EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations pursuant to Article 14 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 plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Health Concern B.V., submitted for authorisation of a claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the Netherlands, 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 plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations. The food which is the subject of the health claim is a combination of plant sterols (free and in esterified form) and Cholesternorm®mix and provides at the levels of the proposed conditions of use around 0.52 g plant sterols, 0.95 g linoleic acid, 0.13 g alpha-linolenic acid and 0.13 g pectins per day. The combination of plant sterols and Cholesternorm®mix, which is the subject of the claim, is sufficiently characterised in relation to the claimed effect. Reduction of blood LDL-cholesterol concentrations is a beneficial physiological effect. A reduction in blood LDL-cholesterol concentrations reduces the risk of coronary heart disease. The Panel notes that no evidence was provided that plant sterols or constituents other than plant sterols in Cholesternorm®mix, which have a role in the claimed effect, could reasonably be expected to have an effect on blood LDL-cholesterol concentrations at the proposed conditions of use. The Panel notes that no human interventions studies were provided from which conclusions could be drawn for the scientific substantiation of the claim. A cause and effect relationship has not been established between the consumption of a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations at the proposed conditions of use.

KEY WORDS

Plant sterols, Cholesternorm®mix, blood cholesterol, LDL-cholesterol, health claims.

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[1] On request from the Competent Authority of the Netherlands following an application by Health Concern B.V., Question No EFSA-Q-2009-00237, EFSA-Q-2011-01114, adopted on 27 June 2012.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. 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, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen for the preparatory work on this scientific opinion.

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SUMMARY

Following an application from Health Concern B.V., submitted for authorisation of a claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of the Netherlands, 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 plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations.

The scope of the application was proposed to fall under a health claim referring to disease risk reduction.

The food constituent that is the subject of the health claim (originally for Claim Serial No 0314_NL and after clarification for Claim Serial No 0239_NL) is "plant sterols in combination with Cholesternorm®mix". The food, which is the subject of the claim, provides, at the levels of the proposed conditions of use, around 0.52 g plant sterols, 0.95 g linoleic acid, 0.13 g alpha-linolenic acid and 0.13 g pectins per day. The Panel considers that the food constituent, a combination of plant sterols (free and in esterified form) and Cholesternorm®mix, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

The claimed effect is "plant sterols together with the Cholestemorm@mix of cholesterol lowering ingredients lowers LDL-cholesterol". The target population proposed by the applicant is individuals who wish to reduce their blood cholesterol levels. The Panel considers that reduction of blood LDL-cholesterol concentrations is a beneficial physiological effect. A reduction in blood LDL-cholesterol concentrations reduces the risk of coronary heart disease.

No information on the literature search strategy used to identify the body of pertinent scientific data for the scientific substantiation of the claim has been provided by the applicant. The Panel considers that the criteria and process used by the applicant for the identification and selection of data is unclear, may be subject to bias, and does not allow an evaluation of whether the totality of the scientific evidence, which may be pertinent for the scientific substantiation of the claim, has been provided.

The applicant provided seven published human intervention studies on plant sterols and stanols and one unpublished human intervention study (claimed to be proprietary) on plant sterols in combination with Cholesternorm®mix on blood cholesterol concentrations for the scientific substantiation of the claim.

In the randomised, double-blind, placebo-controlled parallel study which investigated the effect of the combination of plant sterols and Cholesternorm®mix on blood cholesterol concentrations, 54 healthy male subjects were randomised to consume daily either intervention or control spreads for six weeks. The Panel notes that even though the applicant was requested during the validation period to provide the full study report, only a summary report was submitted. The Panel also notes that the composition of the control spread, which contained around twice the amount of alpha-linolenic acid and of linoleic acid than the intervention spread as well as a comparable amount of fibres, did not allow conclusions to be drawn on an effect of the combination of plant sterols and Cholesternorm®mix on blood cholesterol concentrations and that there is uncertainty whether the study was properly randomised. The Panel also notes that only per protocol analysis was presented, that baseline values and repeated measures were not taken into account in the analysis, that a requested re-analysis of data was not presented by the applicant and that the set of raw data provided was incomplete. The Panel considers that owing to the major methodological limitations of this study no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that none of the human intervention studies provided on plant sterols and stanols alone investigated dose ranges in line with the proposed conditions of use and considers that these

studies do not provide any additional information to the Panel's previous evaluations of claims on plant sterols and stanols and maintenance/reduction of blood LDL-cholesterol concentrations, which have been assessed with favourable outcomes.

