

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175), maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175) and maintenance of muscles (ID 2254, 2311) 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 food(s)/food constituent(s) and maintenance of joints, maintenance of bone and maintenance of muscles. The scientific substantiation is based on the information provided by the

1 On request from the European Commission, Question No EFSA-Q-2008-2497, EFSA-Q-2008-2532, EFSA-Q-2008-2640, EFSA-Q-2008-2706, EFSA-Q-2008-2755, EFSA-Q-2008-2911, EFSA-Q-2008-2935, EFSA-Q-2008-2987, EFSA-Q-2008-2988, EFSA-Q-2008-3044, EFSA-Q-2008-3127, EFSA-Q-2008-3150, EFSA-Q-2008-3151, EFSA-Q-2008-3191, EFSA-Q-2008-3382, EFSA-Q-2008-3527, EFSA-Q-2008-3531, EFSA-Q-2008-3851, EFSA-Q-2008-3876, EFSA-Q-2008-4006, EFSA-Q-2008-4015, EFSA-Q-2008-4050, EFSA-Q-2008-4070, EFSA-Q-2008-4222, EFSA-Q-2008-4238, EFSA-Q-2008-4250, EFSA-Q-2008-4281, EFSA-Q-2008-4349, EFSA-Q-2008-4422, EFSA-Q-2008-4468, EFSA-Q-2008-4489, EFSA-Q-2008-4551, EFSA-Q-2008-4600, EFSA-Q-2008-4608, EFSA-Q-2008-4620, EFSA-Q-2008-4659, EFSA-Q-2008-4693, EFSA-Q-2008-4726, EFSA-Q-2008-4732, EFSA-Q-2008-4768, EFSA-Q-2008-4848, EFSA-Q-2008-4886, adopted on 15 October 2009.

2 Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

3 Acknowledgement: The Panel wishes to thank for the preparation of this opinion: The members of the Working Group on claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Bone/Teeth/Connective Tissue: Rikke Andersen, Olivier Bruyère, Albert Flynn, Ingegerd Johansson, Jukka Meurman and Hildegard Przyrembel.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175), maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175) and maintenance of muscles (ID 2254, 2311) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010; 8(2):1493. [22 pp.]. doi:10.2903/j.efsa.2010.1493. Available online: www.efsa.europa.eu

Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

Maintenance of joints

The claimed effects are “joint health/mobility/comfort”, “joints”, “joint support”, “helps to maintain mobility of joint during and after climacterium”, “contributes to physical well-being”. The target population is assumed to be the general population for all claims except for ID 3144, for which the target population is assumed to be post-menopausal women. The Panel considers that maintenance of normal joints is a beneficial physiological effect.

No human studies investigating the effects of the food(s)/food constituent(s) on the maintenance of normal joints have been provided. The evidence provided does not establish that results obtained in studies on subjects with osteoarthritis or (osteo)arthritis of different origin relating to the treatment of symptoms of these diseases (e.g. erosion of articular cartilage, reduced mobility of joints) can be extrapolated to the maintenance of normal joints in the general population. The evidence provided in the animal and *in vitro* studies submitted is not sufficient to predict the occurrence of an effect of the food(s)/food constituent(s) on the maintenance of normal 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 the food(s)/food constituent(s) evaluated in this opinion and the maintenance of normal joints.

Maintenance of bone

The claimed effects are “bone” and “bone health”. The target population is assumed to be the general population. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this opinion and the maintenance of normal bone.

Maintenance of muscles

The claimed effect is “muscle”. The target population is assumed to be the general population. The Panel considers that maintenance of normal muscles is a beneficial physiological effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this opinion and the maintenance of normal muscles.

KEY WORDS

Joints, bone, muscles, 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
Information as provided in the consolidated list	5
Assessment	5
1. Relevance of the claimed effect to human health	5
1.1. Maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175)	5
1.2. Maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175).....	5
1.3. Maintenance of muscles (ID 2254, 2311).....	5
2. Scientific substantiation of the claimed effect	6
2.1. Maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175)	6
2.2. Maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175).....	6
2.3. Maintenance of muscles (ID 2254, 2311).....	7
Conclusions	7
Documentation provided to EFSA	8
Appendices	9

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

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 from similar health claims. 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. Relevance of the claimed effect to human health

1.1. Maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175)

The claimed effects are “joint health/mobility/comfort”, “joints”, “joint support”, “helps to maintain mobility of joint during and after climacterium”, “contributes to physical well-being”. The Panel assumes that the target population is the general population for all claims except for ID 3144, for which the Panel assumes that the target population is post-menopausal women.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance of normal joints.

