

## SCIENTIFIC OPINION

### General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to provide general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims of Regulation (EC) No 1924/2006 which harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. This general guidance is a combined and updated version of two previous briefing documents (frequently asked question document related to the assessment of Article 14 and 13.5 health claim applications, and a briefing document for Member States and the European Commission on the evaluation of Article 13.1 health claims). This guidance document summarises the general principles applied by the NDA Panel in the evaluation of health claims, and covers issues such as the totality of available scientific evidence, pertinent studies for substantiation of health claims, wording of claims, the extent to which a food needs to be characterised for the claimed effect, claimed effects which are beneficial physiological effects, definition of a risk factor for the development of a human disease, compliance/eligibility issues for health claims, and procedural aspects. The guidance document (previously called briefing document) was subject to public consultation (17 May 2010 to 1 June 2010), and was also discussed at a stakeholder meeting on 1 June 2010. The general guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims, and it may be further updated as appropriate as additional issues are addressed.

#### KEY WORDS

Health claims, scientific requirements, Article 13 claims, health claims applications, general principles.

<sup>1</sup> On request from EFSA, Question No EFSA-Q-2011-00216, adopted on 25 March 2011.

<sup>2</sup> 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](mailto:nda@efsa.europa.eu)

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	2
Background as provided by EFSA .....	3
Terms of reference as provided by EFSA .....	3
Assessment .....	4
1. Introduction .....	4
2. Overview of the main issues addressed by the NDA Panel in the evaluation of Article 13.1, 13.5 and 14 health claims .....	7
3. How does the NDA Panel decide whether a health claim is substantiated? .....	9
4. What is the totality of the available scientific data? .....	10
4.1. Article 13.1 health claims .....	10
4.2. Article 13.5 and Article 14 health claims .....	11
5. What are the pertinent studies for the substantiation of a health claim?.....	11
5.1. Extrapolation from studies in groups other than the target group .....	12
6. On what basis does the NDA Panel propose wordings of health claims?.....	12
7. To what extent should a food/constituent be characterised?.....	12
8. How should the claimed effect be shown to be beneficial? .....	14
9. What is a risk factor for the development of a human disease? .....	15
10. Comparative health claims .....	16
11. Compliance/eligibility issues for health claims.....	16
11.1. Compliance with the criteria laid down in the Regulation .....	16
11.2. Borderline issues with respect to the Regulation.....	16
12. Procedural aspects for Article 13.1, 13.5 and 14 health claims .....	17
12.1. Article 13.1 health claims .....	17
12.2. Article 13.5 and 14 applications .....	18
12.2.1. Communication with applicants .....	19
12.2.2. Use of proprietary data .....	19
12.2.3. Use of confidential data.....	20
Appendix .....	21
Glossary and Abbreviations .....	24

## **BACKGROUND AS PROVIDED BY EFSA**

Regulation (EC) No 1924/2006<sup>3</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. According to the Regulation, health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard has been carried out by EFSA.

EFSA and its NDA Panel have been engaging in consultation with stakeholders, and have published guidance on scientific substantiation of health claims since 2007<sup>4</sup>. Amongst others, a scientific report related to a briefing document on the scientific evaluation of Article 13.1, 13.5 and 14 health claims was published for consultation in May 2010, followed by a technical meeting with experts from the food industry, Member States and the European Commission in Parma, in June 2010<sup>5</sup>.

## **TERMS OF REFERENCE AS PROVIDED BY EFSA**

The NDA Panel is requested by EFSA to issue a guidance document on the scientific requirements and general principles for the substantiation of Article 13 and 14 health claims, which should be based on the draft Scientific Report related to a briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims (M-2009-0211 and M-2008-1061; EFSA-Q-2010-00822 and EFSA-Q-2010-00821).

This guidance document shall address all issues already addressed in the briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, and take into account all relevant comments received during the public consultation for this briefing document.

A report on the outcome of the public consultation on the briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims shall be published. The guidance document should be finalised by June 2011.

