, Martin Stern, Daniel Tomé, Henk Van Loveren, Marco Vinceti,
Peter Willatts, Ambroise Martin, John Joseph Strain and Alfonso Siani

Abstract

Following an application from Loc Troi group, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the Netherlands, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood cholesterol concentrations. The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence. The food proposed by the applicant as the subject of the health claim is Vibigaba. The Panel considers that the germinated brown rice Vibigaba is sufficiently characterised. The claimed effect proposed by the applicant is 'contribution to the maintenance of normal blood cholesterol levels'. The Panel considers that maintenance of normal blood cholesterol concentrations is a beneficial physiological effect. The Panel notes that the applicant did not perform a comprehensive literature search to identify human intervention studies which could be pertinent to the claim. The applicant did not reply to a specific request from EFSA to provide this information. The applicant identified one human intervention study as being pertinent to the claim. The Panel notes the important methodological limitations of the study (e.g. statistical methods used for data analysis not appropriate for the study design) and that the information provided on the design and conduct of the study is insufficient for a complete scientific evaluation. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration.

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Keywords: germinated brown rice, Vibigaba, blood cholesterol, health claim

Requestor: Competent Authority of the Netherlands following an application by Loc Troi Group

Question number: EFSA-Q-2017-00030

Correspondence: nda@efsa.europa.eu

Panel members: Jean-Louis Bresson, Barbara Burlingame, Tara Dean, Susan Fairweather-Tait, Marina Heinonen, Karen Ildico Hirsch-Ernst, Inge Mangelsdorf, Harry J McArdle, Androniki Naska, Monika Neuhäuser-Berthold, Grażyna Nowicka, Kristina Pentieva, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Martin Stern, Daniel Tomé, Dominique Turck, Hendrik Van Loveren, Marco Vinceti and Peter Willatts.

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Summary

Following an application from Loc Troi group, submitted for authorisation of a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of the Netherlands, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to Vibigaba (germinated brown rice) and contribution to the 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 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 and the guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health.

The food proposed by the applicant as the subject of the health claim is Vibigaba (germinated brown rice). The Panel considers that the germinated brown rice Vibigaba, which is the subject of the health claim, is sufficiently characterised.

The claimed effect proposed by the applicant is 'contribution to the maintenance of normal blood cholesterol levels'. The proposed target population is 'adults with metabolic syndrome'. The Panel considers that maintenance of normal blood cholesterol concentration is a beneficial physiological effect.

The Panel notes that the applicant did not perform a comprehensive literature search to identify human intervention studies which could be pertinent to the claim other than the one provided by the applicant. The applicant did not reply to a specific request from the European Food Safety Authority (EFSA) to provide this information.

The applicant identified one human intervention study as being pertinent to the claim. The Panel notes the important methodological limitations of the study (e.g. statistical analysis not appropriate for the study design) and that the information provided on the design and conduct of the study is insufficient for a complete scientific evaluation. Upon a request from EFSA to provide additional information on the study which would allow a full scientific evaluation, the applicant did not reply. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claim.

On the basis of the data provided, the Panel concludes that a cause and effect relationship has not been established between the consumption of Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration.

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.....	6
3.3. Scientific substantiation of the claimed effect.....	7
4. Conclusions.....	8
Steps taken by EFSA.....	8
References.....	8
Abbreviations.....	8

1. Introduction

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

Regulation (EC) No 1924/2006¹ 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: Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood cholesterol concentration.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of Vibigaba, a positive assessment of its safety, nor a decision on whether Vibigaba 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 Vibigaba (germinated brown rice).

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to: 'contribution to the maintenance of normal blood cholesterol levels. During the human intervention study provided, the changes of the blood cholesterol levels were obtained. The conclusion of the study is that after three months of intervention, cholesterol, triglycerides and LDL cholesterol decreased in the intervention group compared with the control group, $p > 0.05$ '.

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

No information provided.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: 'contributes to the maintenance of normal blood cholesterol levels'.

¹ 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 adults with metabolic syndrome between 55 and 70 years of age. The product should be used 100 g/meal, 2 meals/day for 3 months. Vibigaba should be cooked 45–60 min with the ratio between brown rice and water 1/1.5. The rice should not be washed before cooking.

