

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets and maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334) and maintenance of normal (fasting) blood concentrations of triglycerides (ID 673, 4334) 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 in relation to oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets and maintenance of normal blood LDL-cholesterol concentrations and maintenance of normal (fasting) blood concentrations of triglycerides. 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 “monounsaturated fatty acids (mainly oleic acid)”, “oleic acid” and “extravirgin olive oil”. This opinion applies to the replacement of mixtures of SFAs as present in foods or diets with oleic acid. The Panel considers that the food constituent, oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets, which is the subject of the health claims, is sufficiently characterised.

¹ On request from the European Commission, Question No EFSA-Q-2008-1460, EFSA-Q-2008-1515, EFSA-Q-2008-1516, EFSA-Q-2008-2040, EFSA-Q-2010-00287, adopted by written procedure on 06 December 2010.

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Maintenance of normal blood LDL-cholesterol concentrations

The claimed effects are “cardiovascular system”, “support healthy cholesterol levels”, “blood cholesterol levels” and “oleic acid helps to maintain healthy blood cholesterol levels, and phenolic compounds help to protect LDL cholesterol by the oxidation”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations. 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 total and blood LDL-cholesterol concentrations relative to mixtures of *cis*-MUFAs.

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 scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

Maintenance of normal (fasting) blood concentrations of triglycerides

The claimed effect is “cardiovascular system”. The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, it is assumed that the claimed effect refers to the maintenance of normal (fasting) blood concentrations of triglycerides. The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

When carbohydrates are replaced with fats, fasting triglyceride concentrations are reduced, but there is no difference between the effects of different fatty acid classes. The Panel notes that carbohydrates are not neutral with respect to their effects on blood concentrations of triglycerides.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between oleic acid replacing saturated fatty acids (SFAs) in foods or diets and maintenance of normal (fasting) blood concentrations of triglycerides.

KEY WORDS

Oleic acid, saturated fatty acids, replacement, LDL-cholesterol, triglycerides, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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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

The foods/food constituents that are the subject of the health claims are “monounsaturated fatty acids (mainly oleic acid)”, “oleic acid” and “extravirgin olive oil”.

In the context of the proposed wordings, clarifications provided by Member States and references submitted for the scientific substantiation of the health claims, the Panel assumes that the food constituent that is the subject of the health claims is oleic acid, which should replace saturated fatty acids (SFAs) in foods or diets in order to obtain the claimed effects.

Oleic acid is the monounsaturated fatty acid (MUFA) with 18 carbon atoms and the double bond in the *9-cis* position. It is found in varying amounts in dietary fats. Beef tallow contains about 43 % oleic acid and 47 % SFAs, lard about 44 % oleic acid and 43 % SFAs, palm oil about 40 % oleic acid and 45 % SFAs, rapeseed oil about 60 % oleic acid and 6 % SFAs. A high proportion of oleic acid is found in olive oil, 71 %, together with 15.5 % SFAs and 12 % polyunsaturated fatty acids (PUFAs). High-oleic acid varieties of sunflower oil and rapeseed oil contain about 75-85 % oleic acid.

Saturated fatty acids (SFAs) are aliphatic monocarboxylic acids with (generally) an even number of carbon atoms (usually from 4 to 20) and no double bonds which 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).

This opinion applies to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

The Panel considers that the food constituent, oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets, which is the subject of the health claims, is 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

2.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334)

The claimed effects are “cardiovascular system”, “support healthy cholesterol levels”, “blood cholesterol levels” and “oleic acid helps to maintain healthy blood cholesterol levels, and phenolic compounds help to protect LDL cholesterol by the oxidation”. 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 effects refer 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.

2.2. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 673, 4334)

The claimed effect is “cardiovascular system”. The Panel assumes that the target population is the general population.

In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal (fasting) blood concentrations of triglycerides.

Triglycerides in plasma are either derived from dietary fats or synthesised in the body from other energy sources like carbohydrates. In fasting conditions, serum triglycerides are mainly transported in very-low-density lipoproteins (VLDL) synthesised in the liver. Hormones regulate the release of triglycerides from adipose tissue in order to meet energy needs between meals. Normal values for blood concentrations of triglycerides have been defined.

The Panel considers that maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334)

The evidence provided by consensus opinions/reports from authoritative bodies and reviews shows that there is good consensus that a mixture of SFAs increases total and blood LDL-cholesterol concentrations relative to mixtures of *cis*-MUFAs (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), and that there is a linear dose-response relationship between blood LDL-cholesterol concentrations and 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 (e.g. oleic acid), 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 potential 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 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 12-16 carbon atoms), which are known to increase LDL-cholesterol concentrations.

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 scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

3.2. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 673, 4334)

The references provided were narrative reviews, opinions of scientific bodies, and reports on intervention studies which assessed the effects of various fatty acids on health outcomes unrelated to the claimed effect. No studies have been provided which addressed independent effects of oleic acid on blood concentrations of triglycerides. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

When carbohydrates are replaced with fats, fasting triglyceride concentrations are reduced, but there is no difference between the effects of different fatty acid classes. Mensink and Katan (1992) found in a meta-analysis of 27 trials that an isocaloric exchange between carbohydrates and fats resulted in similar predicted effects on triglyceride concentrations for SFA, MUFA and PUFA. The Panel notes that carbohydrates are not neutral with respect to their effects on blood concentrations of triglycerides.

