



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328), “powerful protectors of our gums” (ID 1365), and “heart health” (ID 2499) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2011.2215](https://doi.org/10.2903/j.efsa.2011.2215)

Publication date:
2011

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

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2011). EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328), “powerful protectors of our gums” (ID 1365), and “heart health” (ID 2499) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. European Food Safety Authority. the EFSA Journal No. 2215
<https://doi.org/10.2903/j.efsa.2011.2215>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328), “powerful protectors of our gums” (ID 1365), and “heart health” (ID 2499) 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 proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract, “powerful protectors of our gums”, and “heart health”. 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 foods/food constituents that are the subject of the health claims are “Squeez Cranberry Juice Drink”, “proanthocyanidins in cranberry juice”, “*Vaccinium macrocarpon*, *oxycoccus* (Common Name: Cranberry)”, “whole cranberry powder from North American Cranberry (*Vaccinium macrocarpon*) Early Black species”, and “cranberry extract powder (*Vaccinium macrocarpon*)”. The Panel notes that the composition and/or manufacturing process for these cranberry-derived food products are not specified in the information provided. The Panel considers that, whereas various food products derived from cranberry fruits, i.e. cranberry juice; diluted cranberry juice concentrate; cranberry juice cocktails; cranberry extracts, powders, and capsules, are not sufficiently characterised

¹ On request from the European Commission, Question No EFSA-Q-2008-2102, EFSA-Q-2008-2574, EFSA-Q-2008-2886, EFSA-Q-2008-3232, EFSA-Q-2008-3503, EFSA-Q-2008-4060, adopted on 13 May 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. EFSA staff: Wolfgang Gelbmann for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328), “powerful protectors of our gums” (ID 1365), and “heart health” (ID 2499) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2215. [18 pp.]. doi:10.2903/j.efsa.2011.2215. Available online: www.efsa.europa.eu/efsajournal

in relation to the claimed effects considered in this opinion, proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit are sufficiently characterised.

Defence against bacterial pathogens in the lower urinary tract

The claimed effects are “urinary tract”, “health of the lower urinary tract”, and “reduce biofilms on uroepithelial cells”. The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, it is assumed that the claimed effects refer to defence against bacterial pathogens in the lower urinary tract. The Panel considers that defence against bacterial pathogens in the lower urinary tract is a beneficial physiological effect.

A claim on cranberry (*Vaccinium macrocarpon* Aiton) fruit products standardised by their proanthocyanidin content and reduction in the risk of urinary tract infections in women by inhibiting the adhesion of certain bacteria in the urinary tract has already been assessed with an unfavourable outcome. The Panel considers that the references provided for this claim did not provide any additional scientific data which could be used to substantiate the claim.

On the basis of the data presented, the Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract.

“Powerful protectors of our gums”

The claimed effect is “powerful protectors of our gums”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings. No clarifications were provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

“Heart health”

The claimed effect is “heart health”. The target population is assumed to be the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings or clarifications provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

KEY WORDS

Vaccinium macrocarpon Aiton, cranberry, proanthocyanidins, urinary tract, gums, heart, 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. Characterisation of the food/constituent	5
2. Relevance of the claimed effect to human health.....	6
2.1. Defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328)6	
2.2. “Powerful protectors of our gums” (ID 1365)	6
2.3. “Heart health” (ID 2499)	6
3. Scientific substantiation of the claimed effect	6
3.1. Defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328)6	
Conclusions	7
Documentation provided to EFSA	8
References	8
Appendices	10
Glossary and Abbreviations	18

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 for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out⁵. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

1. Characterisation of the food/constituent

The foods/food constituents that are the subject of the health claims are “Squeez Cranberry Juice Drink”, “proanthocyanidins in cranberry juice”, “*Vaccinium macrocarpon*, *oxycoccus* (Common Name: Cranberry)”, “whole cranberry powder from North American Cranberry (*Vaccinium macrocarpon*) Early Black species”, and “cranberry extract powder (*Vaccinium macrocarpon*)”.

In the information provided, a number of food products derived from two varieties of cranberry (*Vaccinium macrocarpon* Aiton and *Vaccinium oxycoccus* L.) fruit were mentioned i.e. cranberry juice; diluted cranberry juice concentrate; cranberry juice cocktails; cranberry extracts, powders, and capsules. The Panel notes that the composition and/or manufacturing process for these cranberry-derived food products are not specified in the information provided. The Panel also notes that no human studies have been provided using cranberry fruit products derived from *V. oxycoccus* L.

