SCIENTIFIC OPINION

Opinion on the substantiation of health claims related to alpha-linolenic acid and maintenance of normal blood cholesterol concentrations (ID 493) and maintenance of normal blood pressure (ID 625) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)

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 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to alpha-linolenic acid and the following claimed effects: maintenance of normal blood cholesterol concentrations and maintenance of normal blood pressure.

The food constituent that is the subject of the health claims is alpha-linolenic acid (ALA). The Panel considers that ALA is sufficiently characterised.

Maintenance of normal blood cholesterol concentrations

The claimed effect is “blood cholesterol”. The Panel assumes that the target population is the general population. The Panel considers that the maintenance of normal blood cholesterol concentrations is beneficial to human health.

On the basis of the data available, the Panel concludes that a cause and effect relationship has been established between the dietary intake of ALA and the reduction of blood cholesterol concentrations.

In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

1 On request from the European Commission, Question No EFSA-Q-2008-1280, EFSA-Q-2008-1412, adopted on 02 July 2009.
Correspondence: nada@efsa.europa.eu

Maintenance of normal blood pressure

The claimed effect is “blood pressure”. The Panel assumes the target population is the general population. The Panel considers that the maintenance of normal blood pressure is beneficial to human health.

In weighing the evidence the Panel took into account that the observed effects of ALA intake on blood pressure in the human intervention studies were inconsistent, the lack of evidence in these studies that study design, including the study size, was appropriate to demonstrate an effect of ALA on blood pressure, that cross-sectional studies have considerable limitations as a source of evidence for the claim, the lack of evidence for a plausible mechanism for the claimed effect.

On the basis of the data available, the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of ALA and the maintenance of normal blood pressure.

KEY WORDS

Alpha-linolenic acid, ALA, blood pressure, blood cholesterol, health claims.
# Table of Contents

Summary .................................................................................................................... 1
Table of contents ........................................................................................................ 3
Background as provided by the European Commission ........................................... 4
Terms of Reference as provided by the European Commission .............................. 4
EFSA Disclaimer ........................................................................................................ 4
Acknowledgements .................................................................................................... 4
Information as provided in the consolidated list .................................................... 5
Assessment .................................................................................................................. 6
1. Characterisation of the food/constituent .............................................................. 6
2. Relevance of the claimed effect to human health .................................................. 6
   2.1. Maintenance of normal blood cholesterol concentrations (ID 493) .............. 6
   2.2. Maintenance of normal blood pressure (ID 625) ......................................... 6
3. Scientific substantiation of the claimed effect ..................................................... 6
   3.1. Maintenance of normal blood cholesterol concentrations (ID 493) .......... 6
   3.2. Maintenance of normal blood pressure (ID 625) ...................................... 7
4. Panel’s comments on the proposed wording ....................................................... 8
   4.1. Maintenance of normal blood cholesterol (ID 493) .................................... 8
5. Conditions and possible restrictions of use ......................................................... 9
   5.1. Maintenance of normal blood cholesterol (ID 493) .................................... 9
Conclusions ............................................................................................................... 9
Documentation provided to EFSA ........................................................................... 9
References ............................................................................................................... 10
Appendices ............................................................................................................. 12
BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION
See Appendix A

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION
See Appendix A

EFSA DISCLAIMER
See Appendix B

ACKNOWLEDGEMENTS
The European Food Safety Authority wishes to thank for the preparation of this opinion:


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.
INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims which are the subject of this opinion is given in Table 1.

Table 1. Main entry health claims related to Alpha-linolenic acid, including conditions of use from similar claims, as proposed in the Consolidated List.

