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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to a combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of intestinal microflora" 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 CSL - Centro Sperimentale del Latte S.p.A., submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of intestinal microflora". The scope of the application was proposed to fall under a health claim referring to children's development and health. The food constituent that is the subject of the health claim, a combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), has not been sufficiently characterised. The claimed effect is "beneficial modulation of the intestinal microflora". The target population, as proposed by the applicant, is children from 3 months to 14 years old. No evidence has been provided by the applicant to establish that the claimed effect, "beneficial modulation of the intestinal microflora", is a beneficial physiological effect. The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), and a beneficial physiological effect related to "beneficial modulation of the intestinal microflora". © European Food Safety Authority, 2011

KEY WORDS

Lactobacillus delbrueckii subsp. *bulgaricus* AY/CSL (LMG P-17224), *Streptococcus thermophilus* 9Y/CSL (LMG P-17225), intestinal "microflora", health claims

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[1] On request from the Competent Authority of Italy following an application by CSL - Centro Sperimentale del Latte S.p.A., Question No EFSA-Q-2008-273, adopted on 30 June 2011.

[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. 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 CSL - Centro Sperimentale del Latte S.p.A., submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Italy, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to a combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of intestinal microflora".

The scope of the application was proposed to fall under a health claim referring to children's development and health.

The food constituent that is the subject of the health claim is a combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225). No complete data on the identification and characterisation of the strains *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225) were provided in the application or after the Panel's request to the applicant for supplementary information. The Panel considers that the food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), which is the subject of the health claim, has not been sufficiently characterised.

The claimed effect is "beneficial modulation of the intestinal microflora". The target population, as proposed by the applicant, is children from 3 months to 14 years old.

According to Regulation (EC) No 1924/2006, the use of health claims shall only be permitted if the food/constituent, for which the claim is made, has been shown to have a beneficial physiological effect. Based on current scientific knowledge, it is not possible to define the exact numbers/proportions of the different microbial groups which constitute a "beneficial" or "normal" intestinal microbiota. Increasing the number of any group of microorganisms, including lactobacilli and/or bifidobacteria, is not considered in itself a beneficial physiological effect. Thus, the applicant was requested to provide the rationale regarding the extent to which the claimed effect is a beneficial physiological effect. No reply was received from the applicant to the Panel's request for supplementary information. The Panel considers that no evidence has been provided by the applicant to establish that the claimed effect, "beneficial modulation of the intestinal microflora", is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), and a beneficial physiological effect related to "beneficial modulation of the intestinal microflora".

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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 application was received on 07/04/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- During the check for completeness[5] of the application, the applicant was requested to provide missing information on 03/06/2008 and subsequently on 20/07/2009 and 06/08/2009.
- The applicant provided the missing information on 10/07/2009, and subsequently on 29/07/2009,07/08/2009 and 31/08/2009.
- The scientific evaluation procedure started on 15/09/2009.
- On 12/11/2009, the NDA Panel Working Group on Claims agreed on a list of questions for the applicant to provide additional information to accompany the application and on 16/11/2009 EFSA requested the applicant to provide this additional information.
- No response to the NDA Panel List of Questions was received from the applicant, even subsequent to EFSA reminders on 03/03/2010 and 18/04/2011.
- During its meeting of 30/06/2011, the NDA Panel, having evaluated the available data submitted, adopted an opinion on the scientific substantiation of a health claim related to a combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of intestinal microflora".

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 *L. delbrueckii*

[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.

[5] In accordance with: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). EFSA Journal, 9(5):2170, 36 pp.

subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of intestinal microflora".

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of a combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), a positive assessment of its safety, nor a decision on whether the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S.thermophilus* 9Y/CSL (LMG P-17225) 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: CSL - Centro Sperimentale del Latte S.p.A., Strada per Merlino, 3 - 26839 Zelo Buon Persico (LO), Italy.

The application includes proprietary data.

Food/constituent as stated by the applicant

Mix of *Lactobacillus delbrueckii* subsp. *bulgaricus* strain AY/CSL (LMG P-17224) and *Streptococcus thermophilus* strain 9Y/CSL (LMG P-17225).

Health relationship as claimed by the applicant

According to the applicant, both strains survive gastro-intestinal transit, colonise the intestine, and balance the intestinal flora.

S. thermophilus is an oxygen scavenger: so creates anaerobic conditions that enhance the growth and survival of strict anaerobes, like bifidobacteria, in the intestine. Furthermore, the ability of *L. bulgaricus* to adhere to the mucosal surfaces is related to various probiotic health effects, and it is regarded as a prerequisite for stimulation of the immune system and for antagonistic activity against enteropathogens. The acidifying activities and the production of H_2O_2 *in situ* by *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus* can lead to a growth-inhibiting pH for most putrefactive and pathogenic bacteria in the intestine, like clostridia and *Enterobacteriaceae.*

Wording of the health claim as proposed by the applicant

"Maintaining the gut health by normalizing the intestinal flora".