The conditions of use related to some of these claims specify the amount of cranberry fruit products to be consumed in order to obtain the claimed effects in relation to their proanthocyanidin (PAC) content. The PAC fraction isolated from cranberries (*V. macrocarpon* Aiton) is a mixture of catechin and epicatechin oligomers of various molecular weights, and consists of predominantly procyanidin pentamers and tetramers containing at least one A-type linkage (Cunningham et al., 2002; Foo et al., 2000).

The Panel considers that whereas various food products derived from cranberry fruits, i.e. cranberry juice; diluted cranberry juice concentrate; cranberry juice cocktails; cranberry extracts, powders, and capsules, are not sufficiently characterised in relation to the claimed effects, PAC from cranberry (*V. macrocarpon* Aiton) fruit 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.

2. Relevance of the claimed effect to human health

2.1. Defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328)

The claimed effects are “urinary tract”, “health of the lower urinary tract”, and “reduce biofilms on uroepithelial cells”. The Panel assumes that the target population is the general population.

In the context of the proposed wordings, clarifications from Member States and references provided, the Panel assumes that the claimed effects refer to defence against bacterial pathogens in the lower urinary tract, which can be assessed *in vivo* as changes in the incidence of symptomatic urinary tract infections (UTIs).

The Panel considers that defence against bacterial pathogens in the lower urinary tract is a beneficial physiological effect.

2.2. “Powerful protectors of our gums” (ID 1365)

The claimed effect is “powerful protectors of our gums”. The Panel assumes that the target population is the general population.

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings. No clarifications were provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

2.3. “Heart health” (ID 2499)

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

The claimed effect is not sufficiently defined, and no further details were provided in the proposed wordings or clarifications provided by Member States.

The Panel considers that the claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

3. Scientific substantiation of the claimed effect

3.1. Defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328)

The references provided for the scientific substantiation of the claim included several narrative reviews and monographs which did not provide original data for the scientific substantiation of the claim, and some human intervention studies which investigated the effects of food constituents other than PAC in cranberry fruit products (e.g. cranberry products in combination with warfarin or flurbiprofen, and mixtures of concentrates from cranberries and lingonberries) or addressed health outcomes (e.g. risk of urolithiasis) other than the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

A systematic review of randomised or quasi-randomised human intervention studies on the effects of cranberry and blueberry products on the incidence of symptomatic UTIs, 12 human intervention

studies and one observational study on the effects of cranberry fruit products on the incidence of UTI, and 17 non-human studies on the mechanisms by which cranberry fruit products could exert the claimed effect were provided.

A claim on cranberry (*V. macrocarpon* Aiton) fruit products standardised by their PAC content and reduction in the risk of UTIs in women by inhibiting the adhesion of certain bacteria in the urinary tract has already been assessed with an unfavourable outcome (EFSA, 2009). The scientific evaluation was based on the insufficient evidence provided by the applicant to establish a cause and effect relationship between the consumption of cranberry fruit products standardised by their PAC content and a reduction in the incidence of UTIs, and on the insufficient evidence provided to establish that the bacterial anti-adherence effects, which were shown *in vitro*, of cranberry fruit products in urine could predict the occurrence of a clinically relevant bacterial anti-adherence effect within the urinary tract *in vivo* in humans.

Most of the references provided in the consolidated list which addressed the effects of cranberry (*V. macrocarpon* Aiton) fruit products standardised by their PAC content on the incidence of UTIs in different population sub-groups, and those which addressed the mechanisms by which cranberry fruit products could exert the claimed effect, were already considered in the previous opinion (EFSA, 2009).

Two additional references, which reported on human intervention studies and which were not considered in the previous opinion, were provided in the consolidated list (Bohbot, 2007; Jepson and Craig, 2008). The Panel notes that the methods used to diagnose UTI infection were not sufficiently described in the study by Bohbot (2007). It is also noted that all human trials analysed in the Cochrane review by Jepson and Craig (2008) were referenced also in the systematic review by Jepson and Craig (2007) which was considered in the previous opinion (EFSA, 2009). The Panel considers that these two references do not provide any additional scientific data which could be used to substantiate the claim.

The Panel considers that the references provided for this claim did not provide any additional scientific data which could be used to substantiate the claim.

The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of proanthocyanidins from cranberry (*V. macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract.

CONCLUSIONS

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

- Whereas various food products derived from cranberry fruits, i.e. cranberry juice; diluted cranberry juice concentrate; cranberry juice cocktails; cranberry extracts, powders, and capsules, are not sufficiently characterised in relation to the claimed effects considered in this opinion, proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit are sufficiently characterised.

