

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs) and maintenance of normal blood LDL-cholesterol concentrations. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The foods/food constituents that are the subject of the health claims are “unsaturated fats/fatty acids (poly and/or mono unsaturates)”, “low or reduced saturated fat (hard fat) or replacement of saturated fat with MUFA, PUFA (soft fat) low cholesterol”, “milk, yoghurt, cheese and butter products based on raw milk with an improved ratio between saturated and unsaturated fatty acids and an increased level of omega 3 fatty acids due to naturally altered feeding of the cows”, “spreadable fats as defined in Article 115 and Annex XV of Council Regulation (EC) No 1234/2007” and “matière grasse laitière optimisée (beurre)”. This opinion applies to the replacement of mixtures of SFAs as present in foods or diets with mixtures of *cis*-MUFAs (e.g. oleic acid) and/or mixtures of *cis*-PUFAs (e.g. LA (linoleic

¹ On request from the European Commission, Question No EFSA-Q-2008-1408, EFSA-Q-2008-1929, EFSA-Q-2008-1942, EFSA-Q-2008-3639, EFSA-Q-2008-3643, EFSA-Q-2008-3797, adopted on 28 January 2011.

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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.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to the replacement of mixtures of saturated fatty acids (SFAs) as present in foods or diets with mixtures of monounsaturated fatty acids (MUFAs) and/or mixtures of polyunsaturated fatty acids (PUFAs), and maintenance of normal blood LDL-cholesterol concentrations (ID 621, 1190, 1203, 2906, 2910, 3065) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(4):2069. [18 pp.]. doi:10.2903/j.efsa.2011.2069. Available online: www.efsa.europa.eu/efsajournal

acid) and ALA (alpha-linolenic acid)). The Panel considers that the food constituent, SFAs as present in foods or diets, and the food constituents by which SFAs should be replaced in foods, i.e. mixtures of *cis*-MUFAs and/or mixtures of *cis*-PUFAs, which are the subject of the health claim, are sufficiently characterised.

The claimed effects are “blood cholesterol and artery/heart health”, “contribution to the maintenance of healthy total and LDL blood cholesterol levels by replacing saturated spreadable fat”, “lipides sanguins, cholestérol sanguin”, “maintains healthy LDL cholesterol levels arterial/heart health”, and “decreased intake of saturated fatty acids and increased intake of unsaturated fatty acids contributes to the maintenance of a healthy heart”. The target population is assumed to be the general population. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases blood total and LDL-cholesterol concentrations relative to mixtures of *cis*-MUFAs and/or *cis*-PUFAs.

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 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 may help maintain normal blood LDL-cholesterol concentrations.

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 on a gram-per-gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010 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.

KEY WORDS

Saturated fatty acids, replacement, monounsaturated fatty acids, polyunsaturated fatty acids, LDL-cholesterol, health claims

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006⁴ submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent (ID 621, 1190, 1203, 2906, 2910, 3065)

The foods/food constituents that are the subject of the health claims are “unsaturated fats/fatty acids (poly and/or mono unsaturates)”, “low or reduced saturated fat (hard fat) or replacement of saturated fat with MUFA, PUFA (soft fat) low cholesterol”, “milk, yoghurt, cheese and butter products based on raw milk with an improved ratio between saturated and unsaturated fatty acids and an increased level of omega 3 fatty acids due to naturally altered feeding of the cows”, “spreadable fats as defined in Article 115 and Annex XV of Council Regulation (EC) No 1234/2007” and “matière grasse laitière optimisée (beurre)”.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the food constituent, which is the subject of the health claim, is saturated fatty acids (SFAs). SFAs should be replaced by *cis*-monounsaturated fatty acids (*cis*-MUFAs) or by *cis*-polyunsaturated fatty acids (*cis*-PUFAs) in foods or diets 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-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)). Humans can synthesise *cis*-MUFAs and they are therefore not required as such from the diet. *cis*-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. Long-chain PUFAs are not considered in this opinion.

This opinion applies to the replacement of mixtures of SFAs 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 constituent SFAs as present in foods or diets, and the food constituents by which SFAs should be replaced in foods, i.e. mixtures of *cis*-MUFAs and/or mixtures of *cis*-PUFAs, which are the subject of the health claim, are sufficiently characterised.

