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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of 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 Lactalis B&C submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations. The food constituents which are responsible for the claimed effect are unsaturated fatty acids (mixtures of *cis*-MUFA and/or *cis*-PUFA), which should replace saturated fatty acids (SFAs) and *trans* fatty acids (TFAs) in the diet in order to obtain the claimed effect. Lowering LDL-cholesterol concentrations is a beneficial physiological effect by reducing the risk of coronary heart disease. There is consensus on the role of *trans*-MUFA in increasing total and LDL-cholesterol concentrations compared to *cis*-MUFA or *cis*-PUFA. Foods containing TFA typically contain high amounts of SFA, which are likely to have similar effects to TFA on a gram-for-gram basis. The Panel concludes that a cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in blood LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations. The following wording reflects the scientific evidence: "Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono- and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease". In order to bear the claim, significant amounts of mixed SFAs should be replaced by *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis. The target population is subjects who want to lower their blood cholesterol. © European Food Safety Authority, 2011

[1] On request from the Competent Authority of France following an application by LACTALIS B&C, Question No EFSA-Q-2009-00458, adopted on 13 May 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 for the preparatory work on this scientific opinion: 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.

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KEY WORDS

Saturated fatty acids, monounsaturated fatty acids, polyunsaturated fatty acids, unsaturated fatty acids, LDL cholesterol, coronary heart disease, health claims

SUMMARY

Following an application from Lactalis B&C submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations.

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

The foods that are the subject of the health claim are "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids ("soft margarine")" which should replace "fat rich in saturated/trans fatty acids ("hard fat", butter, stick margarine)" in order to obtain the claimed effect. In the context of the information provided by the applicant, the Panel notes that the food constituents which are responsible for the claimed effect are unsaturated fatty acids (mixtures of *cis*-MUFA and/or *cis*-PUFA), which should replace saturated fatty acids (SFAs) and *trans* fatty acids (TFAs) in the diet in order to obtain the claimed effect. The Panel considers that the food constituents, mixtures of SFAs and TFAs as present in foods or diets, and the food constituents by which SFAs and TFAs should be replaced in foods or diets, i.e. mixtures of *cis*-MUFAs and/or mixtures of c*is*-PUFAs, which are the subject of the health claim, are sufficiently characterised.

The claimed effect is "helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor". The target population as proposed by the applicant is moderately hypercholesterolaemic subjects in the general population and people who want to improve their diet. The Panel considers that lowering blood LDL-cholesterol concentrations is a beneficial physiological effect by reducing the risk of coronary heart disease.

A claim on the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome.

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of *trans*-MUFA in increasing total and blood LDL-cholesterol concentrations compared to *cis*-MUFA or *cis*-PUFA. The Panel notes that foods containing TFA typically contain high amounts of SFA, which are likely to have similar effects to TFA on LDL-cholesterol concentrations on a gram-for-gram basis. The Panel also notes that the effects of replacing marginal amounts of TFA in foods high in SFA may be small as compared to the effects of replacing SFA in those foods.

The Panel concludes that a cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations.

The Panel considers that the following wording reflects the scientific evidence: "Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono- and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease".

The Panel considers that in order to bear the claim, significant amounts of mixed SFAs should be replaced by *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis as per Annex of

Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010[4] and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[5] (section 2.2.3). The target population is subjects who want to lower their blood cholesterol.

[4] Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims. OJ L 37, 10.2.2010, p. 16–18 .

[5] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1924/2006[6] 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, and 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 16/03/2009.
- The scope of the application was proposed to fall under a health claim referring to disease risk reduction.
- During the check for completeness[7] of the application, the Competent Authority of the Member State responsible for the application was consulted by EFSA regarding the scope of the application. The Competent Authority of the Member State replied to EFSA on 14/06/2009.
- The applicant was requested to provide missing information on 29/09/2009.
- The applicant provided the missing information on 17/11/2009.
- The scientific evaluation procedure started on 15/12/2009.
- On 26/03/2010 the NDA Panel agreed on a list of questions which requested the applicant to provide additional particulars to accompany the application.
- The applicant submitted the responses to the NDA Panel's list of questions on 20/04/2011.
- During the meeting on 13/05/2011, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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: "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations.

[6] European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

[7] In accordance with EFSA "Scientific and Technical guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim"

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids", a positive assessment of its safety, nor a decision on whether "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" 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: Lactalis B&C, ZA Les Placis, 35230, Bourgbarré, France.
The applicant indicates proprietary rights for one clinical intervention study.