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

1.2. Maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175)

The claimed effects are “bone” and “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 effects refer to the maintenance of normal bone.

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

1.3. Maintenance of muscles (ID 2254, 2311)

The claimed effect is “muscle”. 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 muscles.

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

⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

2. Scientific substantiation of the claimed effect

Most of the references provided addressed food(s)/food constituent(s) other than those for which the specific claims are proposed, and/or claimed effects unrelated to the structure and/or function of joints, bone and muscles. This literature includes general reviews on the “antioxidant” or “anti-inflammatory” properties of food(s)/food constituent(s) used in certain countries in the management of medical conditions associated with acute or chronic joint damage of either inflammatory or degenerative origin (e.g. osteoarthritis, rheumatoid arthritis, psoriatic arthritis, arthritis of infectious origin). The Panel considers that no scientific conclusions can be drawn from these references for the substantiation of the claims.

2.1. Maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175)

No human studies investigating the effects of the food(s)/food constituent(s) on the maintenance of normal joints have been provided in relation to any of the health claims evaluated in this section.

Some human intervention studies investigating the effects of the food(s)/food constituent(s) on the treatment of osteoarthrosis or (osteo)arthritis of different origin (rheumatoid arthritis, psoriatic arthritis, arthritis of infectious origin) were submitted. The Panel considers that the evidence provided does not establish that patients with osteoarthrosis or (osteo)arthritis of different origin are representative of the general population with regard to the status of joint tissues, or that results obtained in studies on subjects with osteoarthrosis or (osteo)arthritis of different origin relating to the treatment of symptoms of these diseases (e.g. erosion of articular cartilage, reduced mobility of joints) can be extrapolated to the maintenance of normal joints in the general population. Thus, for claims supported only by references to human studies on patients with osteoarthrosis or (osteo)arthritis of different origin, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect in the general population.

A number of *in vitro* studies were provided addressing the effects of different food(s)/food constituent(s) on human chondrocytes/cartilage explants and chondrocyte cell lines. Also, studies were provided on the relationship between the intake of the food(s)/food constituent(s) and the claimed effect in animal models of experimentally-induced arthritis. The Panel considers that the evidence provided in the animal and *in vitro* studies submitted is not sufficient to predict the occurrence of an effect of the food(s)/food constituent(s) on the maintenance of normal joints *in vivo* in humans. The Panel considers that while effects shown in animal and *in vitro* studies may be used as supportive evidence, human studies are required for substantiation of a claim. Thus, for claims supported by references to animal studies and/or *in vitro* studies only, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal joints.

2.2. Maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175)

No intervention studies in humans investigating the effects of the food(s)/food constituent(s) on bone in healthy subjects have been provided in relation to any of the health claims evaluated in this section.

A number of *in vitro* studies were provided addressing the effects of different food(s)/food constituent(s) on human osteoblast/osteoclast cell lines. Also, studies were provided on the

relationship between the intake of the food(s)/food constituent(s) and the claimed effect in animal models of experimentally-induced osteoporosis. The Panel considers that the evidence provided in the animal and *in vitro* studies submitted is not sufficient to predict the occurrence of an effect of the food(s)/food constituent(s) on the maintenance of normal bone *in vivo* in humans. The Panel considers that while effects shown in animal and *in vitro* studies may be used as supportive evidence, human studies are required for substantiation of a claim. Thus, for claims supported by references to animal studies and/or *in vitro* studies only, the Panel considers that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal bone.

2.3. Maintenance of muscles (ID 2254, 2311)

No studies investigating the effects of the food(s)/food constituent(s) on muscle outcomes have been provided in relation to any of the health claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal muscles.

CONCLUSIONS

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

Maintenance of joints (ID 1799, 1973, 2022, 2178, 2202, 2254, 2255, 2311, 2394, 2417, 2418, 2458, 2649, 2794, 2798, 3119, 3144, 3274, 3283, 3318, 3339, 3495, 3511, 3523, 3555, 3624, 3699, 3748, 3770, 3835, 3884, 3892, 3904, 3943, 3978, 4012, 4020, 4056, 4137, 4175)

- The claimed effects are “joint health/mobility/comfort”, “joints”, “joint support”, “helps to maintain mobility of joint during and after climacterium”, “contributes to physical well-being”. The target population is assumed to be the general population for all claims except for ID 3144, for which the target population is assumed to be post-menopausal women. Maintenance of normal joints is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal joints.

