SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to vitamin K and maintenance of bone (ID 123, 127, 128, and 2879), blood coagulation (ID 124 and 126), and function of the heart and blood vessels (ID 124, 125 and 2880) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

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 vitamin K and the following claimed effects: maintenance of normal bone, normal blood coagulation, and normal function of the heart and blood vessels. 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 constituent that is the subject of the health claims is vitamin K (i.e. phylloquinone and menaquinone) which is a well recognized nutrient and is measurable in foods by established methods. The Panel considers that vitamin K is sufficiently characterised.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin K and the maintenance of normal bone and normal blood coagulation.

The Panel considers that, in order to bear the claims, a food should be at least a source of vitamin K as per Annex to Regulation 1924/2006. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin K2 and the normal function of the heart and blood vessels.

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1 On request from the European Commission, Question No EFSA-Q-2008-910, EFSA-Q-2008-911, EFSA-Q-2008-912, EFSA-Q-2008-913, EFSA-Q-2008-914, EFSA-Q-2008-915, EFSA-Q-2008-3612, EFSA-Q-2008-3613, adopted on 02 July 2009.

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KEY WORDS

Vitamin K, phylloquinone, menaquinones, bone, heart, blood vessels, health claims.

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The members of the Claims Sub-Working Group on Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel.

INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[3] 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 subject to this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is vitamin K (i.e. phylloquinone and menaquinone) which is a well recognized nutrient and is measurable in foods by established methods.

Vitamin K is a family of structurally similar, fat soluble, 2-methyl-1, 4-naphthoquinones, including phylloquinone (2-methyl-3-phytyl-1,4-naphthoquinone, vitamin K1) and menaquinones (collectively known as vitamin K2). Menaquinones are a large series of compounds containing an unsaturated side chain with differing numbers of isoprenyl units at the 3 position in the methyl-1,4-naphthoquinone nucleus. Depending on the number of isoprenyl units, the individual compounds are designated as menaquinone-n-(MK-n). Phylloquinone (vitamin K1) is found in higher plants and algae, with the highest concentration in green leafy vegetables. Menaquinones (vitamin K2) occur naturally in foods and can also be produced by many bacteria.

Phylloquinone and menaquinones are naturally present in foods and phylloquinone has been authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006[4] and Annex I of Directive 2002/46/EC[5]). This evaluation applies to vitamin K naturally present in foods and to the form authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006 and Annex II of Directive 2002/46/EC).

The Panel considers that the food constituent, vitamin K, which is the subject of the health claim, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of bone (ID 123, 127, 128, and 2879)

The claimed effects are “bone structure”, “bone integrity”, “bone calcification” and “bone health”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to the maintenance of normal bone.

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

[3] 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.
[4] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38.
[5] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12.7.2002, p. 51–57.

2.2. Blood coagulation (ID 124 and 126)

The claimed effects are "heart health" and "blood coagulation". The Panel assumes that the target population is the general population.

The Panel considers that normal blood coagulation is beneficial to human health.

2.3. Function of the heart and blood vessels (ID 124, 125 and 2880)

The claimed effects are "cardiovascular health", "vascular health", and "heart health". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel notes that the claimed effects relate to the normal function of the heart and blood vessels.

The Panel considers that the normal function of the heart and blood vessels is beneficial to human health.

3. Scientific substantiation of the claimed effect

Proteins containing γ-carboxy-glutamic acid (Gla) residues are known to be dependent on vitamin K for their synthesis. These include (but are not limited to) the plasma clotting factors II, VII, IX, X; proteins S, C and Z (which play an anticoagulant rather than a procoagulant role in normal haemostasis); and osteocalcin and matrix Gla protein (MGP), which are abundant in bone and appear to play a role in the control of tissue mineralisation and skeletal turnover.

Vitamin K status is determined through measures of the ratio of carboxylated to non carboxylated vitamin K – dependent proteins.

3.1. Maintenance of bone (ID 123, 127, 128, and 2879)

Vitamin K functions as a cofactor in the post-translational carboxylation of several bone proteins, of which the most abundant one is osteocalcin. Osteocalcin (OC) is a small Gla-protein uniquely synthesized in bone and circulating under- carboxylated osteocalcin (ucOC) provides a measure of the vitamin K status of bone (IoM, 2001).

There is evidence that OC plays a role in the control of tissue mineralisation and skeletal turnover (Adams and Pepping, 2005; Berkner, 2005). In addition, some epidemiological studies suggest that low vitamin K intake or status is associated with osteoporosis, osteopenia and increased risk of fracture (Booth et al., 2000; Hodges et al., 1991; Hodges et al., 1993; Ikeda et al., 2006; Kanai et al., 1997; Katsuyama et al., 2002; Katsuyama et al., 2004; Tamatani et al., 1998), and intervention trials provide some evidence of an effect of vitamin K1 and vitamin K2 supplementation in reducing bone loss and of vitamin K2 supplementation in reducing the risk of fracture, the latter primarily in Japanese populations (Cockayne et al., 2006, Bolton-Smith, 2001; Bolton-Smith et al., 2007; Braam et al., 2003; Bunyaratavej et al., 2001; Feskanich et al., 1999; Ishida and Kawai, 2004; Knapen et al., 2007; Ozuru et al., 2002; Orimo et al., 1998; Ushiroyama et al., 2002). In a population based cohort study in 2,016 peri-menopausal and early postmenopausal women, vitamin K1 intake was not associated with any effects on bone mineral density (BMD) or fracture risk (Rejnmark et al., 2006).