Food/constituent as stated by the applicant

The applicant states that the health claim is for low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids ("soft margarine") as a replacement for a fat rich in saturated/trans fatty acids ("hard fat", butter, stick margarine).

Health relationship as claimed by the applicant

The applicant states that plasma total cholesterol is the surrogate marker for the claimed effect, since LDL cholesterol is considered as an important cardiovascular risk factor by studies over the last 40 years, that epidemiological studies have clearly shown that high SFAs intake is correlated and UFAs intake inversely correlated to LDL cholesterol, and that SFAs raise plasma total and LDL-cholesterol concentrations compared with PUFAs and MUFAs. The applicant also states that in addition to SFAs, trans-unsaturated fatty acids also raise plasma total cholesterol and LDL cholesterol and may lower HDL cholesterol concentrations.

Wording of the health claim as proposed by the applicant

The applicant proposes the following wording: "Replacing a fat rich in saturated/*trans* fatty acids by a fat rich in unsaturated fatty acids helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor".

Specific conditions of use as proposed by the applicant

The applicant proposes that the target population consists of moderately hypercholesterolaemic subjects in the general population and people who want to improve their diet. The minimum quantity concerned by this replacement corresponds to an initial and usual estimated intake of "hard fat" (butter, stick margarine) of 25 g/d (=20 g/fat/day), which represents around 10 % of the total energy intake. In order to bear the claim the spreadable fat should contain 10 %≤ fat % ≤62 %; total SFAs+TFAs <30 % expressed on total fat; total TFAs: ≤1 g/100 g of the product; UFAs ≥70 % of total fat and % E UFAs ≥20 % E of the product; ALA ≥30 % of the reference intake value (2 g/d) for 100 g and 100 kcal of spread; LA ≥30 % of the reference intake value (10 g/d) for 100 g and 100 kcal of spread; total MUFAs *quantum satis* 100 % total fat.

ASSESSMENT

1. Characterisation of the food/constituent

The foods that are the subject of the health claim are "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids ("soft margarine")" which should replace "fat rich in saturated/trans fatty acids ("hard fat", butter, stick margarine)" in order to obtain the claimed effect.

In the context of the information provided by the applicant, the Panel notes that the food constituents which are responsible for the claimed effect are unsaturated fatty acids (UFAs), which should replace saturated fatty acids (SFAs) and *trans* fatty acids (TFAs) in the diet in order to obtain the claimed effect.

SFAs are aliphatic monocarboxylic acids with (generally) an even number of carbon atoms (usually from 4 to 20) and no double bonds, that can be liberated by hydrolysis of triacylglycerols from fats and oils. The most prevailing SFAs in the diet are lauric acid (12:0), myristic acid (14:0), palmitic acid (16:0) and stearic acid (18:0).

Cis-monounsaturated fatty acids (MUFAs) have one double bond in the fatty acid chain and the quantitatively most important representative in the diet and in tissue lipids is oleic acid (18:1 (n-9)). *Cis*-polyunsaturated fatty acids (PUFAs) have 2 to 6 double bonds in the fatty acid chain and the most abundant n-6 and n-3 PUFAs in the diet are linoleic acid (LA, 18:2 (n-6)) and alpha-linolenic acid (ALA, 18:3 (n-3)), respectively. The long-chain PUFAs, with chain length greater than 18C, are not considered in this opinion. Most UFAs (i.e., MUFA and PUFA) in the diet have the *cis* configuration, but TFAs are also present. These fatty acids originate from several sources and *trans*-MUFAs are the most common TFA in the diet. *Trans*-PUFAs, however, are also present. *Trans*-PUFAs have at least one *trans* double bond and may therefore also have double bonds in the *cis* configuration.

This opinion applies to the replacement of mixtures of SFAs and TFAs as present in foods or diets with mixtures of *cis*-MUFAs (e.g. oleic acid) and/or mixtures of *cis*-PUFAs (e.g. LA and ALA).

The Panel considers that the food constituents, mixtures of SFAs and TFAs as present in foods or diets, and the food constituents by which SFAs and TFAs should be replaced in foods or diets, i.e. mixtures of *cis*-MUFAs and/or mixtures of c*is*-PUFAs, which are the subject of the health claim, are sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor". The target population as proposed by the applicant is moderately hypercholesterolaemic subjects in the general population and people who want to improve their diet.

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 (Pedersen 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 concentrations can be decreased by drugs and by dietary and lifestyle changes (Denke, 2005; Gordon, 2000; Katan, et al., 2003; Ornish et al., 1998; van Horn et al., 2008).