The Panel notes that no evidence was provided that plant sterols or constituents other than plant sterols in Cholesternorm®mix, which have a role in the claimed effect, could reasonably be expected to have an effect on blood LDL-cholesterol concentrations at the proposed conditions of use.

The Panel notes that no human interventions studies were provided from which conclusions could 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 a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations at the proposed conditions of use.

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BACKGROUND

Regulation (EC) No 1924/2006[4] 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, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation 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 applications were received on 03/02/2009 (Claims Serial No 0239_NL) and on 14/10/2011 (Claims Serial No 0314_NL).
- The scope of the applications was proposed to fall under a health claim referring to disease risk reduction and the applications include requests for the protection of proprietary data.
- For Claims Serial No 0239_NL, which was related to a claim on plant sterols and reduction of blood cholesterol concentrations, EFSA sent a request for clarification to the Competent Authority of the Netherlands on 22/04/2009.
- On 26/06/2009, the applicant expressed his intention to EFSA to withdraw the application Claims Serial No 0239_NL.
- The Competent Authority of the Netherland informed EFSA on 19/11/2009 that the withdrawal of the application Claims Serial No 0239_NL could not be confirmed.
- On 11/10/2011, EFSA requested the Competent Authority of the Netherlands to clarify the status of application Claims Serial No 0239_NL.
- On 07/11/2011, the Competent Authority of the Netherlands informed EFSA that the applicant expressed his wish to proceed with the evaluation of the application Claims Serial No 0239_NL.
- On 04/11/2011 (Claims Serial No 0314_NL) and on 09/11/2011 (Claims Serial No 0239_NL), during the validation period of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information for Claims Serial No 0239_NL and Claims Serial No 0314_NL on 09/02/2012 and requested that the food which is the subject of the claim for Claims Serial No 0239_NL to be amended from plant sterols to plant sterols in combination with Cholesternorm®mix.
- The scientific evaluation procedure started on 20/02/2012.
- During its meeting on 21-23 March 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, and the clock was stopped on 26/03/2012 in compliance with Article 16(1) 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.

- On 06/06/2012, EFSA received the requested information as submitted by the applicant and the clock was restarted.
- During its meeting on 27/06/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 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 plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of a combination of plant sterols and Cholesternorm®mix, a positive assessment of its safety, nor a decision on whether a combination of plant sterols and Cholesternorm®mix 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 17 of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Health Concern B.V., Randhoeve 225a 3995 GA Houten, the Netherlands.

The applications include requests for the protection of proprietary data in accordance with Article 21 of Regulation (EC) No 1924/2006

Food/constituent as stated by the applicant

According to the applicant, the food, which is the subject of the claim for Claim Serial No 0314_NL, is plant sterols and a mix of ingredients (Cholesternorm®mix) used in fat based product including fat spreads and low-fat products. The mix is a combination of ingredients: high oleic sunflower oil, omega 6 from sunflower oil, inulin, sunflower lecithin, primrose oil, safflower oil, vitamin A, E, B3, B6, folic acid, D3, B12, omega 3 from fish oil, shellac, apple pectin, choline, anti-oxidant: E304, E306 and plant sterols. The ratio plant sterols: mix is 1:8.9. For Claim Serial No 0239_NL the initial application was made for a claim on plant sterols alone. During the validation of the application, the applicant requested that the food which is the subject of the claim for Claims Serial No 0239_NL to be amended from plant sterols to plant sterols in combination with Cholesternorm®mix in line with Claim Serial No 0314_NL.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect relates to: "Plant sterols together with the Cholestemorm®mix of cholesterol lowering ingredients lowers LDL-cholesterol. Not only the plant sterols but also the ingredients of the Cholestemorm®mix contribute to the cholesterol lowering effect."