Maintenance of bone (ID 1764, 1907, 2418, 4012, 4020, 4056, 4175)

- The claimed effects are “bone” and “bone health”. The target population is assumed to be the general population. Maintenance of normal bone is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal bone.

Maintenance of muscles (ID 2254, 2311)

- The claimed effect is “muscle”. The target population is assumed to be the general population. Maintenance of normal muscles is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) evaluated in this section and the maintenance of normal muscles.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13(1) of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2497, EFSA-Q-2008-2532, EFSA-Q-2008-2640, EFSA-Q-2008-2706, EFSA-Q-2008-2755, EFSA-Q-2008-2911, EFSA-Q-2008-2935, EFSA-Q-2008-2987, EFSA-Q-2008-2988, EFSA-Q-2008-3044, EFSA-Q-2008-3127, EFSA-Q-2008-3150, EFSA-Q-2008-3151, EFSA-Q-2008-3191, EFSA-Q-2008-3382, EFSA-Q-2008-3527, EFSA-Q-2008-3531, EFSA-Q-2008-3851, EFSA-Q-2008-3876, EFSA-Q-2008-4006, EFSA-Q-2008-4015, EFSA-Q-2008-4050, EFSA-Q-2008-4070, EFSA-Q-2008-4222, EFSA-Q-2008-4238, EFSA-Q-2008-4250, EFSA-Q-2008-4281, EFSA-Q-2008-4349, EFSA-Q-2008-4422, EFSA-Q-2008-4468, EFSA-Q-2008-4489, EFSA-Q-2008-4551, EFSA-Q-2008-4600, EFSA-Q-2008-4608, EFSA-Q-2008-4620, EFSA-Q-2008-4659, EFSA-Q-2008-4693, EFSA-Q-2008-4726, EFSA-Q-2008-4732, EFSA-Q-2008-4768, EFSA-Q-2008-4848, EFSA-Q-2008-4886). 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>

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation (EC) No 1924/2006 on nutrition and health claims made on foods⁵ (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 FOOD⁶

Foods are commonly involved in many different functions⁷ 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.

⁵ OJ L12, 18/01/2007

⁶ The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

⁷ 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 food(s)/food constituent(s) claiming maintenance of joints, maintenance of bone, or maintenance of muscles, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1764	Hesperidin (a component of citrus peel extract and precursor of hesperitin) (ingredient not found in the spanish food laws)	Bone health	Helps maintain healthy/strong bones (to be evaluated by EFSA)
	Conditions of use ≥ 500 mg (particularly suited for peri- and post-menopausal women)		
1799	Citrus bioflavonoids	Joints	May help to keep joints healthy.
	Conditions of use - Food supplement with 100 mg of citrus bioflavonoids in the daily dose.		
1907	Naringin (a component of citrus peel extract and precursor of naringenin)	Bone health	Helps maintain healthy/strong bones
	Conditions of use - ≥ 500 mg (particularly suited for peri- and post-menopausal women)		
1973	SAME (S-adenosylmethionine)	Joint health, mobility and joint comfort	joint health, mobility and joint comfort additional statement : “If you are taking prescription antidepressant medications, consult your physician before using this product. Individual with bipolar (manic) depression should not use this product unless under medical supervision.”
	Conditions of use - 200 to 400 mg / day		
2022	Cherries (Prunus cerasus), including Montmorency, Balaton or other sour/tart cherry varieties	Joint support	[Tart/sour] cherries help support healthy joints
	Conditions of use - Variable, depending on formulation e.g. concentrate for dilution in water (typically 30 ml		

