SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to various food(s)/food constituent(s) claiming biotransformation of xenobiotic substances (ID 1378, 2388, 2401, 3900, 3942, 4039, 4510, 4513, 4544, 4628, 4639), "elimination", "cleansing" and "purification" (ID 1347, 4024, 4442, 4457), elimination of heavy metals (ID 1887, 3156), and maintenance of normal bowel function (ID 4039) 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 related to various food(s)/food constituent(s) claiming biotransformation of xenobiotic substances, "elimination", "cleansing" and "purification", elimination of heavy metals and maintenance of normal bowel function. 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.

Biotransformation of xenobiotic substances

The claimed effects are "purification", "purifying/detoxifying", "urinary elimination", "depurative, detoxificant", "detoxification", "blood health", "supports the natural mechanism for body's purification", "elimination and detox", and "favours toxin elimination". The target population is

[1] On request from the European Commission, Question No EFSA-Q-2008-2084, EFSA-Q-2008-2115, EFSA-Q-2008-2620, EFSA-Q-2008-3121, EFSA-Q-2008-3134, EFSA-Q-2008-3888, EFSA-Q-2008-4616, EFSA-Q-2008-4658, EFSA-Q-2008-4736, EFSA-Q-2008-4751, EFSA-Q-2010-00395, EFSA-Q-2010-00410, EFSA-Q-2010-00463, EFSA-Q-2010-00466, EFSA-Q-2010-00497, EFSA-Q-2010-00581, EFSA-Q-2010-00592, adopted on 09 July 2010.

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[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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assumed to be the general population. In the context of the proposed wordings and/or the clarifications provided by Member States, the Panel assumes that the claimed effect relates to the biotransformation of xenobiotic substances.

The Panel notes that from the proposed wordings or the clarifications provided by Member States it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

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.

"Elimination", "cleansing" and "purification"

The claimed effects are "elimination", "cleansing" and "purification". The target population is assumed to be the general population.

"Elimination", "cleansing" and "purification" are not sufficiently defined. No clarifications have been provided by Member States and no more details were contained in the proposed wording.

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

Elimination of heavy metals

The claimed effects are "helps eliminate toxins/heavy metals from the body" and "might support detoxication processes". The target population is assumed to be the general population. In the context of the proposed wording, the Panel assumes that the claimed effect is related to the elimination of heavy metals. The Panel considers that elimination of heavy metals is a beneficial physiological effect.

No references have been provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claim and elimination of heavy metals.

Maintenance of normal bowel function

The claimed effect is "elimination and detox". The target population is assumed to be the general population. In the context of the clarification provided by Member States, the Panel assumes that the claimed effect is related to maintenance of normal bowel function. The Panel considers that maintenance of normal bowel function might be a beneficial physiological effect.

No references have been provided from which conclusions could be drawn for the scientific substantiation of the claimed effect.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food/food constituent which is the subject of the health claim and maintenance of normal bowel function.

KEY WORDS

Xenobiotic substances, biotransformation, heavy metals, bowel function, 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

The approach used in the evaluation of Article 13(1) health claims is explained in the EFSA published briefing document for stakeholders[6].

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;

2. the claimed effect is defined and is a beneficial physiological effect ("beneficial to human health");

3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.

1. Relevance of the claimed effect to human health

1.1. Biotransformation of xenobiotic substances (ID 1378, 2388, 2401, 3900, 3942, 4039, 4510, 4513, 4544, 4628, 4639)

The claimed effects are "purification", "purifying/detoxifying", "urinary elimination", "depurative, detoxificant", "detoxification", "blood health", "supports the natural mechanism for body's purification", "elimination and detox", and "favours toxin elimination". The Panel assumes that the target population is the general population.

[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] Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf
[6] See footnote 5

In the context of the proposed wordings and/or the clarifications provided by Member States, the Panel assumes that the claimed effect relates to the biotransformation of xenobiotic substances.

Enzymatic biotransformation reactions of xenobiotic substances after absorption involve Phase I and Phase II biotransformation reactions, which usually work together in a sequential manner to convert xenobiotics into more readily excretable metabolites (Yu, 2005; Buhler and Williams, 1988). Phase I biotransformation reactions include oxidation, reduction, and hydrolysis, while Phase II biotransformation consists essentially of conjugation reactions (Yu, 2005). Whereas biotransformation reactions normally result in detoxification, some chemicals may also be enzymatically converted to highly reactive, electrophilic metabolites which may induce cytotoxic, teratogenic, mutagenic or carcinogenic effects through reaction with various cellular constituents (Buhler and Williams, 1988).

