



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and gamma-linolenic acid (GLA) and contribution to normal cognitive function (ID 532) and maintenance of normal bone (ID 642, 697, 1552) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and gamma-linolenic acid (GLA) and contribution to normal cognitive function (ID 532) and maintenance of normal bone (ID 642, 697, 1552) pursuant to Article 13(1) of Regulation (EC) No 1924/2006¹

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA) and gamma-linolenic acid (GLA) and contribution to normal cognitive function and maintenance of normal bone. 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 constituents that are the subjects of the health claims are “omega-3 and omega-6 fatty acids (GLA)”, “gamma-linolenic acid + eicosapentaenoic acid (GLA+EPA)”, and “evening primrose oil and fish oil”. From the references provided, the Panel assumes that the food constituents that are the subject of the claims are the n-6 fatty acid gamma-linolenic acid (GLA) in evening primrose oil and the n-3 long-chain polyunsaturated fatty acids docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in fish oil. The Panel considers that the food constituents, DHA, EPA and GLA, are sufficiently characterised.

Contribution to normal cognitive function

The claimed effect is “brain function (adult & children)”. The Panel assumes that the target population is the general population. In the context of the clarifications provided by Member States,

¹ On request from the European Commission, Question No EFSA-Q-2008-1319, EFSA-Q-2008-1429, EFSA-Q-2008-1484, EFSA-Q-2008-2289, adopted on 25 March 2011.

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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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the Panel assumes that the claimed effect refers to the contribution to normal cognitive function. The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

No human studies have been provided on the effect of the consumption of a combination of DHA, EPA and GLA on cognitive endpoints.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and contribution to normal cognitive function.

Maintenance of normal bone

The claimed effect is “bone health”. The Panel assumes that the target population is the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal bone through the promotion of calcium absorption. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that two of the human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of the food constituents on bone mineral density, that in a third study acute changes in markers of bone turnover did not predict the occurrence of an effect on bone mineral density and/or mass, and that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of DHA, EPA and GLA on the maintenance of bone *in vivo* in humans.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and maintenance of normal bone.

KEY WORDS

Docosahexaenoic acid, eicosapentaenoic acid, gamma-linolenic acid, DHA, EPA, GLA, cognitive function, bone mineral density, health claims.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

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

ASSESSMENT

1. Characterisation of the food/constituent

The food constituents that are the subjects of the health claims are “omega-3 and omega-6 fatty acids (GLA)”, “gamma-linolenic acid + eicosapentaenoic acid (GLA+EPA)”, and “evening primrose oil and fish oil”.

Evening primrose oil and fish oil are not sufficiently defined in the information provided with respect to manufacturing process or fatty acid composition. From the references provided, the Panel assumes that the food constituents that are the subject of the health claims are the n-6 fatty acid gamma-linolenic acid (GLA) in evening primrose oil and the n-3 long-chain polyunsaturated fatty acids (LC-PUFAs) docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in fish oil.

The n-3 LC-PUFAs, DHA and EPA, are well recognised nutrients which are measurable in foods by established methods. They are well absorbed when consumed in the form of triglycerides.

GLA is an n-6 LC-PUFA which is present in small amounts in a variety of foods of both plant and animal origin, and which can also be synthesised in the human body from its precursor linoleic acid (LA). GLA is a well recognised nutrient and can be measured in foods by established methods.

The Panel considers that the food constituents, DHA, EPA and GLA, which are the subject of the health claims, are sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Contribution to normal cognitive function (ID 532)

The claimed effect is “brain function (adult & children)”. The Panel assumes that the target population is the general population.

In the context of the clarifications provided by Member States, the Panel assumes that the claimed effect refers to contribution to normal cognitive function. Cognitive function includes memory,

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 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.

attention (concentration), learning, intelligence and problem solving, which are well defined constructs and which can be measured by validated psychometric cognitive tests.

The Panel considers that contribution to normal cognitive function is a beneficial physiological effect.

2.2. Maintenance of normal bone (ID 642, 697, 1552)

The claimed effect is “bone health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal bone through the promotion of calcium absorption.