per day) or freeze-dried extract (typically, 1-2 capsules daily)			
	Food or Food constituent	Health Relationship	Proposed wording
2178	Balsamodendron mukul (common name: Balsamodendron mukul)	Joint health	Supports joint health and flexibility Helps to maintain healthy joints
	Conditions of use - Gum/ The equivalent of 1000mg daily of dry extract		
	Food or Food constituent	Health Relationship	Proposed wording
2202	Alchemilla vulgaris	Joint health	For healthy joints Contributes to healthy muscles and joints
	Conditions of use - Nebulizate (1:5) 600-1200 mg per day		
	Food or Food constituent	Health Relationship	Proposed wording
2254	Eucalyptus globulus	Muscles and joint health	For healthy joints Contributes to healthy muscles and joints
	Conditions of use - Herb / Usual consumption as traditional foodstuff in a normal diet oil per day / The equivalent of 4 g leaf per day		
	Food or Food constituent	Health Relationship	Proposed wording
2255	Filipendula ulmaria - common name : meadowsweet	Joint health	Used for the good function of joints Helps to maintain joint health Contributes to maintain joint health Supports joint flexibility
	Conditions of use - Traditional use of the flower and the flowering top / 3-6g of dried flowering tops as an infusion in hot water, many times daily , or equivalent quantity in extract - herb, flowers, flowering tops Infusion : 12-18g of dried flowering tops per day - Flowering tops/ 3-6g of dried flowering tops as an infusion in hot water, many times daily , equivalent preparations		
	Food or Food constituent	Health Relationship	Proposed wording
2311	Myristica fragrans	Muscles and joint health	For healthy joints/contributes to healthy muscles and joints
	Conditions of use - Seed / Usual consumption as traditional foodstuff in a normal diet oil per day / The equivalent of 0.3-1 g seed per day		
	Food or Food constituent	Health Relationship	Proposed wording
2394	Arctium lappa (Burdock)	Joint health	For joint health — improves functional state and mobility of joints, activates metabolism,

			protects and renews cartilage tissue
Conditions of use			
- 1 - 360 mg / Used as part of a multibotanical combination			
2417	Food or Food constituent	Health Relationship	Proposed wording
	Comarum palustre	Joint health	For joint health — improves functional state and mobility of joints, activates metabolism, protects and renews cartilage tissue Contains herbs with joint inflammation reducing properties and herbs that promote resilience of joint cartilage
Conditions of use			
- Root: 400- 800 mg / Herb: 400 mg / Used as part of a multibotanical combination			
2418	Food or Food constituent	Health Relationship	Proposed wording
	Commiphora wighti (Indian Bedellium, Guggal)	Joint, bone health	Joint inflammation reducing properties, promotes renewal of joint cartilage Helps strengthen bones and protect bones and joints from the effect of free radicals
Conditions of use			
- Powder: 105 - 400 mg / Used as part of a multibotanical combination			
2458	Food or Food constituent	Health Relationship	Proposed wording
	Ledebouriella seseloides	Joint health	For joint health — improves functional state and mobility of joints, activates metabolism, protects and renews cartilage tissue
Conditions of use			
- 0,6- 1,2 g / Used as part of a multibotanical combination			
2649	Food or Food constituent	Health Relationship	Proposed wording
	ginger extract (Zingiberis officinale)	helps to maintain mobility of joints	helps to maintain mobility of joints and to avoid morning avoid morning stiffness
Conditions of use			
<ul style="list-style-type: none"> - Powder: 5.0-0.1 g/day; aqueous extract 2.5-0.05 g/day. - Food supplement with 1.8 g of ginger root in the daily dose. - Food supplements containing ginger extract, in which the daily dose is equivalent to 3.5-7 g of dried ginger root. - 140 až 280 mg of ginger oil per day - Root extract / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 1-2g of root per day 			

	Food or Food constituent	Health Relationship	Proposed wording
2794	Avocado-soy extract	Joints	<p>Natural flexibility for the joints.</p> <p>Accelerates the formation of new cartilage by increasing the formation of cartilage growth factors.</p> <p>Facilitates exercise.</p> <p>Activates the building of joint cartilage.</p> <p>Natural flexibility remains.</p> <p>Accelerates the formation of collagen in joint membrane cells (synoviocytes).</p>
	<p>Conditions of use</p> <p>- Food supplement with 310 mg of ASU extract (avocado-soy-unsaponified) in the daily dose.</p>		
2798	Bilberry + pine bark	Musculoskeletal system	<p>For joint health.</p> <p>Good for the connective tissues.</p>
	<p>Conditions of use</p> <p>- Food supplement with 40 mg of bilberry extract, 20 mg of mixture of bilberry leaf extract and powder, 200 mg of bilberry powder and 60 mg of pine bark in the daily dose.</p>		
3119	Scutellaria baicalensis Georgi (root) for use as a food supplement. (Common name: Chinese skullcap) Currently on the market as traditional tea decoctions and food supplements. (Also known as Ben Cao; Huang gin; Baikal Skullcap; Scutellariae Radix)	Supports joint function	<ul style="list-style-type: none"> •Acts as natural occurring anti-oxidant. •Reduces the oxidative stress caused by collagen damage. •Supports joint health. •Maintain joint flexibility and protects tendons. •Contributes to the proper function of skeleton muscles in normal physical activity, physical exercise, or sport activity. •Improves mobility.
	<p>Conditions of use</p> <p>- 10mg - 2200mg/day or more</p>		
3144	isoflavones	helps to maintain mobility of joint during and after climacterium	helps to maintain mobility of joint during and after climacterium
	<p>Conditions of use</p>		

