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EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of health claims related to supercritical CO2 extracted blackcurrant seed oil and maintenance of normal blood pressure (ID 572) and maintenance of normal blood LDL-cholesterol concentrations (ID 572) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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European Food Safety Authority

EFSA Journal 2011;9(6):2208

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood pressure (ID 572) and maintenance of normal blood LDL-cholesterol concentrations (ID 572) 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 supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood pressure and maintenance of normal blood LDL-cholesterol concentrations. 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 that is the subject of the health claims is "blackcurrant seed oil (carbon dioxide extracted) + vitamin E". From the information provided in the proposed health relationship and wordings, the Panel assumes that the food, which is the subject of the health claims, is supercritical carbon dioxide (CO_2) extracted blackcurrant seed oil. The Panel considers that supercritical CO_2 extracted blackcurrant seed oil is sufficiently characterised.

Maintenance of normal blood pressure

The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood pressure. The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

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[1] On request from the European Commission, Question No EFSA-Q-2008-1359, adopted on 08 April 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 the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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In weighing the evidence, the Panel took into account that the one human intervention study provided, from which conclusion can be drawn for the scientific substantiation of the claimed effect, did not show an effect of supercritical CO_2 extracted blackcurrant seed oil on blood pressure.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood pressure.

Maintenance of normal blood LDL-cholesterol concentrations

The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations. The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

No studies, which investigated whether supercritical CO_2 extracted blackcurrant seed oil has an LDL-cholesterol-lowering effect beyond what could be expected from its fatty acid composition, have been provided.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from its fatty acid composition.

A claim on the replacement of mixtures of saturated fatty acids with *cis*-monounsaturated fatty acids and/or *cis*-polyunsaturated fatty acids in foods or diets and maintenance of normal blood LDL-cholesterol concentrations, and claims on linoleic acid and on alpha-linolenic acid and maintenance of normal blood cholesterol concentrations have already been assessed with favourable outcomes.

KEY WORDS

Blackcurrant seed oil, LDL, blood cholesterol, blood pressure, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[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

The food that is the subject of the health claims is "blackcurrant seed oil (carbon dioxide extracted) + vitamin E".

From the information provided in the proposed health relationship and wordings, the Panel assumes that the food that is the subject of the health claims is supercritical carbon dioxide (CO_2) extracted blackcurrant seed oil (BSO).

Supercritical CO_2 is a fluid state of carbon dioxide where it is held at or above its critical temperature and critical pressure. The intention of such an extraction is that the relatively low temperature of the process and the stability of CO_2 would allow most compounds to be extracted with little damage or denaturation. Supercritical CO_2 extracted BSO contains approximately 47.5 % linoleic acid (LA) (18:2 n-6), 14.5 % α-linolenic acid (ALA) (18:3 n-3), 13.3 % oleic acid (18:1 n-9), 12.6 % γ-linolenic acid (GLA) (18:3 n-6), 5.6 % palmitic acid, 2.7 % stearidonic acid (18:4 n-3), and minor compounds of other fatty acids. It also contains 1.17 % free and esterified phytosterols, mainly sitosterol, 1.28 mg/g α-tocopherol, 0.86 mg/g γ-tocopherol and 0.05 mg/g δ-tocopherol (Tahvonen et al., 2005).

The Panel considers that the food, supercritical CO_2 extracted blackcurrant seed oil, which is the subject of the health claims, is sufficiently characterised.

2. Relevance of the claimed effect to human health

2.1. Maintenance of normal blood pressure (ID 572)

The claimed effect is "cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood pressure.

[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.

Blood pressure is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated blood pressure, by convention ≥140 mmHg (systolic) and/or ≥90 mmHg (diastolic), may compromise the normal function of the arteries.

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

2.2. Maintenance of normal blood LDL-cholesterol concentrations (ID 572)

The claimed effect is "cardiovascular system". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of normal blood LDL-cholesterol concentrations.

Low-density lipoproteins (LDL) carry cholesterol from the liver to peripheral tissues, including the arteries. Elevated LDL-cholesterol, by convention >160 mg/dL (>4.1 mmol/L), may compromise the normal structure and function of the arteries.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The references provided for the scientific substantiation of the claim included narrative reviews and monographs which referred to the clinical studies provided and described below. Some reviews and non-human studies were provided on the effects of unsaturated fatty acids, particularly of n-3 and n-6 fatty acids. In three human studies, the effects of supercritical CO_2 extracted blackcurrant seed oil were investigated.

3.1. Maintenance of normal blood pressure (ID 572)

One randomised controlled trial (RCT) evaluated the effect of 6 g supercritical CO_2 extracted BSO consumed daily over eight weeks on resting blood pressure in 28 mildly hypertensive males (Deferne and Leeds, 1996). Subjects received three times per day four gelatine-coated capsules containing either 500 mg BSO (n=14) or capsules with 500 mg safflower oil (control, n=14). One subject dropped out in the control group after five weeks of treatment for reasons unrelated to the study. Resting blood pressure was measured, after an overnight fast, at baseline and weekly for the duration of the study. No significant differences in systolic or diastolic blood pressure were observed between BSO and control groups at any time point during the study. The Panel notes that this study does not show an effect of BSO on blood pressure.

In weighing the evidence, the Panel took into account that the one human intervention study provided, from which conclusion can be drawn for the scientific substantiation of the claimed effect, did not show an effect of supercritical CO_2 extracted BSO on blood pressure.

The Panel concludes that a cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood pressure.