---

<sup>3</sup> 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.

<sup>4</sup> <http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm>

<sup>5</sup> <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

## ASSESSMENT

### 1. Introduction

As foreseen in Regulation (EC) No 1924/2006, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) issued an opinion in 2007 which provided scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim under Article 14 (applications related to claims referring to children's development and, health and disease risk reduction claims)<sup>6</sup>. This opinion of the NDA Panel formed the basis for Commission Regulation (EC) No 353/2008<sup>7</sup> establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006, which also applies to claims submitted under Article 13.5 of the health claims Regulation (health claim applications based on newly developed scientific evidence and/or proprietary data).

EFSA has also published pre-submission guidance on administrative and procedural questions which applicants intending to submit applications for health claims authorisation may have<sup>8</sup>.

The Standing Committee on the Food Chain and Animal Health at its meeting on 14 December 2007 adopted guidance on the implementation of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods<sup>9</sup> for (1) interaction with other Community legislation (relating to foodstuffs for particular nutritional uses, novel foods), (2) the use of comparative nutrition claims, and (3) classification of nutrition and health claims, including borderline cases between function claims and reduction of disease risk claims, and between claims referring to children's development and health and other health claims.

In the context of Article 13.1 of Regulation (EC) No 1924/2006, in July 2008 the European Commission requested EFSA to give a scientific opinion on the Community list of permitted health claims<sup>10</sup>. To this end, EFSA received from the European Commission the terms of reference and a consolidated list of claims submitted by Member States.

In the light of the experience gained from the health claims evaluations, in 2009 EFSA provided further advice and organised two meetings with various stakeholders. For health claim applications (Article 14 and 13.5 health claims), EFSA provided additional advice to applicants in the form of a frequently asked question document (FAQ). The draft FAQ was subject to public consultation and discussed at a meeting with applicants in June 2009, before its finalisation and publication in September 2009<sup>11</sup>. In order to update Member States and the European Commission on the evaluation of Article 13.1 health claims, EFSA held a meeting in October 2009. To this end, a draft briefing

---

<sup>6</sup> EFSA (European Food Safety Authority), 2007. Opinion of the Panel on Dietetic Products, Nutrition and Allergies (NDA) related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim. The EFSA Journal, 530, 1-44.

<sup>7</sup> Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. OJ L 109, 19.4.2008, pp. 11–16.

<sup>8</sup> EFSA pre-submission guidance for applicants intending to submit applications for authorisation of health claims made on foods.

<sup>9</sup> [http://ec.europa.eu/food/food/labellingnutrition/claims/guidance\\_claim\\_14-12-07.pdf](http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf)

<sup>10</sup> Article 13 health claims, often referred to as general function claims, are health claims other than those referring to the reduction of disease risk and to children's development and health. Article 13 claims describe or refer to the role of a nutrient or other substance in the functions of the body, or to the psychological and behavioural functions, or to slimming or weight control or to a reduction in the sense of hunger or to an increase in the sense of satiety or to the reduction of the available energy from the diet.

<sup>11</sup> EFSA (European Food Safety Authority), 2009. Frequently Asked Questions (FAQ) related to the assessment of Article 14 and 13.5 health claims applications on request of EFSA. EFSA Journal, 7(9):1339, 18 pp.

document was prepared and discussed at the meeting. This document was updated after the meeting and published in December 2009<sup>12</sup>.

As the NDA Panel is applying similar criteria for the evaluation of all health claims, these two documents have been combined into a single briefing document, and updated taking into account the latest developments. This briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims was subject to public consultation (17 May 2010 – 1 June 2010), and served as a basis for discussion at a technical meeting with stakeholders, which was held in Parma on 1 June 2010.

The draft briefing document has been transformed into a Panel output, taking into account the questions/comments received during the public consultation. This document constitutes the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, and outlines the approach of the NDA Panel to the evaluation of health claims in general. A report on the outcome of the public consultation has been published on the EFSA website.

