EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to sodium and potassium salts of citric acid and maintenance of normal bone (ID 330) pursuant to Article 13(1) of Regulation (EC) No 1924/2006.

EFSA Publication; Tetens, Inge

Link to article, DOI:
10.2903/j.efsa.2011.2302

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2011;9(7):2302

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to sodium and potassium salts of citric acid and maintenance of normal bone (ID 330) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

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 sodium and potassium salts of citric acid 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 subject of the health claim are sodium and potassium salts of citric acid. The Panel considers that sodium and potassium salts of citric acid are sufficiently characterised.

The claimed effect is "acid-base balance and bone health". The target population is assumed to be the general population. In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal bone by maintaining acid-base balance. The Panel considers that maintenance of normal bone is a beneficial physiological effect.

In weighing the evidence, the Panel took into account that the results from the two human intervention studies provided which investigated the effects of potassium citrate on bone mineral density in post-menopausal women are conflicting, and that the adequately powered intervention study of longer duration using a higher dose of potassium citrate did not show an effect on bone mineral density.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the dietary intake of potassium or sodium salts of citric acid and maintenance of normal bone.

---

[1] On request from the European Commission, Question No EFSA-Q-2008-1117, adopted on 30 June 2011.

[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 preparatory work on this scientific 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 sodium and potassium salts of citric acid and maintenance of normal bone (ID 330) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(7):2302. [16 pp.]. doi:10.2903/j.efsa.2011.2302. Available online: www.efsa.europa.eu/efsajournal

KEY WORDS

Sodium citrate, potassium citrate, bone, health claims.

TABLE OF CONTENTS

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 1924/2006[4] 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 out[5]. 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 (ID 330)

The food constituent that is the subject of the health claim is "citrates as Na-, K-, Ca, Mg-salts".

In the context of the information provided, the Panel assumes that the food constituents that are the subject of the health claim are calcium, magnesium, sodium and potassium salts of citric acid.

A claim on calcium (including calcium salts of citric acid) and maintenance of normal bone, and a claim on magnesium (including magnesium salts of citric acid) and maintenance of normal bone, have already been assessed with favourable outcomes (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009, 2010).

This opinion refers to sodium and potassium salts of citric acid.

Potassium and sodium salts of citric acid are soluble in water and occur naturally in foods, particularly in fruits.

Sodium citrate (includes mono-, di- and tricitrate, E331) and potassium citrate (includes mono- and tricitrate, E332) are authorised for addition to foods for technological purposes. Potassium and sodium salts of citric acid are also authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006[6], Annex II of Directive 2002/46/EC[7] and Regulation (EC) No 1333/2008[8]). This evaluation applies to potassium and sodium salts of citric acid naturally present in foods, and those forms authorised for addition to foods and for use in food supplements (Annex II of the Regulation (EC) No 1925/2006, Annex II of Directive 2002/46/EC and Regulation (EC) No 1333/2008).

The Panel considers that the food constituents, potassium and sodium salts of citric acid, which are the subject of the health claim, are sufficiently characterised.

[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.

[6] 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.

[7] 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.

[8] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

2. Relevance of the claimed effect to human health (ID 330)

The claimed effect is "acid-base balance 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 effect refers to the maintenance of normal bone by maintaining acid-base balance.

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

3. Scientific substantiation of the claimed effect (ID 330)

Among the references provided for the scientific substantiation of the claim were narrative reviews on for example acid-base homeostasis and dietary potential renal acid load (PRAL) on various chronic diseases, including osteoporosis, or on the influence of dietary PRAL and/or net endogenous acid production (NEAP) on urine pH and renal excretion of minerals, acids and/or bases, which did not include original data that could be used for the scientific substantiation of the claim. A number of references referred to food constituents (e.g. carbonates and/or bicarbonates) other than the citrate salts of sodium and potassium or reported on health outcomes (e.g. back pain and rheumatoid arthritis) other than bone mineral density (BMD). One reference was not available to the Panel after every effort was made to retrieve it. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Three human intervention studies assessed the effects of potassium citrate on urinary calcium excretion and markers of bone turnover (Marangella et al., 2004; Sakhaee et al., 2005; Sellmeyer et al., 2002).