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin K and the maintenance of normal bone.

3.2. Blood coagulation (ID 124 and 126)

Vitamin K is needed for the normal function of many of the enzymes involved in the coagulation cascade through carboxylation of glutamic acid in the side chain, and hence allowing calcium fixation (IoM, 2001).

Restriction of vitamin K intakes to levels almost impossible to achieve in any nutritionally adequate, self-selected diet (10 µg/day for several weeks) do not impair normal haemostatic control in healthy subjects. Although there is some interference in the hepatic synthesis of the vitamin K-dependent clotting factors that can be measured by sensitive assays, standard clinical measures of pro-coagulant potential are not changed, except in some breast-fed infants.

The Panel concludes that a cause and effect relationship has been established between the dietary intake of vitamin K and normal blood coagulation.

3.3. Function of the heart and blood vessels (ID 124, 125 and 2880)

Vitamin-K dependent proteins have been identified in vascular tissue, including a matrix Gla-protein (MGP). In a MGP knockout mouse model, spontaneous calcification of soft tissues (mostly arteries) occurs (Luo et al., 1997). In the Keutel syndrome, due to a mutation of the gene encoding the human MGP, patients display several of the same features as the knockout mice, including abnormal calcification of cartilage of ears, nose, and respiratory tract. However, they do not appear to have increased incidence of coronary arterial disease or rupture of abdominal aortic aneurysm (Munroe et al., 1999).

The health claims (ID 124, 125 and 2880) are made on vitamin K2. From the literature available, four papers refer to the role of vitamin K from all sources and/or vitamin K2 in relation to the heart and/or blood vessels (Jie et al., 1995; Maas et al., 2007; Geleijnse et al., 2004; Beulens et al., 2009). The Panel considers that studies investigating the relationship between vitamin K intake (from all sources and/or as vitamin K2) and arterial calcification or the elastic properties of the arteries (which may interfere with normal vascular structure and function) are pertinent to the claimed effect.

Three cross-sectional studies investigated the relationship between vitamin K intake and arterial calcification in women. Whereas one study found lower vitamin K (mainly vitamin K1) intakes in women with aortic atherosclerosis (Jie et al., 1995) as compared to controls, another study reported that vitamin K2 (but not vitamin K1) intake was inversely related to the presence of coronary calcification (Beulens et al., 2008), and the third showed no association between either vitamin K1 or vitamin K2 intake and breast arterial calcification after adjustment for confounders (Maas et al., 2007).

An observational prospective study in 4,807 older men and women found that high intakes of vitamin K2 (but not of K1) were associated with a significantly lower degree of aortic calcification and lower incidence of coronary heart disease after adjustment for confounders (Geleijnse et al., 2004). The Panel notes that no definite conclusion can be drawn from this single prospective study on a causal link between the intake of vitamin K2 and the normal function of the heart and blood vessels.

In weighing the evidence, the Panel took into account the inconsistency of the results reported in three cross-sectional studies, and that no definite conclusion can be drawn from a single prospective study on a causal link between the intake of vitamin K2 and the normal function of the heart and blood vessels.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin K2 and the normal function of the heart and blood vessels.

4. Panel's comments on the proposed wording

4.1. Maintenance of bone (ID 123, 127, 128, and 2879)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin K contributes to maintenance of normal bone".

4.2. Blood coagulation (ID 124 and 126)

The Panel considers that the following wording reflects the scientific evidence: "Vitamin K contributes to normal blood coagulation".

5. Conditions and possible restrictions of use

The Panel considers that in order to bear the claims a food should be at least a source of vitamin K as per Annex to Regulation 1924/2006. Such amounts 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, vitamin K, which is the subject of the health claims is sufficiently characterised.

Maintenance of bone (ID 123, 127, 128, and 2879)

- The claimed effects are "bone structure", "bone integrity", "bone calcification" and "bone health". The target population is the general population. Maintenance of normal bone is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin K and the maintenance of normal bone.
- The following wording reflects the scientific evidence: "Vitamin K contributes to maintenance of normal bone".

Blood coagulation (ID 124 and 126)

- The claimed effects are "heart health" and "blood coagulation". The target population is the general population. Normal blood coagulation is beneficial to human health.
- A cause and effect relationship has been established between the dietary intake of vitamin K and normal blood coagulation.
- The following wordings reflect the scientific evidence "Vitamin K contributes to normal blood coagulation".

Function of the heart and blood vessels (ID 124, 125 and 2880)

- The claimed effects are "cardiovascular health", "vascular health", and "heart health". The target population is the general population. Normal function of the heart and blood vessels is beneficial to human health.

- The evidence provided is insufficient to establish a cause and effect relationship between the dietary intake of vitamin K2 and normal function of the heart and blood vessels.