Wording of the health claim as proposed by the applicant

The following wording is proposed by the applicant: "Actively lowers cholesterol."

Specific conditions of use as proposed by the applicant

The applicant proposes the target population to be people who want to lower their cholesterol level and the quantity to be consumed to be three portions (30 grams) per day of the spread, which is corresponding to 0.52 grams of plant sterols and 4.5 grams of Cholestemorm®mix per day.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim (originally for Claim Serial No 0314_NL and after clarification for Claim Serial No 0239_NL) is plant sterols in combination with Cholesternorm®mix.

Plant sterols are naturally occurring compounds structurally similar to cholesterol. Plant sterols are derived from vegetable oil (such as soybean or rape seed oil) or from tall oil sterols (wood sterols). Throughout this opinion, quantities of plant sterols are expressed as the equivalent weights of free (i.e. un-esterified) plant sterols.

Cholesternorm®mix is a mixture of different plant oils, fish oil, lecithin, inulin, pectins, choline, shellac wax and vitamins, and contains around 21 wt% linoleic acid (LA), 3 wt% alpha-linolenic acid (ALA) and 3 wt% pectins. The exact composition of the mixture and the fatty acid profile has been provided by the applicant. The food constituent, which is the subject of the claim, provides, at the levels of the proposed conditions of use, around 0.52 g plant sterols, 0.95 g LA, 0.13 g ALA and 0.13 g pectins per day.

The Panel considers that the food constituent, a combination of plant sterols (free and in esterified form) and Cholesternorm®mix, which is the subject of the health claim, is sufficiently characterised in relation to the claimed effect.

2. Relevance of the claimed effect to human health

The claimed effect is "plant sterols together with the Cholestemorm®mix of cholesterol lowering ingredients lowers LDL-cholesterol". The target population proposed by the applicant is individuals who wish to reduce their blood cholesterol levels.

Coronary heart disease (CHD) is a leading cause of mortality and morbidity in European populations with over 1.9 million deaths in the European Union and over 4.35 million deaths in Europe each year (Petersen et al., 2005). Elevated blood cholesterol is an important modifiable risk factor in the development of CHD (WHO, 2002).

It has been shown that blood cholesterol can be decreased by drugs, and by dietary and lifestyle changes (Denke, 2005; Gordon, 2000; Katan et al., 2003; Law, 2000; Ornish et al., 1998; Pedersen et al., 2005; Van Horn et al., 2008).

The Panel considers that reduction of blood LDL-cholesterol concentrations is a beneficial physiological effect. A reduction in blood LDL-cholesterol concentrations reduces the risk of CHD.

3. Scientific substantiation of the claimed effect

Claims on plant sterols/stanols in amounts of 0.8 g/day, on LA in amounts of 1.5 g/day, on ALA in amounts of 0.3 g/day, and on pectins in amounts of 6 g/day and maintenance/reduction of blood LDL-cholesterol concentrations have already been assessed by the Panel with favourable outcomes (EFSA, 2008a, 2008b, 2009a, 2009b; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a, 2009b, 2010a, 2010b), while the food constituent, which is the subject of the claim, provides, at the levels of the proposed conditions of use, around 0.52 g plant sterols, 0.95 g LA, 0.13 g ALA and 0.13 g pectins per day.

No information on the literature search strategy used to identify the body of pertinent scientific data for the scientific substantiation of the claim has been provided by the applicant. Upon request from EFSA to specify the search strategy, the applicant provided general information on the strategy for selecting the food constituents, which are the subject of the claim, but did not submit any further details on the literature search strategy. The Panel considers that the criteria and process used by the applicant for the identification and selection of data is unclear, may be subject to bias, and does not allow an evaluation of whether the totality of the scientific evidence, which may be pertinent for the scientific substantiation of the claim, has been provided.

The applicant provided seven published human intervention studies on plant sterols and stanols (Amundsen et al., 2002; Cleghorn et al., 2003; Hendriks et al., 1999; 2003; Jones et al., 2000; Miettinen et al., 1995; Weststrate and Meijer, 1998) and one unpublished human intervention study (claimed to be proprietary) on plant sterols in combination with Cholesternorm®mix on blood cholesterol concentrations (Beukelman, 2008, unpublished; Gutjahr et al., 2006, unpublished) for the scientific substantiation of the claim.