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food component</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>493</td>
<td>Essential fatty acid</td>
<td>Blood cholesterol</td>
<td>- Alpha-linolenic acid (omega 3) contributes to healthy blood cholesterol level;</td>
</tr>
<tr>
<td></td>
<td>Alpha-linolenic acid (LNA - omega 3)</td>
<td></td>
<td>- Alpha-linolenic acid (omega 3) helps to maintain healthy blood cholesterol level;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- maintenance of normal blood cholesterol level</td>
</tr>
</tbody>
</table>

Conditions of use
- 1-2 energy % (around 2-4 g/day). ; The product shall contain a significant amount of n-3 PUFA compared to the recommended daily allowance. The product shall comply with the conditions of nutrition claim „Source/high omega-3 fatty acids”
- min 10% fat (product basis), min 70% UFA (fat basis), max 2% TFA (fat basis); min 0,3g Alpha-linolenic acid per 100g/ml and 100kcal (product basis), based on 15% of 2,0g GDA for Omega3(ALA);
- Vegetable fat spreads 30% and margarines 40% containing 5 g/100 g, 0.25 g/tsp (=5 g), 1.25 g/5 tsp (=25 g) of omega-3 fatty acid/alpha-linoleic acid.
- Vegetable fat spreads 70% and margarines 60% containing 5 g/100 g, 0.25 g/tsp (=5 g), 1.25 g/5 tsp (=25 g) of omega-3 fatty acid/alpha-linoleic acid.
- Liquid rapeseed oil products 8-9 g/100 g, 1.3 g/15 g (=1 tbsp) of omega-3 fatty acids/alpha-linoleic acid.
- Five servings (5 tsp = 25 g) of spreadable food fat are recommended each day. This provides half of the daily recommended intake of omega-3 fatty acids.

<table>
<thead>
<tr>
<th>ID</th>
<th>Food or Food component</th>
<th>Health Relationship</th>
<th>Proposed wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>625</td>
<td>Alpha-linolenic acid (LNA-Omega 3)</td>
<td>Blood pressure - n-3 LNA cause relaxation in the neighbouring blood vessel to dilate influencing blood pressure</td>
<td>Omega 3 Alpha-linolenic acid helps maintain a healthy blood pressure.</td>
</tr>
</tbody>
</table>

Conditions of use
- 5g LNA/day for a man, and 4g/day for a woman

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ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claims is alpha-linolenic acid (ALA), an essential n-3 polyunsaturated fatty acid with 18 carbon atoms and three double bonds. ALA is a well recognised nutrient, is well absorbed when consumed in the form of triglycerides and is measurable in foods by well established methods.

The Panel considers that the food constituent, ALA, that is the subject of the health claims is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood cholesterol concentrations (ID 493)

The claimed effect is “blood cholesterol”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effect relates to the maintenance of normal blood 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, may compromise the normal structure and function of the arteries.

The Panel considers that the maintenance of normal blood cholesterol concentrations is beneficial to human health.

2.2. Maintenance of normal blood pressure (ID 625)

The claimed effect is “blood pressure”. The Panel assumes the target population is the general population.

In the context of the proposed wording, the Panel notes that the claimed effect relates to the maintenance of normal blood pressure.

Blood pressure (BP) is the pressure (per unit area) exerted by circulating blood on the walls of blood vessels. Elevated BP, by convention ≥140 mmHg (systolic) and/or ≥90 mmHg (diastolic), may compromise the normal function of the arteries.

The Panel considers that the maintenance of normal blood pressure is beneficial to human health.

3. Scientific substantiation of the claimed effect

3.1. Maintenance of normal blood cholesterol concentrations (ID 493)

Clinical trials comparing the effects of different vegetable oils on serum lipids in normolipidaemic subjects have shown that the effect of alpha-linolenic acid (ALA) on serum cholesterol is similar to that of linoleic acid (LA) (Mantzioris et al., 1994; Valsta et al., 1995; Pand et al., 1998). In a meta-analysis of 60 randomised controlled clinical trials, the replacement of 1% of energy from carbohydrates by polyunsaturated fatty acids (PUFA), mainly as LA, reduced serum LDL cholesterol levels by 0.02 mmol/l (Mensink et al., 2003). The estimated change in the total to HDL cholesterol...
ratio was -0.032. Although LA was the main source of PUFA in the studies above, smaller amounts of ALA were also used in some of the studies. Moreover, as indicated in the studies by Mantzioris et al. (1994), Valsta et al. (1995) and Pand et al. (1998), the effects of LA and ALA on serum lipoproteins are similar and the n-6/n-3 ratio of dietary PUFA does not affect the serum lipid profile (Goyens and Mensink, 2005).

No specific data on the effects of ALA intake on cholesterol levels have been presented for children, but there is no scientific evidence for different effects in children as compared to adults.