The Panel notes that from the proposed wordings or the clarifications provided by Member States it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

In the absence of such information, 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.

1.2. "Elimination", "cleansing" and "purification" (ID 1347, 4024, 4442, 4457)

The claimed effects are "elimination", "cleansing" and "purification". The Panel assumes that the target population is the general population.

"Elimination", "cleansing" and "purification" are not sufficiently defined. No clarifications have been provided by Member States and no more details were contained in the proposed wording.

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

1.3. Elimination of heavy metals (ID 1887, 3156)

The claimed effects are "helps eliminate toxins/heavy metals from the body" and "might support detoxication processes". The Panel assumes that the target population is the general population.

In the context of the proposed wording, the Panel assumes that the claimed effect is related to the elimination of heavy metals.

The Panel considers that elimination of heavy metals is a beneficial physiological effect.

1.4. Maintenance of normal bowel function (ID 4039)

The claimed effect is "elimination and detox". The Panel assumes that the target population is the general population.

In the context of the clarification provided by Member States, the Panel assumes that the claimed effect is related to aspects of "laxative action". Changes in bowel function within the normal range e.g. reduced transit time, increased frequency of bowel movements or bulk of stools might be interpreted as improvement of bowel function.

The Panel considers that maintenance of normal bowel function might be a beneficial physiological effect.

2. Scientific substantiation of the claimed effect

2.1. Elimination of heavy metals (ID 1887, 3156)

No human studies that contained data which could be used to substantiate the claim were cited in the references provided.

The references provided comprised some animal studies and human studies which were not related to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

One reference was an animal study on the reduction of blood lead concentrations. One was an *in vitro* study which investigated the removal of copper and nickel from solution. The Panel considers that while effects shown in animal and *in vitro* studies may be used as supportive evidence, human studies are required for the substantiation of a claim, and that the evidence provided in animal and *in vitro* studies alone is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on the elimination of heavy metals in humans.

One reference was a textbook, describing a study which examined the reduction of cadmium, copper, chromium, nickel and lead in children. The information provided regarding the study design, methodology and statistical analyses given in this textbook was insufficient for a complete scientific evaluation and the original reference cited in the textbook was not available to the Panel, even after having made all reasonable efforts to retrieve it. The Panel considers that no conclusions can be drawn from this reference for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the health claim and elimination of heavy metals.

2.2. Maintenance of normal bowel function (ID 4039)

The references provided included some textbooks in which the claimed effect was mentioned. The remaining references were animal or *in vitro* studies which were not related to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food/food constituent which is the subject of the health claim and maintenance of normal bowel function.

CONCLUSIONS

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

Biotransformation of xenobiotic substances (ID 1378, 2388, 2401, 3900, 3942, 4039, 4510, 4513, 4544, 4628, 4639)

- The claimed effects are "purification", "purifying/detoxifying", "urinary elimination", "depurative, detoxificant", "detoxification", "blood health", "supports the natural mechanism for body's purification", "elimination and detox", and "favors toxin elimination". The target population is assumed to be the general population. In the context of the proposed wordings and/or the clarifications provided by Member States, it is assumed that the claimed effect relates to the biotransformation of xenobiotic substances. From the proposed wordings or the

clarifications provided by Member States it could not be established which xenobiotic substance or which biotransformation reaction related to the elimination of xenobiotic substances is the target for the claim.

- 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.

"Elimination", "cleansing" and "purification" (ID 1347, 4024, 4442, 4457)

- The claimed effects are "elimination", "cleansing" and "purification". The target population is assumed to be the general population. The claimed effects, "elimination", "cleansing" and "purification" are not sufficiently defined. No clarifications have been provided by Member States and no more details were contained in the proposed wording.

- The claimed effects are general and non-specific and do not refer to any specific health claim as required by Regulation (EC) No 1924/2006.

Elimination of heavy metals (ID 1887, 3156)

- The claimed effects are "helps eliminate toxins/heavy metals from the body" and "might support detoxication processes". The target population is assumed to be the general population. Elimination of heavy metals is a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of the foods(s)/food constituent(s) which are the subject of the health claim and elimination of heavy metals.

