European Food Safety Authority

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to olive oil and maintenance of normal blood LDL-cholesterol concentrations (ID 1316, 1332), maintenance of normal (fasting) blood concentrations of triglycerides (ID 1316, 1332), maintenance of normal blood HDL-cholesterol concentrations (ID 1316, 1332) and maintenance of normal blood glucose concentrations (ID 4244) pursuant to Article 13(1) 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

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 olive oil and maintenance of normal blood LDL-cholesterol concentrations, maintenance of normal (fasting) blood concentrations of triglycerides, maintenance of normal blood HDL-cholesterol concentrations and maintenance of normal blood glucose 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 food that is the subject of the health claims is olive oil. The Panel considers that olive oil is sufficiently characterised in relation to the claimed effects.

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[1] On request from the European Commission, Question No EFSA-Q-2008-2053, EFSA-Q-2008-2069, EFSA-Q-2008-4954, adopted by written procedure on 06 December 2010.

[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 for the preparatory work on this scientific opinion: The members of the Working Group on Claims Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Cardiovascular Health/Oxidative Stress: Antti Aro, Marianne Geleijnse, Marina Heinonen, Ambroise Martin, Wilhelm Stahl and Henk van den Berg.

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Maintenance of normal blood LDL-cholesterol concentrations

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of normal LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the evidence provided did not establish that olive oil consumption had an effect on blood LDL-cholesterol concentrations beyond what could be expected from the fatty acid composition of olive oil, and that the only study which assessed the effects of olive oil while controlling for its fatty acid composition did not find any significant changes in LDL-cholesterol concentrations when comparing olive oils with high, moderate and low polyphenol content.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from the fatty acid composition of olive oil.

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 been assessed with a favourable outcome. A claim on linoleic acid and maintenance of normal blood cholesterol concentrations has also already been assessed with a favourable outcome.

Maintenance of normal (fasting) blood concentrations of triglycerides

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effects refer 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 levels are reduced, but there is no difference between the effects of different fatty acid classes. In clinical trials, no differences have been observed between olive oil, rapeseed oil, corn oil and sunflower oil 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 the consumption of olive oil and maintenance of normal (fasting) blood concentrations of triglycerides.

Maintenance of normal blood HDL-cholesterol concentrations

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". The target population is assumed to be the general population. In the context of the proposed wording and clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of normal HDL-cholesterol concentrations. The Panel considers that maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that based on its fatty acid composition olive oil is not expected to have an effect on HDL-cholesterol concentrations, that a linear dose-response effect of olive oil polyphenols on HDL-cholesterol concentrations was observed in one study only, and that no evidence on a plausible mechanism by which olive oil polyphenols could exert an effect on HDL-cholesterol concentrations has been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal HDL-cholesterol concentrations.

Maintenance of normal blood glucose concentrations

The claimed effect is "permet de réguler le glucoses dans le sang". The target population is assumed to be the general population. The Panel assumes that the claimed effect refers to the maintenance of normal blood glucose concentrations. The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

No references were provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood glucose concentrations.

KEY WORDS

Olive oil, LDL, HDL, cholesterol, triglycerides, glucose, health claims.

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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 1924/2006[4] 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 out[5]. 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 food that is the subject of the health claims is olive oil.

Olive oil is produced from the fruits of the olive tree. The composition varies by cultivar, region, altitude, time of harvest and extraction process, particularly with regard to its polyphenol content. Its fatty acid composition is less variable and includes about 70 % oleic acid, 15 % saturated fatty acids (SFAs) and 11 % polyunsaturated fatty acids (PUFAs), mainly linoleic acid (LA), by weight.

The Panel considers that the food, olive oil, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effects.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 1316, 1332)

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer to the maintenance of normal 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.

[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

2.2. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 1316, 1332)

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer 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.

2.3. Maintenance of normal blood HDL-cholesterol concentrations (ID 1316, 1332)

The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer to the maintenance of normal HDL-cholesterol concentrations.

High-density lipoproteins (HDL) act as cholesterol scavengers and are involved in the reverse transport of cholesterol in the body (from peripheral tissues back to the liver). Conversely, low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries.

The Panel considers that maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

2.4. Maintenance of normal blood glucose concentrations (ID 4244)

The claimed effect is "permet de réguler le glucoses dans le sang". The Panel assumes that the target population is the general population.

The Panel assumes that the claimed effect refers to the maintenance of normal blood glucose concentrations.

The Panel considers that long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

Most of the references provided in relation to the claims evaluated in this opinion were narrative reviews that did not contain any original data which could be used for the scientific substantiation of the claimed effects, reports on epidemiological and intervention studies on foods or diets other than olive oil (e.g. Mediterranean diet) and/or on health outcomes other than the claimed effects (e.g. cardiovascular events, oxidative stress, endothelium-dependent vasodilation, blood pressure). The

Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effects.

