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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (ID 1639, further assessment) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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European Food Safety Authority

EFSA Journal 2012;10(8):2848

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (ID 1639, further assessment) 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

This scientific output, published on 7 September 2012, replaces the earlier version published on 7 August 2012[4]

ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a health claim pursuant to Article 13 of Regulation (EC) No 1924/2006 in the framework of further assessment related to polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations. The food constituent, polyphenols in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) standardised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex), that is the subject of the health claim is sufficiently characterised. The claimed effect, maintenance of normal blood HDL-cholesterol concentrations, which is eligible for further assessment, is a beneficial physiological effect. The proposed target population is the general population. No evidence from which conclusions could be drawn for the scientific substantiation of the claim, in addition to the Panel's earlier opinion, was provided. The Panel considers that no data were submitted which would require a reconsideration of the conclusions expressed in its previous opinion, in which it concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of olive oil polyphenols (standardised by the content of hydroxytyrosol and its derivatives) and maintenance of normal blood HDL cholesterol concentrations.

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KEY WORDS

Polyphenols, olive, cholesterol, HDL, health claims.

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[1] On request from the European Commission, Question No EFSA-Q-2012-00164, adopted on 28 June 2012.

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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.

[4] The Appendices were missing from the original publication and have been added to this output.

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SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. This opinion addresses the scientific substantiation of a health claim in relation to polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations. The assessment is based on the information provided by the Member States in the consolidated list of Article 13 health claims, references that EFSA has received from Member States or directly from stakeholders and the additional information provided by the competent Authority of Germany for further assessment of this claim.

The food constituent that is the subject of the health claim is polyphenols in olive. The Panel considers that polyphenols in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) standardised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex) are sufficiently characterised.

The claimed effect, which is eligible for further assessment, relates to the maintenance of normal blood HDL-cholesterol concentrations. The proposed target population is the general population. The Panel considers that maintenance of normal blood HDL-cholesterol concentrations (without increasing LDL-cholesterol concentrations) is a beneficial physiological effect.

In the framework of further assessment nine human intervention and four animal studies were provided. The Panel notes that none of these studies allowed conclusions to be drawn for the scientific substantiation of the claim owing to the fact that the content of hydroxytyrosol or its derivatives (e.g. oleuropein complex) in the olive oils administered in the studies was not reported, that studies showed major methodological limitations, and that results from rat studies could not be extrapolated to humans because of differences in lipid metabolism between these two species.

The Panel notes that no evidence from which conclusions could be drawn for the scientific substantiation of the claim, in addition to the Panel's earlier opinion, was provided.

The Panel considers that no data were submitted which would require a reconsideration of the conclusions expressed in its previous opinion, in which it concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of olive oil polyphenols (standardised by the content of hydroxytyrosol and its derivatives) and maintenance of normal blood HDL-cholesterol concentrations.

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INTRODUCTION

The Commission has agreed with EU Member States that a certain number of Article 13 health claims would be eligible for further assessment by EFSA in order to be able to take a final decision on whether or not to include these claims in the list of permitted health claims. These claims include already assessed claims related to micro-organisms which the Panel considered to be not sufficiently characterised and claims for which the NDA Panel concluded that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect.

Following an opinion of the NDA Panel pursuant to Article 13 of Regulation (EC) No 1924/2006[5] in which the Panel concluded that the evidence provided was insufficient to establish a cause and effect relationship between polyphenols in olive and maintenance of normal blood HDL-cholesterol concentrations (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011), EFSA received additional information from the competent Authority of Germany for further assessment of this claim.

ASSESSMENT

1. Characterisation of the food/constituent (ID 1639)

The food constituent that is the subject of the health claims is polyphenols in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) standardised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex).

Polyphenols comprise a very wide group (several thousands of compounds) of plant secondary metabolites including flavonoids, isoflavonoids, phenolic acids, proanthocyanidins and other tannins, and lignans with different biological activities. The major polyphenols in olive oil are phenolic alcohols (e.g. hydroxytyrosol and tyrosol), secoiridoids (e.g. oleuropein) and lignans (e.g. pinoresinol). Table olives typically contain hydroxytyrosol, tyrosol, caffeoylquinic acid, verbacoside, luteolin and rutin. Hydroxytyrosol, a major polyphenol typically present in olives, is also present in olive mill waste water. In nature, hydroxytyrosol is found in olives also in the form of a glucoside of its elenolic acid ester, oleuropein. These polyphenolic compounds can be measured in foods by established methods.

Total polyphenols are usually expressed as gallic acid equivalents, but other phenolic compounds such as catechin/epicatechin or caffeic acid have also been used for standardisation. This standardisation refers to the traditional spectrophotometric measurement of total polyphenols using the Folin-Ciocalteau method (Singleton and Rossi, 1965), which is based on reducing capacity. The method is not specific for polyphenols because other reducing compounds such as ascorbic acid, sugars and proteins will also be included in the quantification, thus leading to an overestimation of the actual polyphenol content. The total polyphenol content assessed with this method is not suitable for characterisation of polyphenols in foods.