Maintenance of normal bowel function (ID 4039)

- The claimed effect is "elimination and detox". The target population is assumed to be the general population. Maintenance of normal bowel function might be a beneficial physiological effect.

- A cause and effect relationship has not been established between the consumption of the food/food constituent which is the subject of the health claim and maintenance of normal bowel function.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-2084, EFSA-Q-2008-2115, EFSA-Q-2008-2620, EFSA-Q-2008-3121, EFSA-Q-2008-3134, EFSA-Q-2008-3888, EFSA-Q-2008-4616, EFSA-Q-2008-4658, EFSA-Q-2008-4736, EFSA-Q-2008-4751, EFSA-Q-2010-00395, EFSA-Q-2010-00410, EFSA-Q-2010-00463, EFSA-Q-2010-00466, EFSA-Q-2010-00497, EFSA-Q-2010-00581, EFSA-Q-2010-00592). 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

Buhler DR and Williams DE, 1988. The role of biotransformation in the toxicity of chemicals. Aquatic Toxicology, 11, 19-28.

Yu, MH, 2005. Biotransformation – Metabolism of Xenobiotics. In: Environmental Toxicology Biological and Health Effects of Pollutants. CRC Press, Boca Raton.

APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[7] (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[8]

Foods are commonly involved in many different functions[9] 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

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

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 various food(s)/food constituent(s) claiming "detoxification", including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1347	Laminaria (Brown seaweed)	Purification	Effectively purifies the body
	Conditions of use – 50g in 30 min before eating		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1378	Apple cider vinegar	Purification	1. Apple cider vinegar has body purifying and healing properties 2. Splits and eliminates harmful toxins/end-products 3. Optimizes and balances the body function 4. Restores the inner balance of the body
	Conditions of use – Powder: 1,2 g		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1887	chlorella pyrenoidosa	purifiant capacité à absorber les toxines Clarification provided Helps eliminate toxins/heavy metals from the body	Purifiant Capacité à absorber les toxines Clarification provided Aids the natural detoxification process in the body/promotes body detoxication
	Conditions of use – 3g/jour		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2388	Andrographis paniculata (Creat)	Purification	Helps eliminate harmful substances from the body and ensures lively mind
	Conditions of use – Extract: 47 mg / Used as part of a multibotanical combination		
	No clarification provided by Member States		

ID	Food or Food constituent	Health Relationship	Proposed wording
2401	Beta vulgaris	Purification	Beneficially affects digestion and promotes body's detoxification processes
	Conditions of use – Root: 100 mg / Used as part of a multibotanical combination		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3156	Zeolite - clinoptilolit	Might support the detoxication processes	Might help to protect the body tissues and cells from oxidative damage, viruses, heavy metals, toxines and free radicals, alergenes and radionuclids. Might helps to keep normal level of blood cholesterol, lipid and sugar. Might be useful in increasing the bioavailability of vitamins, minerals and nutritive substances from food. Balances the pH level of organism and it might rejuvenate the intestine peristaltic.
	Conditions of use – Adults: 1g in the morning, 1,5g in the evening for the period one month. Children: 0,5g in the morning, 0,75g in the evening for the period of one month. The cyclus can be repeated twice a year. The use of zeolite is not recommended by stomach and duodenal diseases in acute state. Zeolit is not recommended for children under 3 years of age.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3900	Aloe vera (Common Name : Aloe)	depurative, detoxificant	Contributes to the natural defences against microorganism/maintenance of the normal immune system
	Conditions of use – Leaf fresh gel / 30-90 ml or equivalent preparations		