The current guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluations of health claims, and it may be further updated as appropriate as additional issues are addressed.

In addition to this general guidance, the NDA Panel is currently preparing more specific guidance for the scientific requirements of health claims in selected areas, which will be subject to public consultation and scientific meetings during 2010-2012<sup>13</sup>. A first guidance on the scientific requirements for health claims related to gut and immune function has already been published<sup>14</sup>.

---

<sup>12</sup> EFSA (European Food Safety Authority), 2009; Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims. EFSA Journal, 7(11):1386, 10 pp.

<sup>13</sup> <http://www.efsa.europa.eu/en/calls/consultations.htm>

<sup>14</sup> EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. Guidance on the scientific requirements for health claims related to gut and immune function. EFSA Journal 2011;9(4):1984, 12 pp.

The following topics are addressed in this guidance document:

- Overview of the main issues addressed by the NDA Panel in evaluation of Article 13.1, 13.5 and 14 health claims.
- How does the NDA Panel decide whether a health claim is substantiated?
- What is the totality of the available scientific data?
- What are the pertinent studies for substantiation of a health claim?
- On what basis does the NDA Panel propose wordings of health claims?
- To what extent should a food/constituent be characterised?
- How should the claimed effect be shown to be beneficial?
- What is a risk factor for the development of a human disease?
- Compliance/eligibility issues for health claims.
- Procedural aspects for Article 13.5 and 14 health claims.
- Procedural aspects for Article 13.1 health claims.

## 2. Overview of the main issues addressed by the NDA Panel in the evaluation of Article 13.1, 13.5 and 14 health claims

The Terms of Reference provided to EFSA for the Article 13.1 health claims list are consistent with the approach adopted by the NDA Panel in the evaluation of claims under Articles 13.5 and 14 of the Regulation. Thus, the NDA Panel has adopted a similar approach to the evaluation of Article 13.1 health claims, with some differences noted in the procedural section.

In assessing each specific food/health relationship, which 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).

If a cause and effect relationship is considered to be established, the NDA Panel considers whether:

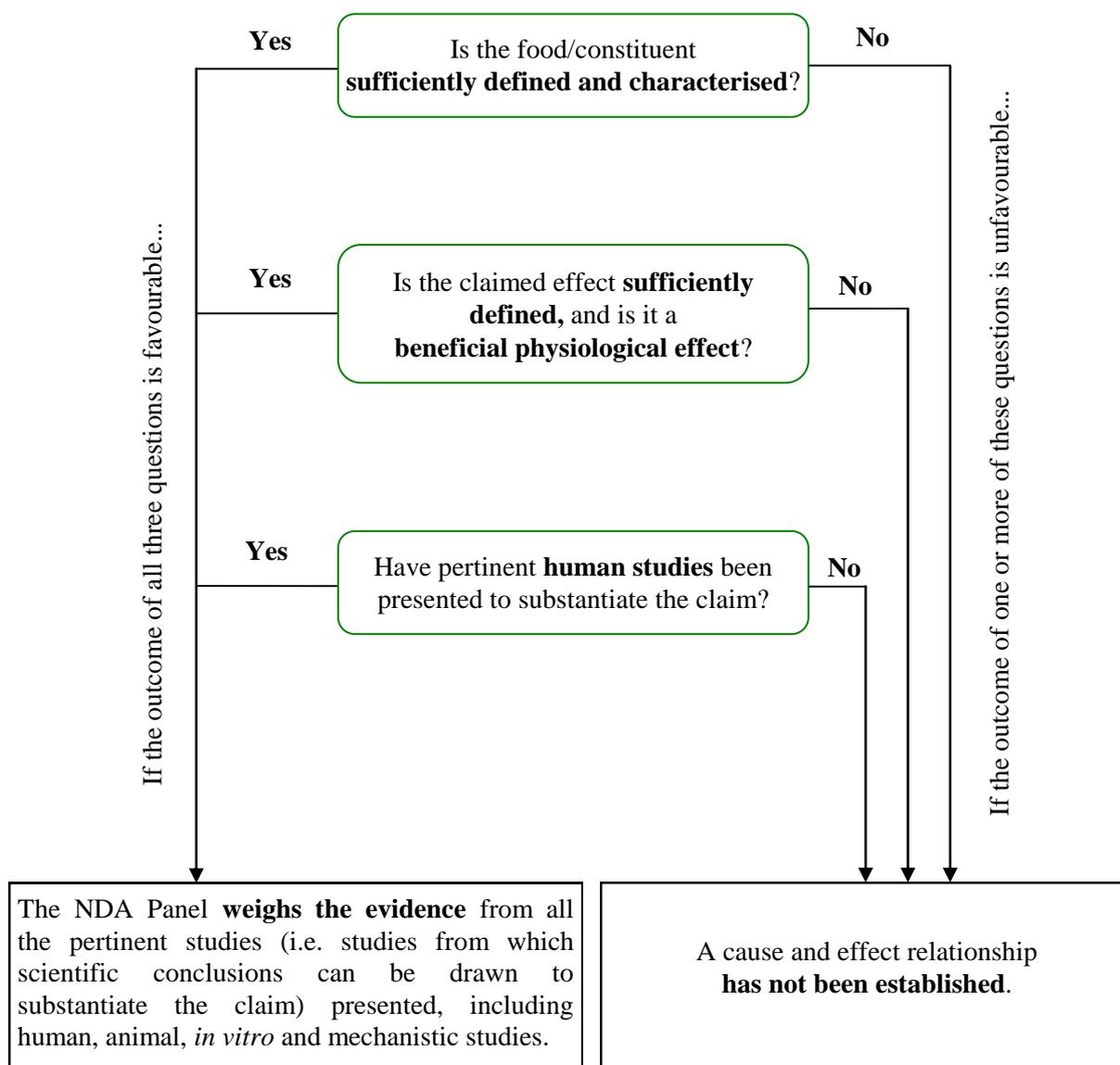
- the quantity of food/pattern of consumption required to obtain the claimed effect can reasonably be consumed within a balanced diet;
- the proposed wording reflects the scientific evidence;
- the proposed wording complies with the criteria for the use of claims specified in the Regulation;
- the proposed conditions/restrictions of use are appropriate;
- in the case of Article 13.5 and 14 claims, substantiation is dependent on data claimed as proprietary by the applicant.

Because health claims are assessed on a case-by-case basis, the detailed application of these steps may vary.

Substantiation of a claim is dependent on a favourable outcome of the assessment of questions 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. Furthermore, if there are no human studies which are pertinent to the claim (i.e. studies using the food/constituent and with appropriate outcome measures in a group that is representative of the target group for the claim), the outcome of question 3 will be unfavourable (see flowchart).

For Article 13.1 claims each relationship between a food/constituent and a claimed effect is assessed separately, and individual assessments are combined, as appropriate, to form coherent opinions.

## Key questions addressed by the EFSA NDA Panel in the scientific evaluation of health claims



### 3. How does the NDA Panel decide whether a health claim is substantiated?

In accordance with Regulation (EC) No 1924/2006, and with the Terms of Reference which were received from the European Commission in relation to Article 13.1 claims, the NDA Panel considers (for all health claims) 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, the NDA Panel evaluates the claim according to consistent criteria on the nature and quality of the totality of the evidence provided.

In assessing each specific food/health relationship which forms the basis of a claim, the NDA Panel makes a scientific judgement on the extent to which 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) by considering the strength, consistency, specificity, dose-response, and biological plausibility of the relationship. All the evidence from the pertinent studies (i.e. studies from which scientific conclusions can be drawn for the substantiation of the claim) is weighed with respect to its overall strength, consistency and biological plausibility, taking into account the quality of individual studies and with particular regard to the population group for which the claim is intended, and to the conditions of use proposed for the claimed effect. A grade is not assigned to the evidence. While studies in animals or *in vitro* may provide supportive evidence (e.g. in support of a mechanism), human data are central for the substantiation of the claim. This procedure is in agreement with the hierarchy of evidence described in the EFSA guidance<sup>15</sup>. The NDA Panel considers the rationale/evidence for the biological plausibility of the claim based on the data provided by the applicant to support the substantiation of the claim.