Data provided by the applicant

Health claim application on Vibigaba (germinated brown rice) and contribution to the maintenance of normal blood cholesterol level and 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.²

As outlined in the General guidance for stakeholders on health claim applications,³ 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 antioxidants, oxidative damage and cardiovascular health are outlined in a specific EFSA guidance (EFSA NDA Panel, 2011).

3. Assessment

3.1. Characterisation of the food/constituent

The food proposed by the applicant as the subject of the health claim is Vibigaba (germinated brown rice).

The nutritional composition of Vibigaba was provided. The content of protein, carbohydrate and fat per 100 g of the uncooked product is 10.0 g, 72.1 g, and 3.6 g (0.8 g saturated fat, 1.6 g monounsaturated fat and 1.2 g polyunsaturated fat), respectively. Vibigaba also contains dietary fibre (3.9 g/100 g), sugars (< 0.2 g/100 g), sodium (20 mg/100 g), calcium (10 mg/100 g), vitamin B1 (0.24 mg/100 g) and vitamin E (1.0 mg/100 g). The Panel notes that batch-to-batch variability and stability data were not provided.

The manufacturing process is described in the application. Fresh paddy (the whole plant) is dried until maximum moisture of 15.5% is reached. Paddy is rinsed to eliminate impurities and then soaked at a temperature of 28–30°C within 24–48 h to initiate the germination stage. After soaking, the germ grows until it is 0.2 mm long (approximately for 24–36 h), then, it is dried, dehusked, sorted and packed.

The Panel considers that the germinated brown rice Vibigaba, 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 'contribution to the maintenance of normal blood cholesterol levels'. The proposed target population is 'adults with metabolic syndrome'.

Low-density lipoproteins (LDLs) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention > 160 mg/dL (> 4.14 mmol/L), may compromise the normal structure and function of the arteries. High-density lipoproteins (HDLs) act as cholesterol scavengers and are involved in the reverse transport of cholesterol in the body (from peripheral tissues back to the liver).

The Panel considers that maintenance of normal blood cholesterol concentration is a beneficial physiological effect.

² EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2017. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal 2011;9(5):2170, 36 pp. <https://doi.org/10.2903/j.efsa.2011.2170>

³ 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>

3.3. Scientific substantiation of the claimed effect

The applicant identified one human intervention study as being pertinent to the claim. The Panel notes that the applicant did not perform a comprehensive literature search to identify human intervention studies which could be pertinent to the claim other than the one provided by the applicant. The applicant did not reply to a specific request from EFSA to provide this information.

In a randomised, two-arm, open-label, parallel study, Mai and Huong (2016), unpublished study report) investigated the effects of Vibigaba germinated brown rice in subjects with metabolic syndrome living in Vietnam.

A two-step procedure for the recruitment of eligible subjects was used. In the first step, subjects aged 55–70 years with waist circumference > 90 cm (men) or > 80 cm (women) and arterial blood pressure between 130/85 and 140/90 mmHg, who did not suffer from chronic diseases, were included. In a second step, subjects having at least three out of the five National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III) diagnostic criteria for metabolic syndrome for Asian populations were included.

Participants were randomly assigned to consume either Vibigaba germinated brown rice (100 g/meal, 2 meals daily) or the same amount of white rice (control group) for 3 months. Paired randomisation was used, taking into account three age groups (55–59 years; 60–65 years and 66–70 years) and sex. The Panel notes that no other information on the randomisation procedure used to allocate subjects to the two study groups was provided.

All participants were instructed to consume rice as part of their usual diet, which should remain unchanged throughout the study. Participants received Vibigaba every 10 days during the entire intervention period (3 months). It is unclear from the study report whether white rice was provided to the control group or not. Instructions for cooking the rice were provided to participants.

The quantity of rice consumed was recorded daily by the participants. The investigators checked randomly the amount of rice available at the participants' houses. All participants were asked to record information related to their diet and physical exercise. Nutrient intakes were assessed by a semiquantitative food frequency questionnaire (FFQ), which focused on foods rich in fibre, carbohydrate and fat using the food composition tables for Vietnam. No other information was provided about the characteristics of the FFQ (e.g. number of questions, validation, time period to which it refers) or its use in the study (e.g. time of administration, self-administered vs dietitian interview).