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 Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

2. Relevance of the claimed effect to human health (ID 621, 1190, 1203, 2906, 2910, 3065)

The claimed effects are “blood cholesterol and artery/heart health”, “contribution to the maintenance of healthy total and LDL blood cholesterol levels by replacing saturated spreadable fat”, “lipides sanguins, cholestérol sanguin”, “maintains healthy LDL cholesterol levels arterial/heart health” and “decreased intake of saturated fatty acids and increased intake of unsaturated fatty acids contributes to the maintenance of a healthy heart”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations.

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

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

3. Scientific substantiation of the claimed effect (ID 621, 1190, 1203, 2906, 2910, 3065)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases blood total and LDL-cholesterol concentrations relative to mixtures of *cis*-MUFAs or *cis*-PUFAs (EFSA, 2004; EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; IoM, 2005; Lichtenstein et al., 2006; Mensink et al., 2003; WHO/FAO, 2003).

The effect shows a linear dose-response relationship with blood LDL-cholesterol concentrations, indicating that effects are proportional to the amounts of long-chain SFAs consumed. It is also well established that consumption of a mixture of SFAs results in increased blood HDL-cholesterol concentrations compared with consumption of mixtures of *cis*-MUFAs or *cis*-PUFAs, and that, in comparison with other fatty acids except *trans* fatty acids (TFAs), SFAs increase the total-to-HDL cholesterol ratio (Mensink et al., 2003).

SFAs differ in their potency to change blood lipid and lipoprotein concentrations. While lauric, myristic and palmitic acid raise blood total and LDL-cholesterol concentrations, effects of stearic acid and of short and medium chain SFAs (with 4-10 carbon atoms) are similar to those of carbohydrates and oleic acid (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010; Mensink et al., 2003). However, SFAs are present in foods as mixtures, so that stearic acid and short and medium chain SFAs are consumed in foods that also contain other long-chain SFAs (with 12 to 16 carbon atoms) which are known to increase LDL-cholesterol concentrations.

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 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 may help maintain normal blood LDL-cholesterol concentrations.

4. Panel’s comments on the proposed wording (ID 621, 1190, 1203, 2906, 2910, 3065)

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 contributes to the maintenance of normal blood cholesterol concentrations”.

5. Conditions and possible restrictions of use (ID 621, 1190, 1203, 2906, 2910, 3065)

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 116/2010⁶ 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 foods⁷ (section 2.2.3).

CONCLUSIONS

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

- The food constituents, SFAs as present in foods or diets, and the food constituents by which SFAs should be replaced in foods, i.e. mixtures of *cis*-MUFAs and/or mixtures of *cis*-PUFAs, which are the subject of the health claim, are sufficiently characterised.
- The claimed effects are “blood cholesterol and artery/heart health”, “contribution to the maintenance of healthy total and LDL blood cholesterol levels by replacing saturated spreadable fat”, “lipides sanguins, cholestérol sanguin”, “maintains healthy LDL cholesterol levels arterial/heart health” and “decreased intake of saturated fatty acids and increased intake of unsaturated fatty acids contributes to the maintenance of a healthy heart”. The target population is assumed to be the general population. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.
- A cause and effect relationship has been established between the consumption of mixtures of dietary SFAs and an increase in blood 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 may help maintain normal blood 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 contributes to the maintenance of normal blood cholesterol concentrations”.
- In order to bear the claim, significant amounts of mixed SFAs should be replaced by *cis*-MUFAs and/or *cis*-PUFAs in foods on a gram-per-gram basis as per Annex of Regulation (EC) No 1924/2006 as amended by Regulation (EC) No 116/2010 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.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1408, EFSA-Q-2008-1929, EFSA-Q-2008-1942, EFSA-Q-2008-3639, EFSA-Q-2008-3643, EFSA-Q-2008-3797). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

⁶ 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 .