Conditions and possible restrictions of use

- In order to bear the claims a food should be at least a source of vitamin K as per Annex to Regulation 1924/2006. Such amounts 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-2008-915, EFSA-Q-2008-914, EFSA-Q-2008-913, EFSA-Q-2008-912, EFSA-Q-2008-911, EFSA-Q-2008-910, EFSA-Q-2008-3613, EFSA-Q-2008-3612). 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.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[6] (hereinafter "the Regulation") entered into force on 19th January 2007.

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

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

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

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

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

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

Foods are commonly involved in many different functions[8] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

[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).

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 DISCAIMER

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 vitamin K, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
123	Vitamin K	Bone structure	Vitamin K is needed to build and maintain healthy bones' Vitamin K is required for the normal structure of the bone; Vitamin K contributes to promote bone remineralization'
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 20 microgram(s) Vitamin K Daily amount to be consumed to produce claimed effect: 20 microgram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption Food supplement with 70µg of vitamin K in the daily dose - MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Applicable to both children and adults Typical adults dosage: up to 10 mg. No RDA established for Vitamin K. Pregnant and nursing mothers should avoid supplemental intakes. Vitamin K should be avoided by those taking warfarin. Guidance level is 1mg/day or less (FSA). - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC The product must contain at least 15% of the RDA - 120 µg per day - 60 mcg / d für Frauen—70 mcg / d für Männer—Erwachsene		
124	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Vitamin K1 + K2	Heart Health	Vitamin K1 and K2 supports a healthy heart Vitamin K1 and K2 stimulates blood clotting.
	Conditions of use - Source of / 15% of RDA per 100 g		
125	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Vitamin K2	Vascular health	Vitamin K2 contributes to vascular health
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 60 micrograms vitamin K2 Daily amount to be consumed to produce claimed effect: 9 microgram(s) Length of time after consumption for claimed effect to become apparent: Habitual intake MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006		

126	Food or Food component	Health Relationship	Proposed wording
	Vitamin K	Blood coagulation	Vitamin K is needed for normal blood coagulation (blood clotting).
	Conditions of use - Es werden nur die Nährstoffe beworben, die lt. Nährwertkennzeichnungs-verordnung (Anlage 1) mindestens 15 Prozent der empfohlenen Tagesdosis in 100 g oder 100 ml enthalten. - Number of nutrients/other substances that are essential to claimed effect: 1 Names of nutrient/other substances and Quantity in Average daily serving: 12 microgram(s) vitamin K Daily amount to be consumed to produce claimed effect: 12 microgram(s) Length of time after consumption for claimed effect to become apparent: Regular consumption MUST AT LEAST BE A SOURCE OF VITAMIN/S AS PER ANNEX TO REGULATION 1924/2006 Guidance level is 1mg/day or less (FSA).		
127	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Vitamin K	Bone integrity	Vitamin K helps build and maintain healthy bones. Vitamin K is necessary for the normal structure of the bone. Vitamin K contributes to bone mineralisation. Vitamin K helps to improve bone health. Vitamin K contributes to the normal structure of bone
	Conditions of use - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC - Minimum 13,5 µg dziennie.		
128	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Vitamin K	Bone calcification	Vitamin K helps build and maintain healthy bones. Vitamin K is necessary for the normal structure of the bone. Vitamin K contributes to bone mineralisation. Vitamin K helps to improve bone health. Vitamin K contributes to the normal structure of bone
	Conditions of use - Minimum 15% RDA per 100g or 100ml or per single servings as per 90/496/EEC		

2879	Food or Food component	Health Relationship	Proposed wording
	Menaquinone-7 (MK-7, a form of vitamin K2)	Bone health	"MK-7 is a highly bioavailable form of vitamin K that helps maintain healthy bones".
	Conditions of use - Products containing a minimum of 15% of the vitamin K Reference Labelling Value (which is 75 micrograms for adults and 12 micrograms for children 6 months to 4 years of age) would be permitted to carry the claim (i.e., products intended for adults must contain a minimum of 11 micrograms MK-7 per 100 g or 100 mL, while products intended for children must contain a minimum of 2 micrograms per 100 g or 100 mL).		
2880	**Food or Food component**	**Health Relationship**	**Proposed wording**
	Menaquinone-7 (MK-7, a form of vitamin K2)	Cardiovascular Health	"MK-7 is a highly bioavailable form of vitamin K that helps maintain a healthy cardiovascular system" "MK-7 is a highly bioavailable form of vitamin K that helps keep the heart and blood vessels healthy"
	Conditions of use - Products containing a minimum of 15% of the vitamin K Reference Labelling Value (which is 75 micrograms for adults and 12 micrograms for children 6 months to 4 years of age) would be permitted to carry the claim (i.e., products intended for adults must contain a minimum of 11 micrograms MK-7 per 100 g or 100 mL, while products intended for children must contain a minimum of 2 micrograms per 100 g or 100 mL).		

GLOSSARY AND ABBREVIATIONS

Gla	γ-carboxy-glutamic acid
MGP	matrix Gla protein
OC	osteocalcin
ucOC	under- carboxylated osteocalcin
BMD	bone mineral density