Each relationship between a food/constituent and a claimed effect is assessed separately. There is no pre-established formula as to how many or what type of studies are needed to substantiate a claim. In this regard, the reproducibility of the effect of the food/constituent as indicated by consistency between studies is an important consideration. The NDA Panel considers what are the accepted norms in the relevant research fields, and consults experts from various disciplines, as appropriate. Scientific requirements for the substantiation of specific types of health claims (e.g. which claimed effects are considered beneficial physiological effects and which outcome measures are accepted for substantiation) are considered by the NDA Panel on an ongoing basis, and are to be found in published opinions. EFSA is currently consolidating these scientific requirements to provide additional guidance to applicants<sup>16</sup>.

Substantiation of reduction of disease risk claims requires evidence on the effect of the food/constituent on risk factors that are predictive of a reduced risk of disease.

The outcome of each assessment is one of three possible conclusions:

1. *A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect.*

This statement represents the best judgement of the NDA Panel on whether a cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect by the evidence provided (i.e. that the claim is substantiated by generally accepted scientific evidence).

---

<sup>15</sup> <http://www.efsa.europa.eu/en/scdocs/doc/530.pdf>

<sup>16</sup> <http://www.efsa.europa.eu/en/ndaclaims/ndaguidelines.htm>

2. *The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.*

This statement represents the best judgement of the NDA Panel that, although there is scientific evidence supporting a cause and effect relationship, the evidence is not conclusive (i.e. that the claim is not substantiated by generally accepted scientific evidence).

There are several possible reasons for reaching a conclusion that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect. For example, it could be due to limited evidence or conflicting evidence. The reasons for such a conclusion are provided in the respective opinions.

3. *A cause and effect relationship has not been established between the consumption of the food/constituent and the claimed effect.*

The NDA Panel considers that there is no, or at most very limited, scientific evidence supporting a cause and effect relationship, and that the claim is not substantiated by generally accepted scientific evidence.

#### **4. What is the totality of the available scientific data?**

The totality of data refers to all the studies available to the NDA Panel that are considered to be pertinent (i.e. the studies from which conclusions can be drawn for the scientific substantiation of the claim), including those supporting the relationship as well as those showing no effect and/or opposing effects.

##### **4.1. Article 13.1 health claims**

The NDA Panel uses references received from the Member States, and references received directly from stakeholders. In the assessment the NDA Panel may use data which are not included in the references provided if they are considered pertinent to the claim. However, it is not required to search for additional references.

There are several limitations regarding the availability of documents cited in the references provided (including inaccurate or incomplete references, references to documents which are not readily accessible (e.g. published in Journals not readily available), and references to documents in languages other than English).

The NDA Panel carries out the evaluation of claims with the data available to it, taking into account the availability of the documents cited in the references provided. The NDA Panel notes that it has no assurance that the references provided represent all the data pertinent to the claim, i.e. that they include evidence of no effect and/or opposing effects, as well as evidence which supports the relationship.

For claims for which there is well established consensus among scientific experts as to their substantiation by generally accepted scientific evidence, e.g. many of the functions of the essential nutrients, the NDA Panel may rely on such consensus as indicated by authoritative scientific sources. In such cases it may not be necessary to review the primary scientific studies on the claimed effect of the food/constituent. For claims for which there is no established consensus, as indicated by authoritative scientific sources, it is necessary to review the primary studies in order to assess whether such claims are substantiated.

The NDA Panel reviews the totality of the scientific data provided, including handbooks and monographs, to see if they contain data from which conclusions can be drawn (pertinent data) for the scientific substantiation of the claim.