3.1. Maintenance of normal blood LDL-cholesterol concentrations (ID 1316, 1332)

Mensink et al. (2003) found in a meta-analysis of 60 controlled trials, that replacing carbohydrates with SFAs in an amount representing 1 E% increased LDL-cholesterol concentrations by 0.032 mmol/L. Replacement with *cis*-MUFAs (oleic acid) reduced LDL-cholesterol concentrations only by 0.009 mmol/L. The corresponding reduction in LDL-cholesterol concentrations by PUFAs was significantly larger (i.e. 0.019 mmol/L).

A number of human intervention studies comparing the effects of olive oils *vs.* other vegetable oils were provided.

Pedersen et al. (2000) investigated the effect of olive oil (35 % of daily energy intake as fat (11 E% SFAs, 21 E% MUFAs, 3 E% PUFAs)), rapeseed oil (35 % of daily energy intake as fat (9 E% SFAs, 18 E% MUFAs, 7 E% PUFAs)), and sunflower oil (35 % of daily energy intake as fat (10 E% SFAs, 9 E% MUFAs, 15 E% PUFAs)) based diets on blood lipids and lipoproteins in 18 healthy subjects in a double-blind, randomised, cross-over study (3-week intervention period) with 50 g oil/10 MJ incorporated into a constant diet. Total and LDL-cholesterol concentrations were significantly higher after consumption of the olive oil diet compared with the rapeseed oil and sunflower oil diets. Lichtenstein et al. (1993) compared rapeseed oil (about 6 % SFAs, 62 % oleic acid, 20 % linoleic acid (LA) and 10 % alpha-linolenic acid (ALA)), maize oil (about 60 % LA, 28 % oleic acid and 13 % SFAs) and olive oil (about 70 % oleic acid, 15 % SFAs, and 11 % PUFAs, mainly LA) as part of the National Cholesterol Education Program (NCEP) Step 2 diet with the average US diet in a randomised cross-over study in 15 persons. Both rapeseed oil and maize oil reduced serum total cholesterol levels more (-12 and -13 %, respectively) than olive oil (-7 %). In the randomised, cross-over intervention by Nydahl et al. (1995), 22 hyperlipidaemic subjects consumed either low erucic acid rapeseed (canola) oil or olive oil in the context of a "lipid-lowering" diet for 3.5 weeks each. LDL-cholesterol concentrations decreased significantly more during the canola oil diet (-17%) than during the olive oil diet (-13%). The Panel notes that the different effects of different oils on blood cholesterol concentrations could be explained by the fatty acid composition of these oils.

The only study presented which assessed the effects of olive oil while controlling for its fatty acid composition was a multicentre (six centres in Finland, Denmark, Germany, Italy and Spain) randomised, cross-over, controlled human intervention study in which olive oils with high (366 mg/kg oil, i.e. 8.0 mg/day), moderate (164 mg/kg oil, i.e. 3.6 mg/day), and low (2.7 mg/kg oil, i.e. 0.1 mg/day) polyphenol content were consumed by 200 male subjects for three weeks (25 mL/day) each (Covas et al., 2006). Changes in LDL-cholesterol concentrations were not significantly different between olive oil treatments.

In weighing the evidence, the Panel took into account that the evidence provided did not establish that olive oil consumption had an effect on blood LDL-cholesterol concentrations beyond what could be expected from the fatty acid composition of olive oil, and that the only study which assessed the effects of olive oil while controlling for its fatty acid composition did not find any significant changes in LDL-cholesterol concentrations when comparing olive oils with high, moderate and low polyphenol content.

The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from the fatty acid composition of olive oil.

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), 2011a).

A claim on linoleic acid and maintenance of normal blood cholesterol concentrations has also already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009).

3.2. Maintenance of normal (fasting) blood concentrations of triglycerides (ID 1316, 1332)

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 levels for SFAs, MUFAs and PUFAs. The Panel notes that carbohydrates are not neutral with respect to their effects on blood concentrations of triglycerides.

In clinical trials, no differences have been observed between olive oil, rapeseed oil, corn oil and sunflower oil with respect to their effects on blood concentrations of triglycerides (Lichtenstein et al., 1993; Nydahl et al., 1995; Pedersen et al., 2000).

The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal (fasting) blood concentrations of triglycerides.

3.3. Maintenance of normal blood HDL-cholesterol concentrations (ID 1316, 1332)

Mensink et al. (2003) concluded in a meta-analysis of 60 controlled trials that all types of fatty acids except *trans* fatty acids increase HDL-cholesterol concentrations as compared with carbohydrates. The effect of SFAs on increasing HDL-cholesterol concentrations is reduced by increasing chain length. Replacement of 1 E% of SFAs with an equal E% of *cis*-MUFAs was predicted to lower HDL-cholesterol by 0.002 mmol/L, and a similar decrease was expected when replacing the same amount of MUFAs with PUFAs. The Panel notes that oleic acid reduces HDL-cholesterol concentrations as compared with SFAs with 12-16 carbon atoms, but less than a similar amount of PUFAs. The Panel also notes that carbohydrates are not neutral with respect to their effects on HDL-cholesterol concentrations.