Specific conditions of use as proposed by the applicant

Cell concentration of the food constituent (in the form of freeze-dried viable cells / starter culture):
L. delbrueckii subsp. *bulgaricus* strain AY/CSL: at least 5 x 10^8 CFU/g
S. thermophilus strain 9Y/CSL: at least 5 x 10^8 CFU/g
Target population: Children from 3 months to 14 years old.
Cow's milk allergic infants should avoid eating cow's milk yoghurt.

ASSESSMENT

1. Characterisation of the food/constituent and relevance of the claimed effect to human health

The food constituent that is the subject of health claim is a combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225).

The applicant provided phenotypic data and some genotypic data to confirm the identity at species level of the strains that are the subject of the claim. The applicant indicated that the strains were identified at species level by species-specific PCR, 16S rRNA gene sequencing and RAPD-PCR, but only data on species-specific PCR were provided. Such data are insufficient to confirm species identity. Data on strain characterisation (genetic typing) were not provided.

The applicant was requested to provide supplementary information about the characterisation of the strains, which are the subject of the claim, and about the identity of the strains used in the studies provided for substantiation of the claim. No reply was received from the applicant.

The strains were deposited in the Belgian Coordinate Collections of Microorganisms (BCCM) and the following culture collection numbers for each strain were provided: LMG P-17224 for *L. delbrueckii* subsp. *bulgaricus* and LMG P-17225 for *S. thermophilus* 9Y/CSL. The BCCM is an International Depositary Authority under the Budapest Treaty and accepts bacterial cultures as patent deposits. These deposits have restricted access and are not catalogued.

The Panel notes that no complete data on the identification and characterisation of the strains *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225) were provided in the application or after the Panel's request to the applicant for supplementary information. The Panel considers that the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), which is the subject of the health claim, has not been sufficiently characterised.

The claimed effect is "beneficial modulation of the intestinal microflora". The target population, as proposed by the applicant, is children from 3 months to 14 years old.

According to Regulation (EC) No 1924/2006, the use of health claims shall only be permitted if the food/constituent, for which the claim is made, has been shown to have a beneficial physiological effect. Based on current scientific knowledge, it is not possible to define the exact numbers/proportions of the different microbial groups which constitute a "beneficial" or "normal" intestinal microbiota. Increasing the number of any group of microorganisms, including lactobacilli and/or bifidobacteria, is not considered in itself a beneficial physiological effect.

The applicant was requested to provide the rationale regarding the extent to which the claimed effect is a beneficial physiological effect. No reply was received from the applicant to the Panel's request for supplementary information.

In the studies provided by the applicant (Dellaglio, 2009, unpublished; Bianchi Salvadori et al., 1967; Salvadori et al., 1973; Bianchi Salvadori et al. 1978), outcome measures included faecal counts of lactobacilli, bifidobacteria and enterobacteria (but characterisation of the pathogenicity of enterobacteria was not provided), stool pH, and survival of the strains after gastro-intestinal transit. The Panel notes that changes in these outcome measures are not considered beneficial physiological effects *per se*.

The Panel considers that no evidence has been provided by the applicant to establish that the claimed effect, "beneficial modulation of the intestinal microflora", is a beneficial physiological effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), and a beneficial physiological effect related to "beneficial modulation of the intestinal microflora".

CONCLUSIONS

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

- The food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), which is the subject of the health claim, has not been sufficiently characterised.

- The claimed effect is "beneficial modulation of the intestinal microflora". The target population, as proposed by the applicant, is children from 3 months to 14 years old.
- No evidence has been provided to establish that the claimed effect, "beneficial modulation of the intestinal microflora", is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food constituent, the combination of *L. delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *S. thermophilus* 9Y/CSL (LMG P-17225), and a beneficial physiological effect related to "beneficial modulation of the intestinal microflora".

DOCUMENTATION PROVIDED TO EFSA

Health claim application on a combination of *Lactobacillus delbrueckii* subsp. *bulgaricus* AY/CSL (LMG P-17224) and *Streptococcus thermophilus* 9Y/CSL (LMG P-17225) and "beneficial modulation of the intestinal microflora" pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0143_IT). 29 July 2009. Submitted by CSL - Centro Sperimentale del Latte S.p.A.

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Dellaglio F, 2009. Effects of probiotic yoghurt ingestion upon the composition of faecal microflora in healthy children (unpublished).

Salvadori P. and Bianchi Salvadori B., 1973. Studio sulle variazioni copro colturali nell'uomo in rapporto alla somministrazione di yoghurt. Minerva Dielogica, 13, 8-12.

GLOSSARY / ABBREVIATIONS

rRNA	Ribosomal RNA
BCCM/LMG	Belgian Co-ordinated Collections of Microorganisms. Belgium
PCR	Polymerase Chain Reaction
RAPD	Randomly Amplified Polymorphic DNA