3.2. Maintenance of normal blood LDL-cholesterol concentrations (ID 572)

A double-blind RCT with a cross-over design compared the effects of 3 g/day supercritical CO_2 extracted BSO with 2.8 g/day fish oil on blood lipids in 15 healthy females (Tahvonen et al., 2005). The two treatment periods and the wash-out phase lasted four weeks each. The fish oil contained about 30 % saturated fatty acids (SFAs), 24 % long-chain polyunsaturated fatty acids (LC-PUFAs), 28 % monounsaturated fatty acids (MUFAs), 6 % polyunsaturated fatty acids (PUFAs) and minor amounts of other fatty acids. A 4.9 % reduction in LDL-cholesterol concentrations during the BSO period and a 3.6 % increase in LDL-cholesterol concentrations during the fish oil period were observed. The between-group difference was statistically significant ($p<0.05$). The Panel notes that the difference in LDL-cholesterol concentrations observed between the BSO and the fish oil interventions could be explained by the different fatty acid composition of the oils (e.g. replacement of SFAs and LC-PUFAs in the fish oil by PUFAs in the BSO oil).

An unpublished manuscript reported on a double-blind, cross-over RCT which compared the effects of 5 g/day supercritical CO_2 extracted BSO and of 5 g/day olive oil (about 70 % oleic acid, 15 % SFAs, and 11 % PUFAs, mainly LA) on blood lipids in 12 normolipidaemic males (Johansson, 1999). The treatment periods lasted four weeks each with a wash-out phase of 4-8 weeks in between. The Panel notes the presence of carry-over effects between intervention periods and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

No studies, which investigated whether supercritical CO_2 extracted BSO has an LDL-cholesterol-lowering effect beyond what could be expected from its fatty acid composition, have been provided.

The Panel concludes that a cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted BSO and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from its fatty acid composition.

A claim on the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations has already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011).

A claim on linoleic acid and maintenance of normal blood cholesterol concentrations has also already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a).

A claim on alpha-linolenic acid and maintenance of normal blood cholesterol concentrations has also already been assessed with a favourable outcome (EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009b).

CONCLUSIONS

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

- The food, supercritical CO_2 extracted blackcurrant seed oil, which is the subject of the health claims, is sufficiently characterised.

Maintenance of normal blood pressure (ID 572)

- The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effect refers to the maintenance of normal blood pressure. Maintenance of normal blood pressure is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood pressure.

Maintenance of normal blood LDL-cholesterol concentrations (ID 572)

- The claimed effect is "cardiovascular system". The target population is assumed to be the general population. In the context of the proposed wordings and clarifications provided by Member States, it is assumed that the claimed effect refers to maintenance of normal blood LDL-cholesterol concentrations. Maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of supercritical CO_2 extracted blackcurrant seed oil and maintenance of normal blood LDL-cholesterol concentrations beyond what could be expected from its fatty acid composition.

- A claim on the replacement of mixtures of SFAs with *cis*-MUFAs and/or *cis*-PUFAs in foods or diets and maintenance of normal blood LDL-cholesterol concentrations, and claims on linoleic acid and on alpha-linolenic acid and maintenance of normal blood cholesterol concentrations have already been assessed with favourable outcomes.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1359). 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.

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EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009a. Scientific Opinion on the substantiation of health claims related to linoleic acid and maintenance of normal blood cholesterol concentrations (ID 489) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1276, 12 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2009b. Scientific Opinion on the substantiation of health claims related to alpha-linolenic acid and maintenance of normal blood cholesterol concentrations (ID 493) and maintenance of normal blood pressure (ID 625) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 7(9):1252, 17 pp.

EFSA Panel on Dietetic Products Nutrition and Allergies (NDA), 2011. Scientific Opinion on the substantiation of health claims related to foods with reduced amounts of saturated fatty acids (SFAs) and maintenance of normal blood LDL-cholesterol concentrations (ID 620, 671, 4332) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal, 9(4):2062, 14 pp.

Johansson A, 1999. Blackcurrant seed oil and sea buckthorn berry oil may affect the risk factors of cardiovascular diseases. University of Turku, Finland.

Tahvonen RL, Schwab US, Linderborg KM, Mykkanen HM and Kallio HP, 2005. Black currant seed oil and fish oil supplements differ in their effects on fatty acid profiles of plasma lipids, and

concentrations of serum total and lipoprotein lipids, plasma glucose and insulin. Journal of Nutritional Biochemistry, 16, 353-359.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

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

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

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

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

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

b) psychological and behavioural functions; or

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

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

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

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

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[7]

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

[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 supercritical CO_2 extracted blackcurrant seed oil, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
572	Blackcurrant seed oil (carbon dioxide extracted) + vitamin E.	Cardiovascular system. Clarification provided Blackcurrant seed oil helps to maintain healthy cholesterol levels. Blackcurrant seed oil helps to maintain normal blood pressure.	Blackcurrant seed oil increases HDL cholesterol levels. Blackcurrant seed oil reduces LDL cholesterol levels. Blackcurrant seed oil improves the HDL/LDL ratio. Blackcurrant seed oil supports cardiovascular health by regulating fat metabolism and blood pressure.
	Conditions of use - Food supplement with 100-2000 mg of blackcurrant seed oil (standardised, carbon dioxide extracted) and 5-10 mg of vitamin E in the daily dose.		
	Comments from Member States Health relationship defined.		

GLOSSARY AND ABBREVIATIONS

ALA	α-linolenic acid
BSO	Blackcurrant seed oil
GLA	γ-linolenic acid
HDL	High density lipoprotein
LA	Linoleic acid
LC-PUFA	Long-chain polyunsaturated fatty acid
LDL	Low density lipoprotein
MUFA	Monounsaturated fatty acid
PUFA	Polyunsaturated fatty acid
RCT	Randomised controlled trial
SFA	Saturated fatty acid