	- 50 mg of isoflavones per day		
3274	Food or Food constituent	Health Relationship	Proposed wording
	Birch Betula pendula Roth. / Betula pubescens Ehrh. Nom français : bouleau	Joint health	Traditionally used to contribute/support/help to healthy joint activity - Traditionally used to contribute/support/help to joint well-being - Traditionally used to contribute/support/help to joint mobility and suppleness - Contribute/support/help to healthy joint activity - Contribute/support/help to joint well-being - Contribute/support/help to joint mobility and suppleness
	Conditions of use Leaf. 2-3g of dried leaves several times per day and equivalent preparations		
3283	Food or Food constituent	Health Relationship	Proposed wording
	CASSIA ANGUSTIFOLIA VAHL.	Contributes to physical well-being.	Helps maintaining mobility and flexibility of joints.
	Conditions of use - Dried extract (tit. hydroxyanthracene ethersides as sennoside B min. 2.2%): 2-4 mg/kg/day, once in the evening		
3318	Food or Food constituent	Health Relationship	Proposed wording
	CIMICIFUGA RACEMOSA NUTT.	Contributes to physical well-being	Helps maintaining mobility and flexibility of joints.
	Conditions of use - Dried extract (tit. triterpenic glycosides as 27-desoxyactein min. 2.5%): 0.6-1.0 mg/kg/day, divided in 2 doses with empty stomach		
3339	Food or Food constituent	Health Relationship	Proposed wording
	ECHINACEA PALLIDA BRITTON	Contributes to physical well-being.	Helps maintaining mobility and flexibility of joints.
	Conditions of use - Dried extract (tit. echinacoside min 0.6%): 12-13 mg/kg/day, divided in 2 doses with empty stomach. Daily echinacoside dose: 0.2-0.3 mg/kg. Duration of treatment should not exceed 8 weeks		
3495	Food or Food constituent	Health Relationship	Proposed wording
	PICRORHIZA KURROA ROYLE	Contributes to physical well-being	Helps maintaining mobility and flexibility of joints.
	Conditions of use - 400-1500 mg/day standardized (4% kutkin) encapsulated powder extract, with dosages up to 3.5 g/day		
3511	Food or Food constituent	Health Relationship	Proposed wording
	PLANTAGO LANCEOLATA	Contributes to physical	Helps maintaining mobility and

	L.	well-being.	flexibility of joints.
	Conditions of use - 3-6 g daily for external or internal use; tea: 2-4 g of the chopped drug in water		
3523	Food or Food constituent	Health Relationship	Proposed wording
	Populus tremuloides Michx	Joint health	Helps strengthen the body's locomotion system / helps maintain joint health / helps to maintain flexible joints and tendons / helps maintain good mobility
	Conditions of use - folia et cortex; 4 g in aqueous preparation; 4-8 ml tincture (1:5, 45% ethanol)		
3555	Food or Food constituent	Health Relationship	Proposed wording
	RHEUM UNDULATUM L.	Contributes to physical well-being	Helps maintaining mobility and flexibility of joints.
	Conditions of use - Powder: 0.3-2 g daily		
3624	Food or Food constituent	Health Relationship	Proposed wording
	Mucopolysaccharides	Mucopolysaccharides are related to joint health.	Mucopolysaccharides help maintaining healthy joints
	Conditions of use - 2.5 grams of fenugreek seed powder in capsule form, twice daily for 3 months, or 100 g debitterized powdered seeds divided in 2 doses		
3699	Food or Food constituent	Health Relationship	Proposed wording
	Boswellia serrata (Common Name : Frankincense)	Joint health	Helps to maintain joint health/supports joint flexibility
	Conditions of use - Resin / The equivalent of 300 to 450 mg boswellic acids per day		
3748	Food or Food constituent	Health Relationship	Proposed wording
	Curcuma longa/domestica (Common Name : Turmeric, kunyit, curcumin)	Joint Health	Cell protection / Helps to protect joints / helps to maintain joints flexibility / Contributes to Joints health
	Conditions of use - Root extract equivalent to 10 to 20 g of fresh root, titrated in 300 mg to 600 mg per day of curcumin - Root 0.5-3g/day		
3770	Food or Food constituent	Health Relationship	Proposed wording
	Harpagophytum procumbens - common name : Devil's claw	Joint health	"Traditionally used for the good function of joints" / "Used for the good function of joints" / "Helps to maintain joint health" / "Contributes to maintain joint