In two of the studies the intervention lasted less than three months (Sakhaee et al., 2005; Sellmeyer et al., 2002, two and four weeks, respectively). The Panel considers that no conclusions can be drawn from these short-term studies with respect to the effect of potassium citrate on markers of bone turnover.

Marangella et al. (2004) performed a controlled non-randomised trial of potassium citrate administration for three months in 30 post-menopausal women (age 58±8.1 years) with BMD T-scores (femoral neck or lumbar spine) less than -1. Twenty-four age-matched women who did not differ from the study group in BMD or urine/serum biochemistry served as controls. Lumbar and femoral BMD were measured by dual-energy X-ray absorptiometry (DXA) at baseline. Markers of bone turnover were measured at the beginning and end of the study. The Panel notes that in this non-randomised, controlled intervention, no direct comparisons between the intervention and control groups are reported for the relevant outcomes, and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In a double-blind, placebo-controlled trial (Jehle et al., 2006), 181 non-vegetarian healthy post-menopausal women (age 58.6±4.8 years) with low bone mass (T-score -1 to -4) were randomised to consume orally either 30 mEq potassium citrate or 30 mEq potassium chloride (control) daily for a period of 12 months while consuming their usual diet. All subjects received a supplement of 500 mg calcium and 10 µg vitamin D. BMD of the lumbar spine and the hip was assessed by DXA twice at baseline (one week apart at all sites), and at three, six, nine and 12 months for spine and hip regions. BMD of the distal radius and the whole body was assessed at baseline, and after six and 12 months. Blood was collected at baseline and at six and 12 months, and morning fasting urine samples were collected at baseline, and after three, six, nine and 12 months. A total of 161 women completed the trial (n=82 in the potassium citrate group), and 20 dropped out before month 12 (7 in the potassium citrate group), mostly because of gastro-intestinal complaints. The primary endpoint was the intergroup difference in mean percentage change in BMD at lumbar vertebrae L2 through L4 at

month 12. Statistical analyses were performed in the population of completers only. *Post-hoc* power calculations for this endpoint, using SD values of 3.8 % reported elsewhere and a two-sided α of 0.05, showed that the study had a 90 % power to detect a 2 % intergroup difference with a sample size of 161. It is unclear why the actual SD values obtained in this study were not used for this *post-hoc* power calculation. Intergroup comparisons were tested by the nonparametric Kruskal-Wallis test. Within-group differences were tested using the nonparametric Wilcoxon rank sum test. The Panel notes that repeated measures at different time points were not considered appropriately in the statistical analyses. BMD at the lumbar spine significantly increased in the potassium citrate group (by 0.89±0.30 %) whilst it significantly decreased in the potassium chloride group (by -0.98±0.38 %). The intergroup difference was 1.87±0.5 % ($p<0.001$). Similar significant differences between groups were observed for the total hip BMD (1.98±0.51 %; $p <0.001$) and femoral neck BMD (1.39±0.48 %; $p<0.001$), but not for the distal radius or total body BMD. Markers for bone formation behaved discordantly but similarly in both groups: bone specific alkaline phosphatase significantly increased and serum osteocalcin significantly decreased. Changes in the urinary markers of bone resorption, deoxypyridinoline (DPD) and pyridinoline (PYR), were not significantly different between groups, except for a significant decrease in DPD at month 3 in the potassium citrate group compared to the potassium chloride group only. No significant differences between groups were observed for changes in beta C-terminal telopeptide of type 1 collagen (CTX), another marker for bone resorption. Potassium citrate significantly decreased renal calcium excretion and increased citrate excretion as well as net acid excretion (NAE; 35±8 mmol/day in the potassium chloride group *vs*. 6±9 mmol/day in the potassium citrate group). NAE was significantly and negatively correlated with the percentage change in lumbar BMD at 12 months. The Panel notes that this study, which had some methodological limitations (i.e. statistical analyses were performed in the sample of completers only, repeated measures at different time points were not considered), showed an effect of potassium citrate compared to potassium chloride on BMD in the lumbar spine at 12 months. The Panel also notes that no consistent differences in bone turnover markers were observed between groups throughout the study.