#### **4.2. Article 13.5 and Article 14 health claims**

For Article 13.5 and 14 applications, it is the responsibility of the applicant to provide the totality of the available data. In its assessment the Panel may use data which are not included in the application if they are considered pertinent to the claim.

### **5. What are the pertinent studies for the substantiation of a health claim?**

As human data are central for the substantiation of a health claim, particular attention is given to whether the human studies provided are pertinent to the claim. In addition, it is important that the human studies provided represent all available evidence pertinent to the claim, including evidence which supports the relationship as well as equivocal evidence and evidence of no effect and/or opposing effects.

In considering whether the human studies (both published and unpublished) described in the references provided are pertinent (i.e. studies providing evidence from which conclusions can be drawn for the scientific substantiation of the specific claim), the NDA Panel addresses the following questions:

- Have the studies been carried out with the food/constituent for which the claim is made? This requirement means that there should be sufficient definition of the food/constituent for which the claim is made and of the food/constituent that is the subject of the studies which have been provided for the substantiation of the claim.
- Have the human studies used (an) appropriate outcome measure(s) of the claimed effect?
- Does the design and quality of the studies provide evidence from which conclusions can be drawn for the scientific substantiation of the specific claim? For example, have intervention studies been appropriately conducted so as to minimise bias? Have observational studies been controlled adequately for factors other than the food/constituent known to have an impact on the claimed effect?
- How do the conditions under which the human studies were performed relate to the conditions of use (e.g. quantity and pattern of consumption of the food/constituent) proposed for the claim?
- Have the human studies been carried out in a study group which is representative of the population group for which the claim is intended? Can the results obtained in the studied population be extrapolated to the target population?

In relation to non-human studies, the NDA Panel addresses to what extent evidence derived from studies in animals/*in vitro* can support the claimed effect in humans, for example by providing evidence on the mechanisms by which the food/constituent could exert the claimed effect, and on the biological plausibility of the specific claim.

If the claim is for a specific formulation or fixed combination of constituents (as distinct from the individual constituents), the pertinent studies are those performed with this specific formulation or combination, and not studies performed with the individual constituents.

The NDA Panel gives a summary of the references provided to support a health claim (both numbers and nature of studies), and of the reasons for excluding studies which are not considered to be pertinent.

### **5.1. Extrapolation from studies in groups other than the target group**

For studies in groups (e.g. subjects with a disease) other than the target group for a claim (e.g. the general population), the NDA Panel considers on a case-by-case basis the extent to which it is established that extrapolation from the study group to the target group is biologically justified. For example, for claims on reducing gastro-intestinal discomfort (in the general population) evidence in patients with irritable bowel syndrome may be accepted. However, for claims on maintenance of normal joints (in the general population), evidence is not accepted from studies with osteoarthritis patients. Based on the available evidence, osteoarthritis patients are not considered to be representative of the general population with regard to the status of their joint tissues; normal cells and tissues are different from osteoarthritic cells and tissues, and therefore may respond differently to an intervention with exogenous substances. It is the responsibility of the applicant to provide evidence that results from a study group other than the target population can be extrapolated to the target population.

### **6. On what basis does the NDA Panel propose wordings of health claims?**

For claims for which a cause and effect relationship has been established, the NDA Panel considers whether the proposed wording reflects the scientific evidence and complies with the criteria laid down in the Regulation (e.g. it should not refer only to general, non-specific health benefits of the food/constituent); if not, the NDA Panel may propose an appropriate wording.

It should be noted that the wording adopted by the European Commission during the authorisation process may have to take into account aspects other than agreement with the scientific evidence, for example consumer understanding. Any issues related to consumer understanding of the wording of a claim should be addressed to the European Commission following publication of the opinion of the NDA Panel. EFSA liaises with the European Commission, as appropriate, on scientific aspects of the wording of the claim.

For reduction of disease risk claims, the wording should refer to the specific risk factor for the disease, for example, 'Plant sterols/stanols have been shown to reduce blood cholesterol levels. High cholesterol levels are a risk factor in the development of coronary heart disease'.