In clinical trials no statistically significant differences have been observed when comparing olive oil with rapeseed oil, sunflower oil or corn oil with respect to their effects on HDL-cholesterol concentrations (Lichtenstein et al., 1993; Nydahl et al., 1995; Pedersen et al., 2000).

The only study presented which assessed the effects of olive oil while controlling for its fatty acid composition was the multicentre study described in section 3.1. A significant linear dose-dependent increase in HDL-cholesterol concentrations was observed for low- (+0.025 mmol/L, 95 % CI = 0.003 to 0.05 mmol/L), medium- (+0.032 mmol/L, 95 % CI = 0.005 to 0.05 mmol/L), and high-polyphenol olive oil (p *per* trend 0.018). The total-to-HDL-cholesterol ratio decreased linearly with the polyphenol content of the olive oils (p *per* trend 0.013).

A claim on olive polyphenols and maintenance of normal blood HDL-cholesterol concentrations has already been assessed with an unfavourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011b).

In weighing the evidence, the Panel took into account that based on its fatty acid composition olive oil is not expected to have an effect on HDL-cholesterol concentrations, that a linear dose-response effect of olive oil polyphenols on HDL-cholesterol concentrations was observed in one study only, and that

no evidence on a plausible mechanism by which olive oil polyphenols could exert an effect on HDL-cholesterol concentrations has been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal HDL-cholesterol concentrations.

3.4. Maintenance of normal blood glucose concentrations (ID 4244)

Only one reference was provided for the scientific substantiation of the claimed effect which was a narrative review on the relationship between impaired fatty acid and phospholipid metabolism, and depression and bipolar disorder in the context of different chronic diseases. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood glucose concentrations.

CONCLUSIONS

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

- The food, olive oil, which is the subject of the health claims, is sufficiently characterised in relation to the claimed effect.

Maintenance of normal blood LDL-cholesterol concentrations (ID 1316, 1332)

- The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer to the maintenance of normal LDL-cholesterol concentrations. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from the fatty acid composition of olive oil.

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

Maintenance of normal (fasting) blood concentrations of triglycerides (ID 1316, 1332)

- The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer to the maintenance of normal (fasting) blood concentrations of triglycerides. Maintenance of normal (fasting) blood concentrations of triglycerides may be a beneficial physiological effect.

- The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal (fasting) blood concentrations of triglycerides.

Maintenance of normal blood HDL-cholesterol concentrations (ID 1316, 1332)

- The claimed effects are "health of the cardiovascular system, general population" and "improves blood lipid profile". 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 effects refer to the maintenance of normal HDL-cholesterol concentrations. Maintenance of normal HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

- The Panel concludes that a cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood HDL-cholesterol concentrations.

Maintenance of normal blood glucose concentrations (ID 4244)

- The claimed effect is "permet de réguler le glucoses dans le sang". The target population is assumed to be the general population. It is assumed that the claimed effect refers to the maintenance of normal blood glucose concentrations. Long-term maintenance of normal blood glucose concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of olive oil and maintenance of normal blood glucose concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2053, EFSA-Q-2008-2069, EFSA-Q-2008-4954). 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.

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EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011b. Scientific Opinion on the substantiation of health claims related to polyphenols in olive and protection of LDL particles from oxidative damage (ID 1333, 1638, 1639, 1696, 2865), maintenance of normal blood HDL cholesterol concentrations (ID 1639), maintenance of normal blood pressure (ID 3781), "anti-inflammatory properties" (ID 1882), "contributes to the upper respiratory tract health" (ID 3468),

"can help to maintain a normal function of gastrointestinal tract" (3779) and "contributes to body defences against external agents" (ID 3467) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2033, 25 pp.

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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 foods[6] (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 FOOD[7]

Foods are commonly involved in many different functions[8] 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 olive oil, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1316	Olive oil and/or olive pomace oil.	Health of the cardiovascular system, General population. Clarification provided Improves blood lipid profile	1. Olive oil consumption helps to maintain the health of the cardiovascular system
	Conditions of use - Olive oil consumption should be at least 22-70g/day (Ref 3 and 12). No maximum limitation has been stated.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1332	Olive Oil	Improves blood lipid profile	Olive Oil promotes your heart health
	Conditions of use - Consumption of at least two soup-spoonfuls (23 g) of olive oil a day for at least three weeks, in the context of a diet low in saturated fatty acids.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4244	Huile d'olive	L'huile d'olive permet de réguler le glucoses dans le sang.	"régule le niveau de sucre dans le sang"
	Conditions of use - No conditions of use provided		
	No clarification provided by Member States		

GLOSSARY AND ABBREVIATIONS

ALA	Alpha-linolenic acid
CI	Confidence interval
HDL	High-density lipoproteins
LA	Linoleic acid
LDL	Low-density lipoproteins
MUFA	Monounstaturated fatty acid
NCEP	National Cholesterol Education Program
PUFA	Polyunsaturated fatty acid
SFA	Saturated fatty acid