The Panel considers that maintenance of normal bone is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

3.1. Contribution to normal cognitive function (ID 532)

The references provided to substantiate the claim included narrative reviews on the role of n-3 and n-6 fatty acids in the brain which did not provide original data for the scientific substantiation of the claim. One study investigated correlations between nutrient intake and the lipid profiles of meibomian gland secretions in women with Sjögren's syndrome. Three studies addressed the effects of food constituents other than DHA, EPA and GLA on cognitive-related outcomes (i.e. DHA and arachidonic acid, total n-3 fatty acids). One animal study investigated the effect of an n-3 fatty acid-depleted diet on the brain, retina, and liver fatty acyl composition of rats. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The Panel notes that no human studies have been provided on the effect of the consumption of a combination of DHA, EPA and GLA on cognitive endpoints.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and contribution to normal cognitive function.

3.2. Maintenance of normal bone (ID 642, 697, 1552)

A number of narrative reviews on the effects of dietary fats and fatty acids on calcium absorption and excretion, and on bone mass and bone turnover in different population subgroups, which included no original data that could be used for the scientific substantiation of the claim, and human intervention studies on the effects of different fats and combinations of fatty acids on health outcomes (e.g. urolithiasis, calcium absorption, and fatty acid profiles in blood and cells) other than the claimed effect, were provided. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

In a pilot randomised controlled intervention (Kruger et al., 1998), 66 elderly women (mean age 79.5 years) living in nursing homes, and with a clinical diagnosis of osteopenia or osteoporosis, were assigned to consume 6 g of a mixture of evening primrose oil and fish oil (60 % linoleic acid (LA), 8 % GLA, 4 % EPA and 3 % DHA) or 6 g of a control oil (coconut oil, 97 % saturated fatty acids, 0.2 % LA) for 18 months. A total of 21 women consumed the evening primrose and fish oil mixture for an additional 18 months, irrespective of the study group to which they were randomised. All women received 600 mg of calcium carbonate daily. The Panel notes that the follow-up is an open label, uncontrolled phase of the study, and considers that no conclusions can be drawn from this

follow-up for the scientific substantiation of the claim. The oils were supplied in 500 mg capsules, and four capsules were consumed three times daily. Bone mineral density (BMD), markers of bone turnover, and plasma and urinary calcium, potassium, creatinine and phosphate were assessed at baseline, and at 6, 12 and 18 months. No significant differences in any of these variables were observed between the intervention and control groups during the study. The Panel notes that this study does not show an effect of the food constituents on the maintenance of bone.

Bassey et al. (2000) reported on one RCT in which 43 pre-menopausal women (age range 25-40 years) and 42 post-menopausal women (age range 50-65 years) were randomly assigned to consume capsules (10 daily) each providing 4 g of evening primrose oil and 440 mg of marine fish oil plus one gram of calcium, or one gram of calcium only (control), for 12 months. The Panel assumes that the composition of the evening primrose oil plus marine fish oil mixture is the same as in the study by Kruger et al. (1998). Randomisation and data analysis were performed separately for pre- and post-menopausal women. BMD (primary outcome) and markers of bone turnover were assessed at the beginning and end of the study. No significant differences between intervention and control groups were observed with respect to any of these variables during the study. The Panel notes that this study does not show an effect of the food constituents on the maintenance of bone.

A randomised controlled intervention study on the effects of evening primrose oil, fish oil, a mixture of evening primrose and fish oil, and olive oil (placebo) given for 16 weeks on calcium absorption and excretion, and on markers of bone turnover, was provided (van Papendorp et al., 1995). BMD was not assessed in this study. The Panel notes that acute changes in markers of bone turnover do not predict the occurrence of an effect on bone mineral density and/or mass, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

Several studies on the effects of different fats and fatty acids on bone loss, bone mass, BMD and bone turnover in different animal models of post-menopausal osteoporosis (e.g. ovariectomised rats), and a series of *in vitro* studies which used osteoblast/osteoclast cell lines, were provided. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of DHA, EPA and GLA on the maintenance of bone *in vivo* in humans.

In weighing the evidence, the Panel took into account that two of the human intervention studies from which conclusions could be drawn for the scientific substantiation of the claim did not show an effect of the food constituents on bone mineral density, that in a third study acute changes in markers of bone turnover do not predict the occurrence of an effect on bone mineral density and/or mass, and that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of DHA, EPA and GLA on the maintenance of bone *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and maintenance of normal bone.