ID	Food or Food constituent	Health Relationship	Proposed wording
3942	Yucca spp.	Detoxification Clarification provided: decrease surface tension of all sediments and harmful elements, dilute them and in this manner help to remove them from the human body	Saponines" substances in Yucca decrease surface tension of all sediments and harmful elements, dilute them and in this manner help to remove them from the human body/helps to remove toxic substances
	Conditions of use – The standard dosage of concentrated yucca saponins is two to four tablets or capsules a day. Capsules and tablets are commonly sold in doses of 500 milligrams.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4024	Commiphora mukul PURIFIED EXUDATE	Cleansing	Helps to cleanse the intestines, blood and tissues.
	Conditions of use – Powder: 0.75-0.05g/day. Unsupervised long-term use of more than 250-500mg/day is not recommended during pregnancy. May occasionally loosen the bowels Do not use in case of diarrhoea. All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4039	Emblica officinalis FRUIT RIND	Elimination & detox Clarification provided It has a gentle laxative action. Its neutralises toxins (alexiteric effect).	Has a gentle cleansing action. Helps neutralise toxins
	Conditions of use – Powder 3-0.2 g/day; aqueous extra 1.5-0.1 g/day All over 2 years old: 2-4 years ¼ adult dose, 4-10 years half adult dose		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4442	Melilotus officinalis-Herba-Melilot	Blood Health	Support for the blood purification.
	Conditions of use – Tincture, tea, capsule/ 5 ml tincture per day/ 2-3 cups of tea per day/ the equivalent of 600 mg powder per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4457	Parmelia perlata-herb-Parmeliaceae-Saileya-Parmelia	Purification	contributes to the blood purification

	Conditions of use – the equivalent of 4-6 g herb powder per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4510	Aloe vera folium, Sambucus ebulus radix, Sambucus nigra fructus, Taraxacum officinale folium, Orthosiphon stamineus folium (aloe leaves, danewort root, black elder fruits, dandelion leaves, java tea leaves)	Support the natural mechanism for body´s purification because of flavonoids, sterols and mucilages, constituients present in this plants combination.	support the natural mechanism for body´s purification / favorise toxin elimination /
	Conditions of use – May be taken 1 capsule (360 mg) to 3-4 times a day between meals. /		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4513	Arctium lappa radix, Urtica dioica herba, Taraxacum officinale herba (burdock root, nettle herb, dandelion herb)	Support the natural mechanism for body´s purification because of flavones and polyphenol-carboxilic acids, constituients present in this plants combination.	support the natural mechanism for body´s purification / favorise toxin elimination / favorise blood purification function
	Conditions of use – May be taken 1 gram to 3-4 times a day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4544	Convolvulus arvensis herba, Plantago species folium, Juniperus communis fructus, Taraxacum officinale herba, Salvia officinalis herba, Crataegus monogyna folium et flore, Hypericum perforatum herba (field bindweed herb, plantain leaves, juniper fruit, dandelion herb, sage herb, howthorn flowers and leaves, St. John's Wort herb)	Favorise toxin elimination because of resins, lactones, catechins, flavonoides and volatil oil, constituients present in this plants combination.	/support the natural mechanism for body´s purification / favorise toxin elimination /
	Conditions of use – To make an infusion, use 1 teaspoonful of the drug (1,5gr.) per cup. Will take 1 cup with tea 3 to 4 times a day between meals. A usually cure can be taken 3 months.		

ID	Food or Food constituent	Health Relationship	Proposed wording
4628	Solanum dulcamara stipes, Fumaria officinalis herba, Ulmus minor cortex, Arctium lappa radix, Rumex Patienta radix, Smilax sarsaparilla radix (bitter nightshade steam, fumitory herbs, field elm bark, burdock root, patience root, smilax root)	Favorise toxin elimination because of saponis, polyphenols, phytosterols and anthracene derivates, constituients present in the plants combination.	support the natural mechanism for body´s purification / favorise toxin elimination
	Conditions of use – To make an infusion, use 1 to 2 teaspoon fuls of the drug (1,5 -3 g) per cup. Will take 1 cup with tea 3-4 times a day, between meals. A usually cure can be taken 6 to 8 weeks.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4639	Viola tricolor herba, Cichorium intybus radix, Arctium lappa radix, Betula alba folium, Juniperus communis Fructus, Sambucus nigra flos, Fraxinus excelsior folium (wild pansy herb, chicory root, burdock root, sweet birch leaves, juniper fruit, black elder flowers, ash leaves)	Support the natural mechanism for body´s purification because of potassium, sesquiterpene lactones, polyphenols and volatil oil, constituients present in this plants combination.	support the natural mechanism for body´s purification / favorise toxin elimination / favorise blood purification function
	Conditions of use – To make an infusion, use 1 to 2 teaspoonfuls (2,15- 4,3 g) per cup. Children over 6 years will take 1 cup with tea 2 to 3 times a day. Adults will take 1 cup with tea 3 to 4 times a day between meals. A usually cure can be taken 6 to 8 weeks.		