In a double-blind, placebo-controlled trial (Macdonald et al., 2008), 276 non-vegetarian, healthy post-menopausal women (55-65 years) were randomised to consume orally a high dose of potassium citrate (55.5 mEq/day, n=70), a low dose of potassium citrate (18.5 mEq/day, n=70), placebo (unspecified, n=70) or 300 g additional fruits and vegetables/day (n=66) for two years. BMD was measured at the spine and the hip at baseline and at two years by the same radiographer using a DXA scanner. Two-hour urine samples (collected early in the morning in the fasted state) and blood samples (collected non-fasted at the same time of day) were taken at baseline and at 3, 6, 12, 18, and 24 months, for the determination of markers of bone turnover (serum N-terminal propeptide of type 1 collagen (P1NP), CTX, and urine free deoxypyridinoline cross links (fDPD)). A sample size of 42 subjects per group was estimated to detect a difference of 2.5±4 % BMD (80 % power, $p=0.05$) between the intervention and placebo groups, assuming an annual BMD loss of 0.75 % in the placebo group, and allowing an annual increase in spine BMD of 0.5 % to be detected in the treatment arms. Statistical analyses were carried out on an intention-to-treat basis, and on a per-protocol basis for women with > 80 % compliance. Compliance was estimated at each 3-month visit by capsule count for the potassium citrate and placebo groups and by dietary reporting for the fruit and vegetable arm. No significant differences in BMD at any site were observed between the intervention and placebo groups in the intention-to-treat or per-protocol analyses. Adjustment for weight, height, age, and social deprivation category did not change the outcome. Repeated-measures ANOVA on an intention-to-treat basis comparing baseline and last visit only (n=260) showed no significant visit x treatment interaction for serum P1NP or CTX. Similarly, for fDPD/Cr (n=258) there was no difference between groups. Repeated-measures ANOVA for the bone marker data that were available for every visit (n=202) also showed no visit x treatment interaction for serum P1NP, CTX, or urinary fDPD/Cr. The outcome was the same when the analysis was repeated with the exclusion of non-compliers or women who were on blood pressure–lowering medication. The Panel notes that this two-year, adequately powered, study did not show an effect of either low (18.5 mEq/day) or high

(55.5 mEq/day) doses of potassium citrate on BMD or markers of bone turnover in post-menopausal women.

The Panel notes that one human intervention study with some limitations showed an effect of potassium citrate administered at doses of 30 mEq/day for one year on BMD in the lumbar spine in osteopenic post-menopausal women, whereas another adequately powered human intervention study without such limitations showed no effect of potassium citrate at doses of either 18.5 or 55.5 mEq/day administered for two years on BMD at any site. The Panel also notes that no consistent effect of potassium citrate on markers of bone turnover was observed in either of the studies.

No studies which investigated the effects of sodium citrate on either BMD or markers of bone turnover were provided.

In weighing the evidence, the Panel took into account that the results from the two human intervention studies provided which investigated the effects of potassium citrate on BMD in post-menopausal women are conflicting, and that the adequately powered intervention study of longer duration using a higher dose of potassium citrate did not show an effect on BMD.

The Panel concludes that a cause and effect relationship has not been established between the dietary intake of potassium or sodium salts of citric acid and maintenance of normal bone.