The Panel considers that lowering LDL-cholesterol concentrations is a beneficial physiological effect by reducing the risk of coronary heart disease.

3. Scientific substantiation of the claimed effect

SFAs and LDL cholesterol

A claim on the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011). The Panel considers that the scientific substantiation of the claimed effect and the conditions of use for the claim also apply to the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and the reduction of blood LDL-cholesterol concentrations.

TFAs and LDL cholesterol

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is consensus on the role of *trans*-MUFA in increasing total and LDL-cholesterol concentrations compared to *cis*-MUFA or *cis*-PUFA (EFSA, 2004; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; WHO/FAO, 2003; IoM, 2005; Lichtenstein et al., 2006; Mensink et al., 2003; Mozaffarian and Clarke, 2009).

The effect shows a linear dose response relationship with blood LDL-cholesterol concentrations, indicating that effects are proportional to the amounts of TFA consumed. While the blood LDL-cholesterol concentration increasing effect of *trans*-MUFA is similar to some SFA, the available evidence does not provide a definitive answer to the question of whether TFA have an effect on blood LDL-cholesterol concentrations different from that of SFA on a gram-for-gram basis. Consumption of diets containing *trans*-MUFA also results in reduced blood HDL-cholesterol concentrations compared with consumption of diets containing SFA, *cis*-MUFA or *cis*-PUFA in a dose-response manner. Therefore, *trans*-MUFA, in comparison with other fatty acids, increase the total cholesterol to HDL cholesterol ratio (Mensink et al., 2003; EFSA, 2004).

The Panel notes that foods containing TFA typically contain high amounts of SFA, which are likely to have similar effects to TFA on LDL-cholesterol concentrations on a gram-for-gram basis. The Panel also notes that the effects of replacing marginal amounts of TFA in foods high in SFA may be small as compared to the effects of replacing SFA in those foods.

The Panel concludes that a cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in blood LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations.

4. Panel's comments on the proposed wording

The Panel considers that the following wording reflects the scientific evidence:

"Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono- and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease".

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claim, significant amounts of mixed SFAs should be replaced by *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010[8] and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[9] (section 2.2.3). The target population is subjects who want to lower their blood cholesterol.

CONCLUSIONS

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

[8] Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims. OJ L 37, 10.2.2010, p. 16–18 .

[9] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

- The food constituents, mixtures of saturated fatty acids and *trans* fatty acids as present in foods or diets, and the food constituents by which saturated fatty acids and *trans* fatty acids should be replaced in foods or diets, i.e. mixtures of *cis*-monounsaturated fatty acids and/or mixtures of *cis*-polyunsaturated fatty acids, which are the subject of the health claim, are sufficiently characterised.

- The claimed effect is "helps to reduce LDL cholesterol. LDL cholesterol is a cardiovascular risk factor". The target population as proposed by the applicant is moderately hypercholesterolaemic subjects in the general population and people who want to improve their diet. Lowering LDL-cholesterol concentrations is a beneficial physiological effect by reducing the risk of coronary heart disease.

- A cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in blood LDL-cholesterol concentrations, and that replacement of a mixture of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis reduces LDL-cholesterol concentrations.

- The following wording reflects the scientific evidence: "Consumption of saturated fat increases blood cholesterol concentrations; consumption of mono- and/or polyunsaturated fat in replacement of saturated fat has been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of (coronary) heart disease".

- In order to bear the claim, significant amounts of mixed SFAs should be replaced by *cis*-MUFAs and/or *cis*-PUFAs in foods or diets on a gram-per-gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010[10] and in accordance with the Guidance on the implementation of Regulation (EC) No 1924/2006 of the Standing Committee on the Food Chain and Animal Health for comparative nutrition claims made on foods[11] (section 2.2.3). The target population is subjects who want to lower their blood cholesterol.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on "low fat and low *trans* spreadable fat rich in unsaturated and omega-3 fatty acids" and reduction of LDL-cholesterol concentrations pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0245_FR). November 2009. Submitted by Lactalis B&C.

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[10] Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims. OJ L 37, 10.2.2010, p. 16–18 .

[11] Guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health, 14 December 2007.

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GLOSSARY AND ABBREVIATIONS

ALA	Alpha-linolenic acid
CHD	Coronary heart disease
HDL	High density lipoprotein
LA	Linoleic acid
LDL	Low density lipoprotein
MUFA	Monounsaturated fatty acid
PUFA	Polyunsaturated fatty acid
SFA	Saturated fatty acid
TFA	*Trans* fatty acid
UFA	Unsaturated fatty acid