Defence against bacterial pathogens in the lower urinary tract (ID 1841, 2153, 2770, 3328)

- The claimed effects are “urinary tract”, “health of the lower urinary tract”, and “reduce biofilms on uroepithelial cells”. The target population is assumed to be the general population. In the context of the proposed wordings, clarifications from Member States and references provided, it is assumed that the claimed effect refers to defence against bacterial pathogens in the lower urinary tract. Defence against bacterial pathogens in the lower urinary tract is a beneficial physiological effect.

- A claim on cranberry (*Vaccinium macrocarpon* Aiton) fruit products standardised by their proanthocyanidin content and reduction in the risk of urinary tract infections in women by inhibiting the adhesion of certain bacteria in the urinary tract has already been assessed with an unfavourable outcome. The references provided for this claim did not provide any additional scientific data which could be used to substantiate the claim.
- The evidence provided is insufficient to establish a cause and effect relationship between the consumption of proanthocyanidins from cranberry (*V. macrocarpon* Aiton) fruit and defence against bacterial pathogens in the lower urinary tract.

“Powerful protectors of our gums” (ID 1365)

- The claimed effect is “powerful protectors of our gums”. The target population is assumed to be the general population. The claimed effect is not sufficiently defined.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

“Heart health” (ID 2499)

- The claimed effect is “heart health”. The target population is assumed to be the general population. The claimed effect is not sufficiently defined.
- The claimed effect is general and non-specific, and does not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2102, EFSA-Q-2008-2574, EFSA-Q-2008-2886, EFSA-Q-2008-3232, EFSA-Q-2008-3503, EFSA-Q-2008-4060). 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

- Bohbot JM, 2007. Results of a randomised, double-blind study on the prevention of recurrent cystitis with GynDelta. The Gynaecologist’s and Obstetrician’s Journal, Special issue from the C.C.D. laboratory.
- Cunningham DG, Vannozzi S, O’Shea E and Turk R, 2002. Analysis and Standardization of Cranberry Products. In: Quality Management of Nutraceuticals. Eds Ho CT, Zheng QY. American Chemical Society, Washington, 151-166.
- EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from Ocean Spray International Services Limited (UK), related to the scientific substantiation of a health claim on Ocean Spray Cranberry Products® and reduced risk of urinary tract infection in women by inhibiting the adhesion of certain bacteria in the urinary tract. The EFSA Journal, 943, 1-16.

- Foo LY, Lu Y, Howell AB and Vorsa N, 2000. A-Type proanthocyanidin trimers from cranberry that inhibit adherence of uropathogenic P-fimbriated *Escherichia coli*. *Journal of Natural Products*, 63, 1225-1228.
- Jepson RG and Craig JC, 2007. A systematic review of the evidence for cranberries and blueberries in UTI prevention. *Molecular Nutrition and Food Research*, 51, 738-745.
- Jepson RG and Craig JC, 2008. Cranberries for preventing urinary tract infections. *Cochrane Database of Systematic Reviews*, CD001321.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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

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

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

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

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

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

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

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD⁷

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

⁶ OJ L12, 18/01/2007

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

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

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

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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

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

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

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

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

WORDING OF HEALTH CLAIMS

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

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

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

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

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

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

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

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

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

TERMS OF REFERENCE

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

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

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

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

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

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

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

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

APPENDIX B

EFSA DISCLAIMER

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

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

APPENDIX C

Table 1. Main entry health claims related to proanthocyanidins from cranberry (*Vaccinium macrocarpon* Aiton) fruit, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1365	Name of Food product: Squeez Cranberry Juice Drink. Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: Yes.	Health benefits of food: Cranberries may be powerful protectors of our gums. Do benefits relate to a disease risk factor: No. Target group: All of the general population including children and adults.	Exact wording of claim as it appears on product: More recently, emerging research suggests that cranberries may also be powerful protectors of our health in other areas of the body, such as the stomach, gums and even the heart. Is claim a picture: No.
	Conditions of use		
	<ul style="list-style-type: none"> - Number of nutrients/other substances that are essential to claimed effect: 1. Names of nutrient/other substances and Quantity in Average daily serving: 200ml cranberry juice. Weight of average daily food serving: 200 millilitre(s). Daily amount to be consumed to produce claimed effect: 200 millilitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: Yes. Please give reason: Storage beyond its shelf life. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: No 		
Comments from Member States			
Further clarification to support the use of this claim was not submitted to the Food Safety Authority of Ireland			
ID	Food or Food constituent	Health Relationship	Proposed wording
1841	Proanthocyanidins in cranberry juice.	Urinary tract.	Cranberry helps to inhibit the attachment of certain E-coli bacteria to the urinary tract.
	Conditions of use		
<ul style="list-style-type: none"> - Cranberry juice with 3.6 mg/100g, 7.2 mg/serving of proanthocyanidins. - pure cranberry juice in powder extract available in capsules or sachets (food supplement) dosage : 36mg proanthocyanidins (PAC) per day measured by DMAC method equivalent in dosage and characterization to the product shown to be effective in clinical studies (i.e. 300 ml of cranberry juice cocktail) 			
ID	Food or Food constituent	Health Relationship	Proposed wording
2153	<i>Vaccinium macrocarpon</i> , <i>oxycoccus</i> (Common Name : Cranberry).	Health of the lower urinary tract. <u>Clarification provided</u> Improves urinary tract	Helps to maintain the health of the urinary system / contributes to urinary tract health / has a beneficial effect on the urinary system / canneberge or <i>Vaccinium macrocarpon</i> by