In the randomised, double-blind, placebo-controlled parallel study which investigated the effect of the a combination of plant sterols and Cholesternorm®mix on blood cholesterol concentrations (Beukelman, 2008, unpublished; Gutjahr et al., 2006, unpublished), 54 healthy male subjects (mean age: 49.7 years) with mean baseline LDL-cholesterol concentrations of 3.35±0.70 mmol/L were randomised to consume daily either 30 g of "Double Active" spread, which contained 0.51 g plant sterols (0.87 g plant sterol esters) and 4.5 g Cholesternorm®mix (containing i.a. 0.95 g/day LA, 0.13 g/day ALA and 0.13 g/day pectins) (n=25) or 30 g of a conventional spread (control, n=29) divided into three equal portions per day for six weeks. The content of ALA and LA in the control spread was around twice the content in the intervention spread and both spreads had a comparable amount of fibres.

Upon request from EFSA to specify the method of randomisation of subjects, the applicant indicated that the test products were coded and were randomly assigned to subjects but did not provide any further information about the generation of codes or the method of assigning the products to subjects.

Blood lipids were measured at baseline and weeks three and six. Five subjects were excluded from analysis due to sickness or non-compliance (three from the intervention and two from the placebo group). Data analysis was carried out on 22 subjects in the intervention and 27 subjects in the control group. Results were reported as percent change from baseline without reporting p-values or the statistical tests applied, as difference between groups of absolute LDL-cholesterol concentrations at week six and of absolute changes from baseline at week six, analysed by the independent Student's t-test. Results of an analysis by the Mann Whitney U test for weeks three and six were also reported. Data analysis did not take into account baseline values and repeated measures and results of an intention-to-treat analysis were not presented. A re-analysis of data, which was requested by EFSA during the clock-stop procedure, was not provided by the applicant. Upon request from EFSA to present the raw data of the study, the applicant provided an incomplete set of raw data from which data of those subjects excluded from analysis were removed.

The Panel notes that even though the applicant was requested during the validation period to provide the full study report, only a summary report was submitted. The Panel also notes that the composition of the control spread used in the study did not allow conclusions to be drawn on an effect of the combination of plant sterols and Cholesternorm®mix on blood cholesterol concentrations and that there is uncertainty whether the study was properly randomised. The Panel also notes that only per protocol analysis was presented, that baseline values and repeated measures were not taken into account in the analysis, that a requested re-analysis of data was not presented by the applicant and that the set of raw data provided was incomplete. The Panel considers that owing to the major methodological limitations of this study no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that none of the human intervention studies provided on plant sterols and stanols alone investigated dose ranges in line with the proposed conditions of use and considers that these studies do not provide any additional information to the Panel's previous evaluations of claims on plant sterols and stanols and maintenance/reduction of blood LDL-cholesterol concentrations, which have been assessed with favourable outcomes (EFSA, 2008a, 2008b, 2009a, 2009b; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010a).

The Panel notes that no evidence was provided that plant sterols or constituents other than plant sterols in Cholesternorm®mix, which have a role in the claimed effect, could reasonably be expected to have an effect on blood LDL-cholesterol concentrations at the proposed conditions of use.

The Panel notes that no human interventions studies were 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 a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations at the proposed conditions of use.

CONCLUSIONS

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

- The food constituent, a combination of plant sterols (free and in esterified form) and Cholesternorm®mix, which is the subject of the claim, is sufficiently characterised in relation to the claimed effect.
- A reduction of blood LDL-cholesterol concentrations is a beneficial physiological effect. A reduction in blood LDL-cholesterol concentrations reduces the risk of coronary heart disease.
- A cause and effect relationship has not been established between the consumption of a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations at the proposed conditions of use.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of plant sterols and Cholesternorm®mix and reduction of blood LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0239_NL and 0314_NL). October 2011. Submitted by Health Concern B.V.

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GLOSSARY AND ABBREVIATIONS

LDL Low density lipoproteins

CHD Coronary heart disease

ALA Alpha-linolenic acid

LA Linoleic acid