⁷ 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 full list of supporting references as provided to EFSA is available on:
<http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

REFERENCES

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁸ (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁹

Foods are commonly involved in many different functions¹⁰ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁸ OJ L12, 18/01/2007

⁹ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

¹⁰ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

- consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
 - the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
 - the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. 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 wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to the replacement of mixtures of SFAs in foods or diets with mixtures of MUFAs and/or PUFAs, including conditions of use from similar claims, as proposed in the Consolidated List.

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|------|--|---|---|
| 621 | Unsaturated fats/ fatty acids (poly and/or mono unsaturates). | Blood cholesterol and artery/heart health. | Decreasing saturated fats and increasing unsaturated fats helps to maintain healthy cholesterol level. Maintenance of normal cholesterol level. Supports healthy cholesterol. |
| | <p>Conditions of use</p> <ul style="list-style-type: none"> - Bei täglichen Verzehr in üblichen Mengen (Orientierung: Durchschnitt nach Bundeslebensmittelschlüssel). - Amount of consumption: 30 gramm (g). Angenommene durchschnittliche Verzehrsmenge an Rapsspeiseöl pro Tag/entspricht ca. drei Esslöffeln, 30Gramm (g). Entspricht einer täglichen Aufnahme von 17,4 g einfach ungesättigten Fettsäuren durch 30 g Rapsspeiseöl pro Tag. - Min 10% fat (product basis), min 70%UFA (fat basis) and based on 15% of GDA for UFA (16 PUFA+34 MUFA) , max 2% TFA (fat basis). | | |
| | <p>No clarification provided by Member States</p> | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1190 | <p>Matières grasses solides type margarines.</p> <p><u>Clarification provided</u></p> <p>Spreadable fats as defined in the Article 115 and Annex XV of Council Regulation (EC) No 1234/2007 : at least 10% but less than 90% of fat by weight solid at 20°C + specifically: Trans < 2g/100 g fat basis and rich in unsaturated fatty acids (>70 g UFA/100 g fat basis) and omega 6/ omega 3 ratio <5.</p> | <p>Cholestérol sanguin.</p> <p><u>Clarification provided</u></p> <p>Contribution to the maintenance of healthy total and LDL blood cholesterol levels by replacing saturated spreadable fat:</p> <p>There is scientific evidence based on human observationnal and intervention studies that replacement of saturated fatty acids (SFA) and trans fatty acids (TFA) in the diet by an equal amount of cis-UFAs (both MUFAs and PUFAs) helps to maintain healthy total and LDL cholesterol levels. Specific nutritional roles have been identified for n-9</p> | <p>Formule riche en acides gras insaturés (oméga 6 et 9) qui contribuent naturellement à lutter contre l'excès de cholestérol.</p> <p>Formule riche en acides gras insaturés (oméga 6 et 9) recommandés dans le cadre d'une alimentation visant à limiter l'excès de cholestérol.</p> <p>Le remplacement de matières grasses saturés par des insaturées aide naturellement à lutter contre l'excès de cholestérol.</p> <p><u>Clarification provided</u></p> <p>Replacement of saturated fats by unsaturated fats helps to maintain healthy cholesterol level - This fat is rich in unsaturated fatty acids.</p> |

| | | MUFA, n-6 PUFA and n-3 PUFA. Thus spreadable fats rich in cis-UFA consumption in replacement of butter or hard fat may play an important nutritional role in limiting SFA intake and helps to control total and LDL-cholesterol levels. | |
|---|--|---|---|
| Conditions of use | | | |
| - Etre riche en acides gras insaturés AGI>70%/AG Totaux. Acides gras trans < 1%/AG Totaux. Apporter moins de 20 g d'acides gras saturés + trans pour 100 g de produit fini. Avoir un rapport équilibré oméga 6/oméga 3 < 5. | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1203 | Matière grasse laitière optimisée (beurre). | lipides sanguins Cholestérol sanguin. | Contribue à l'équilibre des lipides sanguins. N'augmente pas le cholestérol* (*mauvais cholestérol). Aide à lutter contre l'excès de cholestérol* (*mauvais cholestérol). Participe au maintien d'un niveau normal de cholestérol. Recommandé dans le cadre d'une alimentation visant à limiter l'excès de cholestérol* (*mauvais cholestérol). |
| Conditions of use | | | |
| - Palmitique inférieur ou égal à 27%, Alpha linoléinique minimum 0,9%, ruménique minimum 0,8% de la matière grasse totale. | | | |
| No clarification provided by Member States | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 2906 | Low or reduced saturated fat (hard fat) or replacement of saturated fat with MUFA PUFA (soft fat) low cholesterol. | Maintains healthy LDL cholesterol levels Arterial/ heart Health. <u>Clarification provided</u> Diets low in saturated fat and high in unsaturated fat maintain heart health by controlling blood (LDL) cholesterol. | A diet low or reduced in saturated fat helps maintain healthy (LDL) cholesterol levels; Replacing hard fat with soft fat helps control blood cholesterol. |
| Conditions of use | | | |
| - Must meet minimum requirements, as per Annex to Regulation 1924/2006. | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |

| 2910 | Unsaturated fats/fatty acids (poly and/or monounsaturates). | <p>Blood cholesterol and artery/heart health.</p> <p><u>Clarification provided</u></p> <p>Unsaturated fat (poly- and monounsaturated) maintain heart health by controlling blood (LDL) cholesterol.</p> <p>Polyunsaturated fat maintain heart health by controlling blood (LDL) cholesterol.</p> <p>Monounsaturated fat maintain heart health by controlling blood (LDL) cholesterol.</p> | <p>Decreasing saturated fats and increasing unsaturated fats helps maintaining a healthy heart;</p> <p>Maintains normal cholesterol levels.</p> |
|-------------|--|---|---|
| | <p>Conditions of use</p> <p>- Min 10% fat (product basis), min 70%UFA (fat basis) and based on 15% of GDA for UFA (16 PUFA+34 MUFA), max 2% TFA (fat basis).</p> | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 3065 | <p>dairy products based on raw milk with an improved ratio between saturated and unsaturated fatty acids and an increased level of omega 3 fatty acids.</p> <p><u>Clarification provided</u></p> <p>milk, yoghurt, cheese and butter products based on raw milk with an improved ratio between saturated and unsaturated fatty acids and an increased level of omega 3 fatty acids due to naturally altered feeding of the cows.</p> | <p>decreased intake of saturated fatty acids and increased intake of unsaturated fatty acids contributes to the maintenance of a healthy heart.</p> | <p>Milk and dairy products with 20% more unsaturated fatty acids contribute to the maintenance of a healthy heart.</p> <p>Milk and dairy products with 10% less saturated fatty acids contribute to the maintenance of a healthy heart.</p> <p>Milk and dairy products with an improved fatty acid composition fit better in a healthy diet.</p> <p>Milk and dairy products with 20% more unsaturated fatty acids fit better in a healthy diet.</p> <p>Milk and dairy products with an improved fatty acid composition have a higher nutritional value.</p> <p>Milk and dairy products with more unsaturated fatty acids contribute to the maintenance of a healthy heart.</p> <p>Milk and dairy products with less saturated fatty acids contribute to the maintenance of a healthy heart.</p> <p>Milk with a better nutritional value through balanced animal nutrition.</p> <p>Milk with 20% more unsaturated fatty acids and increased levels of omega-3 fatty acids has a better</p> |

| | | |
|--|---|--------------------|
| | | nutritional value. |
| | <p>Conditions of use</p> <ul style="list-style-type: none"> - the fat composition of the raw milk has changed through naturally altered feeding of the cows. | |
| | <p>Comments from Member States</p> <p>Additionally the example of wording is modified as follows: Milk, yoghurt, cheese and butter products with an improved ratio between saturated and unsaturated fatty acids fit better in a healthy diet.</p> <p>Milk, yoghurt, cheese and butter products with a better nutritional value through balanced animal nutrition.</p> | |

GLOSSARY AND ABBREVIATIONS

| | |
|------|----------------------------|
| ALA | Alpha-linolenic acid |
| HDL | High-density lipoproteins |
| LA | Linoleic acid |
| LDL | Low-density lipoproteins |
| MUFA | Monounsaturated fatty acid |
| PUFA | Polyunsaturated fatty acid |
| SFA | Saturated fatty acid |
| TFA | <i>Trans</i> fatty acid |