The Panel considers that polyphenols (e.g. hydroxytyrosol and oleuropein complex) in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) can be characterised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex).

The Panel considers that the food constituent, polyphenols in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) standardised by their content of hydroxytyrosol and its

[5] 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.

derivatives (e.g. oleuropein complex), which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health (ID 1639)

The claimed effect, which is eligible for further assessment, relates to the maintenance of normal blood HDL-cholesterol concentrations. The proposed target population is the general population.

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.

3. Scientific substantiation of the claimed effect (ID 1639)

In its earlier opinion (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011) the Panel took into account that the results from the two human intervention studies provided (Covas et al., 2006; Marrugat et al., 2004) were inconsistent, and that no evidence for a biologically plausible mechanism by which olive oil polyphenols could exert the claimed effect was provided.

In the framework of further assessment, nine human intervention and four animal studies were provided. In five of the human intervention studies (Estevez-Gonzalez et al., 2010; Haban et al., 2004; Perona et al., 2011; Ruano et al., 2007; Violante et al., 2009), as well as in one animal study (Mangas-Cruz et al., 2001), the content of hydroxytyrosol or its derivatives (e.g. oleuropein complex) in the olive oils administered in the studies was not reported. In one human intervention study (Susalit et al., 2011), designed to assess the effects of olive polyphenols on blood pressure, 23 % of subjects were withdrawn from the study due to stopping rules related to the primary outcome of the study, which might have led to selection bias through breaking randomisation with respect to blood lipid outcomes. Two human intervention studies described in one publication (Perrinjaquet-Moccetti et al., 2008) with 10 subjects per group each, which showed no effect on HDL-cholesterol concentrations, were likely to have been underpowered to detect a significant effect of polyphenols in olive on blood HDL-cholesterol concentrations. Another intervention study (Weinbrenner et al., 2004) was of a duration of four days, which does not allow conclusions to be drawn on a sustained effect of consumption of polyphenols in olive on changes in blood HDL-cholesterol concentrations, and in one cross-over study (Vissers et al., 2001) and a study in rabbits (Gonzalez-Santiago et al., 2006) no baseline measurements were taken. The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of the claim.

The remaining animal studies assessed the effect of hydroxytyrosol on blood lipid concentrations in male Wistar rats (Fki et al., 2007; Jemai et al., 2008). The Panel considers that results from rat studies cannot be extrapolated to humans because of differences in lipid metabolism between these two species, and considers that no conclusions can be drawn from these animal studies for the scientific substantiation of the claim.

The Panel notes that no evidence from which conclusions can be drawn for the scientific substantiation of the claim, in addition to the Panel's earlier opinion, was provided.

The Panel considers that no data were submitted which would require a reconsideration of the conclusions expressed in its previous opinion, in which it concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of olive oil

polyphenols (standardised by the content of hydroxytyrosol and its derivatives) and maintenance of normal blood HDL-cholesterol concentrations.

CONCLUSIONS

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

- The food constituent, polyphenols in olive (olive fruit, olive mill waste waters or olive oil, *Olea europaea* L. extract and leaf) standardised by their content of hydroxytyrosol and its derivatives (e.g. oleuropein complex), which is the subject of the health claim, is sufficiently characterised.

- The claimed effect eligible for further assessment relates to the maintenance of normal blood HDL-cholesterol concentrations. The target population is the general population. Maintenance of normal blood HDL-cholesterol concentrations (without increasing LDL cholesterol concentrations) is a beneficial physiological effect.

- No data were submitted which would require a reconsideration of the conclusions expressed in its previous opinion, in which it concluded that the evidence provided was insufficient to establish a cause and effect relationship between the consumption of olive oil polyphenols (standardised by the content of hydroxytyrosol and its derivatives) and maintenance of normal blood HDL-cholesterol concentrations.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 for further assessment (No: EFSA-Q-2012-00164). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims, references that EFSA has received from Member States or directly from stakeholders and the additional information provided by the competent Authority of Germany for further assessment of this claim (available at: http://www.efsa.europa.eu/en/topics/topic/article13.htm).

REFERENCES

Covas MI, Nyyssonen K, Poulsen HE, Kaikkonen J, Zunft HJ, Kiesewetter H, Gaddi A, de la Torre R, Mursu J, Baumler H, Nascetti S, Salonen JT, Fito M, Virtanen J and Marrugat J, 2006. The effect of polyphenols in olive oil on heart disease risk factors: a randomized trial. Annals of Internal Medicine, 145, 333-341.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. 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, 12 pp.