		<p>health by reducing/inhibiting adherence of unfavourable bacteria in the urinary tract.</p> <p>Daily consumption of 36 mg PAC of cranberry <i>vaccinium macrocarpon</i> (measured by DMAC method) and contributing effect to decrease the adherence of certain uropathogenic P-fimbriated <i>E.coli</i> to the walls of the urinary tract.</p> <p>Helps to preserve the urinary tract's integrity thanks to its antimicrobial effect.</p>	<p>concentrated juices, by food supplements and a juice cocktail/nectar).</p>
<p>Conditions of use</p> <ul style="list-style-type: none"> - owoce/zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie/ równowartość 36 mg proantocyjanidyn na dzień lub minimum 400 mg owocu żurawiny na dzień. - 300 bis 400 mg - auf zwei Einnahmen täglich verteilt (standardisierter Extrakt) – Erwachsene. - Frucht, Positive Studienergebnisse erst ab 200 mg Cranberry-konzentrat/ Tag. - Formen: 100 % Fruchtsaft, Fruchtsaftkonzentrat, Extrakte aus der ganzen Frucht oder dem Fruchtsaft. - 360-600 mg - Fruit / The equivalent of 36 mg of proanthocyanidines per day. - Food supplement containing 500 mg/day of cranberry extract (<i>Vaccinium macrocarpon</i>). The cranberry extract is the patented CranMax extract. - Jus du fruit. 6 x 250 mg/jour. - <i>Vaccinium macrocarpon</i>–Standardisierter Extrakt auf DEV 25:1–Tagesdosis Cranberry: 1200 mg–Erwachsene. - 450 mg cranberry solids (500 mg CranMax™ /day). - Product ready-to-drink (diluted juice, nectar or syrup) containing 11.3 g of juice concentrate; used daily over 12 month. - <i>Vaccinium macrocarpon</i>–Standardisierter Extrakt auf DEV 25:1–Tagesdosis Cranberry: 1200 mg–Erwachsene - Pure cranberry juice in powder extract available in capsules or sachets (food supplement) dosage: 36 mg proanthocyanidins (PAC) per day measured by DMAC method equivalent in dosage and characterization to the product shown to be effective in clinical studies (i.e. 300 ml of cranberry juice cocktail). - Fruit / 400mg of dry extract per day. 			

ID	Food or Food constituent	Health Relationship	Proposed wording
2499	Vaccinium macrocarpon, oxycoccus (Cranberry).	Heart health.	Helps maintain a healthy heart and blood vessels.
	Conditions of use <ul style="list-style-type: none"> - Concentrated cranberry (12:1): 140 mg / Concentrated cranberry juice: 2.7 g / Used as part of a multi-botanical combination. - Fruit. The equivalent of minimum 15 ml of cranberry juice or 800 mg of cranberry solids per day. 		
	Comments from Member States Contributes to vascular health, which in turn helps to maintain a healthy heart.		
ID	Food or Food constituent	Health Relationship	Proposed wording
2770	Food supplement/Food ingredient: Whole cranberry powder from North American Cranberry (<i>Vaccinium macrocarpon</i>) Early Black species.	Health of the lower urinary tract.	Helps to maintain the health of the urinary system. Contributes to urinary tract health. Has a beneficial effect on the urinary system. Helps to eliminate pathogenic bacteria from urinary tract.
	Conditions of use <ul style="list-style-type: none"> - 500 mg/day. - Fruit / Usual consumption als traditional foodstuff in a normal diet / The equivalent of 36 mg of proanthocyanides per day or a minimum of 400 mg of cranberry solids per day. 		
	No clarification provided by Member States		
ID	Food or Food constituent	Health Relationship	Proposed wording
3328	Cranberry extract powder (<i>Vaccinium macrocarpon</i>).	Reduce biofilms on uroepithelial cells.	Helps to increase growth of beneficial microflora.
	Conditions of use <ul style="list-style-type: none"> - 500 mg of cranberry powder per day. 		

GLOSSARY AND ABBREVIATIONS

PAC Proanthocyanidins

UTI Urinary tract infection