The Panel concludes that a cause and effect relationship has not been established between oleic acid replacing saturated fatty acids (SFAs) in foods or diets and maintenance of normal (fasting) blood concentrations of triglycerides.

CONCLUSIONS

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

- The food constituent, oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets, which is the subject of the health claims, is sufficiently characterised.

Maintenance of normal blood LDL-cholesterol concentrations (ID 673, 728, 729, 1302, 4334)

- The claimed effects are “cardiovascular system”, “support healthy cholesterol levels”, “blood cholesterol levels” and “oleic acid helps to maintain healthy blood cholesterol levels, and phenolic compounds help to protect LDL cholesterol by the oxidation”. The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- 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 scientific conclusions in that opinion apply to the replacement of mixtures of SFAs as present in foods or diets with oleic acid.

Maintenance of normal (fasting) blood concentrations of triglycerides (ID 673, 4334)

- The claimed effect is “cardiovascular system”. The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, it is assumed that the claimed effect refers to the maintenance of normal (fasting) blood concentrations of triglycerides. Maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.
- A cause and effect relationship has not been established between oleic acid replacing saturated fatty acids (SFAs) in foods or diets and maintenance of normal (fasting) blood concentrations of triglycerides.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1460, EFSA-Q-2008-1515, EFSA-Q-2008-1516, EFSA-Q-2008-2040, EFSA-Q-2010-00287). 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 full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

REFERENCES

- EFSA (European Food Safety Authority), 2004. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies (NDA) related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids (Request N° EFSA-Q-2003-022). The EFSA Journal. 81, 1-49.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol. EFSA Journal, 8(3):1461, 107 pp.
- EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. 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, 9(4):2069, 18 pp.
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Mensink RP, Zock PL, Kester AD and Katan MB, 2003. Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials. *American Journal of Clinical Nutrition*, 77, 1146-1155.

WHO/FAO (World Health Organization/Food and Agriculture Organization), 2003. Expert Report: Diet, nutrition and prevention of chronic diseases. Report of a Joint WHO/FAO Expert Consultation. WHO Technical Report Series. WHO Technical Report Series 916.

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 foods⁶ (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 FOOD⁷

Foods are commonly involved in many different functions⁸ 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.

6 OJ L12, 18/01/2007

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

8 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 oleic acid intended to replace saturated fatty acids (SFAs) in foods or diets, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
673	Monounsaturated fatty acids (mainly oleic acid)	Cardio-vascular system	Replacement saturated fatty acids by monounsaturated fatty acids in the diet is beneficial for the blood total cholesterol, LDL cholesterol and triglyceride levels.
	Conditions of use - 10-20 energy % (around. 22-44 g/day). The product shall contain a significant amount of MUFA compared to the recommended daily allowance. Health claims can be applied on foods complying with requirements of nutrition claims “High mono-unsaturated fatty acids”.		
	Comments from Member States This health relationship can be classified as a general dietary guideline, but as a part of commercial communication it should be handled under Reg. 1924/2006/EK.		
ID	Food or Food constituent	Health Relationship	Proposed wording
728	Acido oleico <u>Clarification provided</u> Oleic acid	colesterol <u>Clarification provided</u> Support healthy cholesterol levels	ayuda a mantener niveles de colesterol Saludables <u>Clarification provided</u> Oleic acid, highly present in olive oil, helps maintaining healthy cholesterol levels
	Conditions of use - 15-20 g. per day		
ID	Food or Food constituent	Health Relationship	Proposed wording
729	Acido oleico <u>Clarification provided</u> Monounsaturated fatty acids, Oleic acid	salud cardiovascular <u>Clarification provided</u> Blood cholesterol levels	ayuda a mantener la salud cardiovascular. <u>Clarification provided</u> Helps maintaining healthy cholesterol levels. Helps maintaining cardiovascular health
	Conditions of use - valorar por EFSA		
	Comments from Member States SIMILAR HEALTH RELATIONSHIP TO ID N° 728		
ID	Food or Food constituent	Health Relationship	Proposed wording
1302	Extravergin olive oil	--- <u>Clarification provided</u>	Extravergin olive oil helps to maintain cardiovascular system healthy, thanks to its peculiar

		Oleic acid helps to maintain healthy blood cholesterol levels, and phenolic compounds helps to protect LDL cholesterol by the oxidation	composition of nutrients and non nutrients with high beneficial effect
Conditions of use - N/A			
ID	Food or Food constituent	Health Relationship	Proposed wording
4334	Monounsaturated fatty acids (mainly oleic acid)	Cardio-vascular system	Replacement saturated fatty acids by monounsaturated fatty acids in the diet is beneficial for the blood total cholesterol, LDL cholesterol and triglyceride levels.
Conditions of use - 10-20 energy % (around. 22-44 g/day).;The product shall contain a significant amount of MUFA compared to the recommended daily allowance.;Health claims can be applied on foods complying with requirements of nutrition claims "High mono-unsaturated fatty acids".			

GLOSSARY AND ABBREVIATIONS

LDL	Low-density lipoproteins
MUFA	Monounsaturated fatty acid
PUFA	Polyunsaturated fatty acid
SFA	Saturated fatty acid
TFA	<i>Trans</i> fatty acid
VLDL	Very-low-density lipoproteins