Estevez-Gonzalez MD, Saavedra-Santana P, Lopez-Rios L, Chirino R, Cebrero-Garcia E, Pena-Quintana L and Betancor-Leon P, 2010. HDL cholesterol levels in children with mild hypercholesterolemia: effect of consuming skim milk enriched with olive oil and modulation by the TAQ 1B polymorphism in the CETP gene. Annals of Nutrition and Metabolism, 56, 288-293.

Fki I, Sahnoun Z and Sayadi S, 2007. Hypocholesterolemic effects of phenolic extracts and purified hydroxytyrosol recovered from olive mill wastewater in rats fed a cholesterol-rich diet. Journal of Agricultural and Food Chemistry, 55, 624-631.

Gonzalez-Santiago M, Martin-Bautista E, Carrero JJ, Fonolla J, Baro L, Bartolome MV, Gil-Loyzaga P and Lopez-Huertas E, 2006. One-month administration of hydroxytyrosol, a phenolic antioxidant present in olive oil, to hyperlipemic rabbits improves blood lipid profile, antioxidant status and reduces atherosclerosis development. Atherosclerosis, 188, 35-42.

Haban P, Klvanova J, Zidekova E and Nagyova A, 2004. Dietary supplementation with olive oil leads to improved lipoprotein spectrum and lower n-6 PUFAs in elderly subjects. Medical Science Monitoring, 10, PI49-54.

Jemai H, Fki I, Bouaziz M, Bouallagui Z, El Feki A, Isoda H and Sayadi S, 2008. Lipid-lowering and antioxidant effects of hydroxytyrosol and its triacetylated derivative recovered from olive tree leaves in cholesterol-fed rats. Journal of Agricultural and Food Chemistry, 56, 2630-2636.

Mangas-Cruz MA, Fernandez-Moyano A, Albi T, Guinda A, Relimpio F, Lanzon A, Pereira JL, Serrera JL, Montilla C, Astorga R and Garcia-Luna PP, 2001. Effects of minor constituents (non-glyceride compounds) of virgin olive oil on plasma lipid concentrations in male Wistar rats. Clinical Nutrition, 20, 211-215.

Marrugat J, Covas MI, Fito M, Schroder H, Miro-Casas E, Gimeno E, Lopez-Sabater MC, de la Torre R and Farre M, 2004. Effects of differing phenolic content in dietary olive oils on lipids and LDL oxidation--a randomized controlled trial. European Journal of Nutrition, 43, 140-147.

Perona JS, Fito M, Covas MI, Garcia M and Ruiz-Gutierrez V, 2011. Olive oil phenols modulate the triacylglycerol molecular species of human very low-density lipoprotein. A randomized, crossover, controlled trial. Metabolism: Clinical and Experimental, 60, 893-899.

Perrinjaquet-Moccetti T, Busjahn A, Schmidlin C, Schmidt A, Bradl B and Aydogan C, 2008. Food supplementation with an olive (Olea europaea L.) leaf extract reduces blood pressure in borderline hypertensive monozygotic twins. Phytotherapy Research, 22, 1239-1242.

Ruano J, Lopez-Miranda J, de la Torre R, Delgado-Lista J, Fernandez J, Caballero J, Covas MI, Jimenez Y, Perez-Martinez P, Marin C, Fuentes F and Perez-Jimenez F, 2007. Intake of phenol-rich virgin olive oil improves the postprandial prothrombotic profile in hypercholesterolemic patients. American Journal of Clinical Nutrition, 86, 341-346.

Singleton VL and Rossi JA, Jr., 1965. Colorimetry of total phenolics with phosphomolybdic-phosphotungstic acid reagents. American Journal of Enology and Viticulture, 16, 144-158.

Susalit E, Agus N, Effendi I, Tjandrawinata RR, Nofiarny D, Perrinjaquet-Moccetti T and Verbruggen M, 2011. Olive (Olea europaea) leaf extract effective in patients with stage-1 hypertension: comparison with Captopril. Phytomedicine, 18, 251-258.

Violante B, Gerbaudo L, Borretta G and Tassone F, 2009. Effects of extra virgin olive oil supplementation at two different low doses on lipid profile in mild hypercholesterolemic subjects: a randomised clinical trial. Journal of Endocrinological Investigation, 32, 794-796.

Vissers MN, Zock PL, Wiseman SA, Meyboom S and Katan MB, 2001. Effect of phenol-rich extra virgin olive oil on markers of oxidation in healthy volunteers. European Journal of Clinical Nutrition, 55, 334-341.

Weinbrenner T, Fito M, de la Torre R, Saez GT, Rijken P, Tormos C, Coolen S, Albaladejo MF, Abanades S, Schroder H, Marrugat J and Covas MI, 2004. Olive oils high in phenolic compounds modulate oxidative/antioxidative status in men. Journal of Nutrition, 134, 2314-2321.

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.

GLOSSARY AND ABBREVIATIONS

HDL	High-density lipoproteins
LDL	Low-density lipoproteins