CONCLUSIONS

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

- The food constituents, DHA, EPA and GLA, which are the subject of the health claims, are sufficiently characterised.

Contribution to normal cognitive function (ID 532)

- The claimed effect is “brain function (adult & children)”. The target population is assumed to be the general population. In the context of the clarifications provided by Member States, it is

assumed that the claimed effect refers to contribution to normal cognitive function. Contribution to normal cognitive function is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and contribution to normal cognitive function.

Maintenance of normal bone (ID 642, 697, 1552)

- The claimed effect is “bone health”. The target population is assumed to be the general population. In the context of the proposed wordings, it is assumed that the claimed effect refers to the maintenance of normal bone through the promotion of calcium absorption. Maintenance of normal bone is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of DHA, EPA and GLA and maintenance of normal bone.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1319, EFSA-Q-2008-1429, EFSA-Q-2008-1484, EFSA-Q-2008-2289). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

REFERENCES

- Bassey EJ, Littlewood JJ, Rothwell MC and Pye DW, 2000. Lack of effect of supplementation with essential fatty acids on bone mineral density in healthy pre- and postmenopausal women: two randomized controlled trials of Efacal v. calcium alone. *British Journal of Nutrition*, 83, 629-635.
- Kruger MC, Coetzer H, de Winter R, Gericke G and van Papendorp DH, 1998. Calcium, gamma-linolenic acid and eicosapentaenoic acid supplementation in senile osteoporosis. *Aging*, 10, 385-394.
- Van Papendorp DH, Coetzer H and Kruger MC, 1995. Biochemical profile of osteoporotic patients on essential fatty acid supplementation. *Nutrition Research*, 15, 325-334.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods⁶ (hereinafter "the Regulation") entered into force on 19th January 2007.

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

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

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

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

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

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

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

Foods are commonly involved in many different functions⁸ of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

⁶ OJ L12, 18/01/2007

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

⁸ The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

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

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

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

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to DHA, EPA and GLA, including conditions of use from similar claims, as proposed in the Consolidated List.

| ID | Food or Food constituent | Health Relationship | Proposed wording |
|--|--|---|--|
| 532 | Omega-3 and Omega-6 fatty acids (GLA) | Brain Function (Adult & Children) | Omega 3 & 6 supports cognitive/brain function |
| | | <u>Clarification provided</u> Brain Function - Omega-3 and Omega-6 Fatty Acids help cognitive functions such as working memory and focus, learning ability and reading ability | |
| Conditions of use - Yes Richtiges Verhältnis von omega-3 und omega-6 Fettsäuren zugunsten der omega-3 Fettsäuren - 100-3000mg EPA+DHA per day | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 642 | Gamma-linolenic acid + eicosapentaenoic acid (GLA+EPA) | Bone health | Helps to maintain strong bones |
| | | | contributes to the maintenance of normal bone strength in post-menopausal women contributes to the maintenance of normal bone strength in the elderly GLA with EPA help to preserve bone density |
| Conditions of use - 320-480 mg GLA/day (current knowledge: GLA/EPA ratio lower or equal to 3/1) | | | |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 697 | Evening primrose oil and fish oil | Bone health | Helps maintain bone strength/helps maintain bone density and strength by increasing intestinal calcium absorption and reducing urinary calcium excretion |
| | | | Conditions of use - Product-specific claim: 4-6 g of 80 % EPO and 20 % FO per day |
| ID | Food or Food constituent | Health Relationship | Proposed wording |
| 1552 | Evening primrose oil and fish oil | Bone health | helps maintain bone density and strength by increasing |

| | | | |
|--|--|--|-------------------------------|
| | | | intestinal calcium absorption |
| <p>Conditions of use</p> <ul style="list-style-type: none"> - Produktspezifische Auslobung: 4-6 g of 80 % EPO und 20 % FO pro Tag - Product-specific claim: 4-6 g of 80 % EPO and 20 % FO per day | | | |

GLOSSARY AND ABBREVIATIONS

| | |
|--------|---------------------------------------|
| BMD | Bone mineral density |
| DHA | Docosahexaenoic acid |
| EPA | Eicosapentaenoic acid |
| GLA | Gamma-linolenic acid |
| LA | Linoleic acid |
| LCPUFA | Long-chain polyunsaturated fatty acid |
| RCT | Randomised controlled trial |