The Panel considers that a cause and effect relationship has been established between the dietary intake of ALA and the reduction of blood cholesterol concentrations.

3.2. Maintenance of normal blood pressure (ID 625)

The consolidated list provided 13 references for the substantiation of this claim. Three references were considered as not pertinent for substantiation of the claim (Abeywardena et al., 2001; Geleijnse et al., 2002; WHO, 2003), as the reports were focussed on long chain-PUFA (LC-PUFA) from marine sources (mainly eicosapentaenoic acid and docosahexaenoic acid). Two general reviews are also excluded as they did not examine the relationship between ALA intake and blood pressure (BP) (Wijendran and Hayes, 2004; Stark et al., 2008).

A systematic review by Wendland et al. (2006) included three RCTs which investigated the effects of ALA intake on BP and concluded that systolic and diastolic BP are not affected by ALA intake (Bemelmans et al., 2002; Finnegan et al., 2003; Kestin et al., 1990). The 2-year randomised study with parallel design by Bemelmans et al. (2002) compared the effect of daily supplementation with ALA-enriched margarine (total daily ALA 6.3 g and LA 26 g, n=96) with that of unenriched margarine (total daily ALA 1 g and LA 27 g, n=141) on BP in middle-aged men and women at risk of cardiovascular disease. The 4-month double-blind, randomised, placebo-controlled study with parallel design by Finnegan et al., (2003) compared the effect of daily supplementation with ALA-enriched margarine (total daily ALA 4.5 g and LA 16 g, n=29, or total daily ALA 9.5 g and LA 13 g, n=29) with that of unenriched margarine (total daily ALA 1.5 g and LA 23 g, n=29) on BP in moderately hyperlipidaemic adults. The 6-week double-blind, randomised, placebo-controlled study with parallel design by Kestin et al., (1990) compared the effect of daily supplementation with ALA (9 g provided as linseed oil, n=11) in place of an equivalent amount of LA (9 g provided as safflower oil, n=11) on blood pressure in normotensive and mildly hypercholesterolemic men. All three studies found no significant differences in systolic BP or diastolic BP between the ALA intervention group and the control group.

Four randomised controlled intervention studies were also provided (Takeuchi et al., 2007; Paschos et al., 2007; Sioen et al., unpublished; Vuksan et al., 2007).

In a randomised controlled study in subjects with normal BP, high-normal BP or mild hypertension consuming a test diet containing 3.4 g/d ALA (flax oil and rice oil in bread rolls), systolic BP was significantly lower (~ -4 mmHg) after 4, 8 and 12 weeks in the test group (n=58) than in the control group (n=53) consuming a diet containing 1.7 g/d ALA (equivalent amount of rapeseed and soybean oils in bread rolls) and returned to control BP values 4 weeks after cessation of the intervention. A significant decrease in diastolic BP (~ -3 mm Hg) was observed only at week 12 in the intervention group compared to controls (Takeuchi et al., 2007).

The 12-week study with parallel design by Paschos et al. (2007) compared the effect of daily supplementation with flaxseed oil (15 ml providing 8 g ALA and 2 g LA, n=59) with safflower oil (15 ml providing 0.1 g ALA and 11 g LA, n=28) on BP in middle-aged dyslipidaemic men. Background diets of the two groups had similar quantities of ALA (1g/d) and total PUFA (12 g/d). After 12 weeks,
a median decrease of 3% in systolic BP and of 6% in diastolic BP was observed (median decrease around -5 mm Hg) in the intervention group compared to controls.

In an unpublished paper (Sioen et al.), a 12-week study compared the effect of substitution of common foods with their naturally ALA-enriched counterparts (to provide 5 g/d ALA, 18 g LA vs 2.8 g/d ALA, 18 g LA in controls) in 48 middle-aged men. It is unspecified how many subjects per group completed the intervention. No effect of the test diet was observed on systolic BP, whereas a significant -3 mm Hg decrease was measured for diastolic BP compared to the control diet.

A 12-week study with single-blind cross-over design (Vuksan et al., 2007) was performed on 27 type II diabetic subjects on conventional anti-diabetic therapy using 34 g of whole grain in a ground form or as bread (Salvia hispanica L.) providing 7.4 ± 4.3 g/day ALA compared with 1.1 ± 0.8 g/day ALA in the control diet (same amount of wheat bran). A 6 mm Hg reduction in systolic BP was observed with the intervention diet as compared to the control diet. The Panel considers that the evidence provided does not establish that results from this study on type II diabetic subjects on conventional anti-diabetic therapy can be extrapolated to the general population.