			health" / "Supports joint flexibility"
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Traditional use of the root / 2-5g of root per day / Equivalent quantity in extract / Quantity of inoidoids does not exceed 40mg per day - root / 2-9 g of dried root daily; equivalent preparations 		
3835	<p>Food or Food constituent</p> <p>Urtica dioica (Common Name : Nettle)</p>	<p>Health Relationship</p> <p>Joint health</p>	<p>Proposed wording</p> <p>Supports the locomotor system /helps strengtheningg the body´s locomotor system /positive for joint health /helps to maintain flexible joints, muscles and tendons</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Aerial parts, root / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 8 g nettle aerial parts per day - Aerial parts / hydroalcoholic extracts corresponding to of 8-12 g per day/ 9-15 g as an infusion daily/ tincture (1:5 25% ethanol) 6-18 ml daily/ fresh juice 45 ml daily /equivalent preparations - Aerial parts, root / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 8 g netle aerial parts per day 		
3884	<p>Food or Food constituent</p> <p>Salix alba (Common Name : Willow)</p>	<p>Health Relationship</p> <p>Joint health</p>	<p>Proposed wording</p> <p>For healthy joints /contributes to healthy muscles and joints</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Equivalent to 120-240 mg salicin or 3-9 g dried bark - Equivalent to 120-240 mg salicin or 3-9 g dried bark 		
3892	<p>Food or Food constituent</p> <p>Uncaria tomentosa (Common Name : cat's claw)</p>	<p>Health Relationship</p> <p>joint health</p>	<p>Proposed wording</p> <p>Helps to maintain flexible joints</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Leaf, flowers, thorns, bark / The equivalent of minimum 1000 mg dried plant material per day - Leaf, flowers, thorns, bark / The equivalent of minimum 350 mg dried plant materials per day 		
3904	<p>Food or Food constituent</p> <p>Boswellia serrata (Common Name : Frankincense)</p>	<p>Health Relationship</p> <p>Joint health</p>	<p>Proposed wording</p> <p>Supports joint flexibility/ Helps keep joints cool and comfortable</p>
	<p>Conditions of use</p> <ul style="list-style-type: none"> - Resin / 900-1200 mg of extract standardized 60% of boswellic acids daily / equivalent preparations 		

	Food or Food constituent	Health Relationship	Proposed wording
3943	Harpagophytum procumbens (Common Name : Devil's Claw - root)	Joint health	Helps strengthen the body's locomotor system /helps maintain joint health /helps to maintain flexible joints and tendons /helps maintain good mobility
	Conditions of use - Root / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 1-4.5 g of dried root or 50-100 mg of harpagoside per day - Root / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 1-4.5 g of dried root or 50-100 mg of harpagoside per day		
3978	Asphaltum/Shilajit - purified	Bones/joints	Helps to maintain the strength of bones Helps maintain the health of joints
	Conditions of use - Powder: 1.0-0.05g/day - All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
4012	Curcuma longa RHIZOME	Joints & bones	Helps maintain the health of joints and bones
	Conditions of use - Powder 3.0-0.1g/day; aqueous extract 1.5-0.05 g/day. (in case of gallstones consult physician), - All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
4020	Commiphora mukul PURIFIED EXUDATE	Joints & bones	Helps maintain the health of joints and bones
	Conditions of use - Powder: 0.75-0.05g/day. Unsupervised long-term use of more than 250-500mg/day is not recommended during pregnancy. May occasionally loosen the bowels Do not use in case of diarrhoea. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose - Résine 6x280mg/jour		
4056	Glycyrrhiza glabra ROOT	Joints & bones	Helps to maintain the health and comfort of joints
	Conditions of use - Powder: 4.0-0.2g/day ; aqueous extract 2.0-0.1g/day . Caution in long-term use. Not more than 3g/day in pregnancy. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		

	Food or Food constituent	Health Relationship	Proposed wording
4137	Symplocos racemosa BARK	Joints	Helps to keep joints healthy and flexible.
	Conditions of use - Powder: 1.2-0.06g/day; aqueous extract: 1.0-0.04 g/day		
	Food or Food constituent	Health Relationship	Proposed wording
4175	Tinospora cordifolia STEM	Joints & bones	Supports the health of the joints by its comprehensive cleansing action and stimulating the immune system.
	Conditions of use - Powder: 1.0-0.1g/day; aqueous extract 0.5-0.05g/day. Caution during pregnancy.		