CONCLUSIONS

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

- The food constituents, potassium and sodium salts of citric acid, which are the subject of the health claim, are sufficiently characterised.
- The claimed effect is "acid-base balance 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 dietary intake of potassium or sodium salts of citric acid and maintenance of normal bone.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1117). 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

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009. Scientific Opinion on the substantiation of health claims related to magnesium and electrolyte balance (ID 238), energy-yielding metabolism (ID 240, 247, 248), neurotransmission and muscle contraction including heart muscle (ID 241, 242), cell division (ID 365), maintenance of bone (ID 239), maintenance of teeth (ID 239), blood coagulation (ID 357) and protein synthesis (ID 364) pursuant to Article 13(1) of Regulation (EC) No 1924/2006 on request from the European Commission. EFSA Journal, 7(9):1216, 20 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2010. Scientific Opinion on the substantiation of health claims related to calcium and maintenance of normal bone and teeth (ID 2731, 3155, 4311, 4312, 4703), maintenance of normal hair and nails (ID 399, 3155), maintenance of normal blood LDL-cholesterol concentrations (ID 349, 1893), maintenance of normal blood HDL-cholesterol concentrations (ID 349, 1893), reduction in the severity of symptoms related to the premenstrual syndrome (ID 348, 1892), "cell membrane permeability" (ID 363), reduction of tiredness and fatigue (ID 232), contribution to normal psychological functions (ID 233), contribution to the maintenance or achievement of a normal body weight (ID 228, 229) and regulation of cell division and differentiation (ID 237) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 8(10):1725, 30 pp.

Jehle S, Zanetti A, Muser J, Hulter HN and Krapf R, 2006. Partial neutralization of the acidogenic Western diet with potassium citrate increases bone mass in postmenopausal women with osteopenia. Journal of the American Society of Nephrology, 17, 3213-3222.

Macdonald HM, Black AJ, Aucott L, Duthie G, Duthie S, Sandison R, Hardcastle AC, Lanham New SA, Fraser WD and Reid DM, 2008. Effect of potassium citrate supplementation or increased fruit and vegetable intake on bone metabolism in healthy postmenopausal women: a randomized controlled trial. American Journal of Clinical Nutrition, 88, 465–474.

Marangella M, Di Stefano M, Casalis S, Berutti S, D'Amelio P and Isaia GC, 2004. Effects of potassium citrate supplementation on bone metabolism. Calcified Tissue International, 74, 330-335.

Sakhaee K, Maalouf NM, Abrams SA and Pak CY, 2005. Effects of potassium alkali and calcium supplementation on bone turnover in postmenopausal women. Journal of Clinical Endocrinology & Metabolism, 90, 3528-3533.

Sellmeyer DE, Schloetter M and Sebastian A, 2002. Potassium citrate prevents increased urine calcium excretion and bone resorption induced by a high sodium chloride diet. Journal of Clinical Endocrinology & Metabolism, 87, 2008-2012.

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[9] (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[10]

Foods are commonly involved in many different functions[11] 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.

[9] OJ L12, 18/01/2007

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

[11] 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 sodium and potassium salts of citric acid, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
330	Citrates as Na-, K-, Ca, Mg-salts	Acid/base balance and bone health	Citrates (e.g. potassium citrate) reduce dietary acid load. Citrates (e.g. potassium citrate) help maintain acid-base balance and support bone health. Citrates (e.g. potassium citrate) maintain bone strength
	Conditions of use MUST AT LEAST BE A SOURCE OF MINERAL/S AS PER ANNEX TO REGULATION 1924/2006		

GLOSSARY AND ABBREVIATIONS

BMD	Bone mineral density
CTX	C-terminal telopeptide of type 1 collagen
DPD	Deoxypyridinoline
DXA	Dual-energy X-ray absorptiometry
NAE	Net acid excretion
NEAP	Net endogenous acid production
P1NP	N-terminal propeptide of type 1 collagen
PRAL	Potential renal acid load
PYR	Pyridinoline