Information about medication use during the study was not provided.

The primary outcomes of the study were glycated haemoglobin (HbA1c), blood concentrations of triglycerides and plasma malondialdehyde (MDA). Secondary outcome variables included body weight, body mass index (BMI), waist circumference, arterial blood pressure, stool consistency, total cholesterol, HDL-cholesterol, LDL-cholesterol, and fasting blood glucose and insulin, which were measured at the start and at the end of the study.

Three separate sample size calculations were made, using a power of 80% and $\alpha < 0.05$:

- HbA1c, with an expected difference between the two groups at the end of the study of 0.23% and a SD of the difference = 0.15%, $n = 32$ subjects per group;
- blood concentrations of triglycerides, with an expected difference between the two groups of 0.4 mmol/L and a SD of the difference = 0.22 mmol/L, $n = 34$ subjects per group;
- plasma MDA, with a difference between the two groups of 0.14 mmol/L and a SD of the difference = 0.10 mmol/L, $n = 25$ subjects per group.

Allowing for a drop-out rate of 20%, the sample size needed in relation to the three primary outcomes was specified as 80 participants (40 per group).

The Panel notes that changes in blood cholesterol concentrations (LDL-cholesterol and HDL-cholesterol) were not a primary outcome of the study.

A Student's t-test was used for statistical analysis of the results. Multiple testing was not considered in data analysis. The Panel notes that the statistical analysis used is not appropriate for the study design.

While 976 subjects were screened, 86 subjects were randomised ($n = 43$ per group) and 80 participants ($n = 40$ per group) completed the study. Six subjects (three in the Vibigaba group and three in the control group) dropped out 'due to personal health reasons'. The Panel notes that the results are reported for completers only and that information related to the treatment of missing data was not provided.

Upon a request from EFSA to provide additional information on the study which would allow a full scientific evaluation, the applicant did not reply.

The Panel notes the important methodological limitations of the study (e.g. statistical analysis not appropriate for the study design) and that the information provided on the design and conduct of the study is insufficient for a complete scientific evaluation. The Panel considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided from which conclusions can be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of Vibigaba (germinated brown rice) and maintenance of normal cholesterol concentrations.

4. Conclusions

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

- The food/constituent, Vibigaba (germinated brown rice), which is the subject of the health claim, is sufficiently characterised.
- The claimed effect proposed by the applicant is 'contribution to the maintenance of normal blood cholesterol levels'. The target population proposed by the applicant is 'adults with metabolic syndrome'. Maintenance of normal blood cholesterol concentration is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration.

Steps taken by EFSA

Health claim application on 'Vibigaba (germinated brown rice)' and 'maintenance of normal blood cholesterol levels' pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0453_NL). Submitted by Loc Troi Group, 23 Ha Hoang Ho Street, Long Xuyen City, An Giang Province, Vietnam represented by Etiketteren.nl, Vughterweg 47Q, 5211 CK Den Bosch, The Netherlands.

- 1) This application was received by EFSA on 9/1/2017.
- 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 17/2/2017.
- 4) On 23/3/2017, 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 13/4/2017 and was restarted on 28/4/2017, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
- 5) During its meeting on 27/6/2017, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to Vibigaba (germinated brown rice) and maintenance of normal blood cholesterol concentration.

References

- EFSA NDA Panel (Panel on Dietetic Products, Nutrition and Allergies), 2011. Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. EFSA Journal 2011;9(12):2474, 13 pp. <https://doi.org/10.2903/j.efsa.2011.2474>
- 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>
- Mai TT and Huong TTG, 2016, unpublished study report. Effects of Vibigaba germinated brown rice on the metabolic syndrome patients 55–70 aged in Bac Ninh.

Abbreviations

BMI	body mass index
FFQ	food frequency questionnaire
HbA1c	haemoglobin A1c
HDL	high-density lipoprotein

LDL	low-density lipoprotein
MDA	malondialdehyde
NCEP	ATP National Cholesterol Education Program Adult Treatment Panel
NDA	EFSA Panel on Dietetic Products, Nutrition and Allergies
SD	standard deviation