Two observational studies were presented. In a cross-sectional study of 4594 adults (Djousse et al., 2005), intake of ALA in consecutive quartiles was on average 0.4, 0.6, 0.8 and 1.2 g per day. Prevalence odds ratios for hypertension (with 95% CI) were 1.0, 0.72 (0.56 to 0.93), 0.70 (0.52 to 0.93), and 0.66 (0.49 to 0.94), from the lowest to the highest quartile of ALA intake. The dietary intake of ALA was also associated with a lower resting systolic BP (≈2.0 mm Hg difference between highest and the lowest quartiles of ALA), but not with diastolic BP. In an international cross-sectional epidemiological study in 17 population sub-groups (Ueshima et al., 2007), a small inverse association was observed between ALA intakes and systolic BP (in the range of -0.5 to -1 mmHg).

An animal study in spontaneously hypertensive rats (Sekine et al., 2007) compared the acute (after 4 hours) effect on systolic BP of administration of 1 ml flaxseed oil and 1 ml of high oleic safflower oil. The Panel considers that evidence provided does not establish that evidence derived from this animal model can be extrapolated to effects on blood pressure in humans.

In weighing the evidence the Panel took into account that the observed effects of ALA intake on BP in the human intervention studies were inconsistent, the lack of evidence in these studies, that the study design, including sample size, was appropriate to demonstrate an effect of ALA alone on BP, that cross-sectional studies have considerable limitations as a source of evidence for the claim, and the lack of evidence for a plausible mechanism for the claimed effect.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of ALA and the maintenance of normal blood pressure.

4. **Panel’s comments on the proposed wording**

4.1. **Maintenance of normal blood cholesterol (ID 493)**

The Panel considers that the following wording reflects the scientific evidence: “Alpha-linolenic acid contributes to maintenance of normal blood cholesterol concentrations”.

EFSA Journal 2009; 7(9):1252
5. Conditions and possible restrictions of use

5.1. Maintenance of normal blood cholesterol (ID 493)

In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day. Such an amount can be easily consumed as part of a balanced diet. The target population is the general population.

CONCLUSIONS

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

- The food constituent, alpha-linolenic acid, which is the subject of the health claim, is sufficiently characterised.

Maintenance of blood cholesterol (ID 493)

- The claimed effect is “contributes to healthy blood cholesterol level/helps to maintain normal cholesterol level/maintenance of normal blood cholesterol level”. The target population is the general population. Maintenance of normal blood cholesterol concentrations is beneficial to human health.

- A cause and effect relationship has been established between the dietary intake of alpha-linolenic acid and the reduction of LDL-cholesterol concentrations.

- The following wording reflects the scientific evidence: “Alpha-linolenic acid contributes to maintenance of normal blood cholesterol concentrations”.

Maintenance of blood pressure (ID 625)

- The claimed effect is “helps maintain a healthy blood pressure”. The Panel assumes the target population is the general population. Maintenance of normal blood pressure is beneficial to human health.

- The evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of ALA and the maintenance of normal blood pressure.

Conditions and possible restrictions of use

In order to bear the claim a food should contain at least 15% of the proposed labelling reference intake value of 2 g ALA per day. Such an amount can be easily consumed as part of a balanced diet. The target population is the general population.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1280, EFSA-Q-2008-1412). The scientific substantiation is based on the information provided by the Members 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


fatty acid intake of individuals (total, linolenic acid, long-chain) and their blood pressure: INTERMAP study. Hypertension 50, 313-319.


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 (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

Foods are commonly involved in many different functions 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.

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4 OJ L12, 18/01/2007
5 The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
6 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
ALA related health claims

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 / ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ALA</td>
<td>Alpha-linolenic acid</td>
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<tr>
<td>BP</td>
<td>Blood pressure</td>
</tr>
<tr>
<td>LDL</td>
<td>Low-density lipoproteins</td>
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<tr>
<td>LA</td>
<td>Linoleic acid</td>
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