### **7. To what extent should a food/constituent be characterised?**

Health claims can be made on a food category, a food or a food constituent (e.g. a nutrient, or other substance, or a combination of nutrients/other substances). These are covered under the term "food/constituent".

The NDA Panel considers whether the specific food/constituent is sufficiently defined and characterised, to establish that the studies provided for substantiation of the claim were performed with the food/constituent for which the claim is made. There should be sufficient definition of the food/constituent used in the studies provided for substantiation of the claim. Characterisation should also be sufficient to allow definition of appropriate conditions of use<sup>17</sup>. It is in the interest of the applicant to provide this information along with information regarding manufacturing processes,

---

<sup>17</sup> Although not required for substantiation of a claim, characterisation should also be sufficient to allow control authorities to verify that the food/constituent which bears a claim is the same one that was the subject of a Community authorisation.

where applicable, in order to show consistency in the final product for those characteristics considered to be pertinent to the claimed effect.

The NDA Panel considers whether the information provided includes those characteristics considered pertinent to the claimed effect, i.e. those characteristics which may influence the specific physiological effect that is the basis of the claim. It may be necessary to distinguish between a specific formulation or a specific constituent/combination of constituents, and the following cases have been identified:

- If the claim is for an individual constituent, then substantiation of the claim is based on studies performed with this constituent.
- If the claim is for a specific formulation or a fixed combination of constituents, then studies are needed on this specific formulation or combination. If individual constituent(s) are identified as contributing to the claimed effect, the NDA Panel considers whether sufficient information is provided to establish such a role for the constituent(s).
- For a food category (e.g. “wholegrain” and “dairy”), the NDA Panel considers whether the information provided sufficiently addresses the variability between individual foods for those characteristics considered pertinent to the claimed effect.
- For plant products, the NDA Panel considers whether the information provided includes the scientific name, the part and the preparation used. The Panel also considers whether the food/constituent has been sufficiently characterised with respect to the claimed effect and the proposed conditions of use, taking into account information extracted from standard reference textbooks.
- For microorganisms (e.g. bacteria and yeast), the NDA Panel considers whether, in addition to species identification, sufficient information is provided for characterisation (genetic typing) at strain level by internationally accepted molecular methods, and regarding the naming of strains according to the International Code of Nomenclature. There should also be sufficient definition of the strain(s) used in the studies provided for substantiation of the claim. Although not required for the substantiation of a claim, it is also desirable that strains be deposited in an internationally recognised culture collection (with access number) for control purposes. In the case of a combination of two or more microorganisms, the Panel considers that if one of the microorganisms used in the combination is not sufficiently characterised, the combination proposed is also not sufficiently characterised.
- For manufacturing processes, information should be provided to show consistency in the final product for those characteristics considered pertinent to the claimed effect.

For the evaluation procedure of Article 13.1 claims, the characterisation of a food constituent which is a microorganism is based on references which were available up to the end of December 2008, including the following:

- The information provided by the Member States in the consolidated list of Article 13 health claims and references which EFSA has received from Member States or directly from stakeholders;
- Generally available data obtained by searching Gene databases, PubMed and Web of Science databases by using the strain name as the search term.

During the scientific evaluation of the Article 13.1 health claims, the NDA Panel considered that the information provided was not sufficient to characterise a number of foods/constituents with respect to

the claimed effects (including some, but not all, 'probiotic' bacteria), and that the foods/constituents did not comply with a key criterion in the Terms of Reference for evaluation of these claims. In these cases, the claims could not be substantiated because the food/constituent was not sufficiently characterised, and it could not be established that the scientific studies which were submitted in support of the claim were performed with the same food/constituent as was proposed for the claim.

It should also be noted that in the Article 13 list of health claims, some foods/constituents are classified only on the basis of the claimed effect, i.e. the name of the food/constituent contains a description or indication of a beneficial effect on a function (e.g. non-cariogenic, low GI, antioxidants). Claims on such foods/constituents cannot be substantiated because these foods/constituents are not sufficiently characterised.

## **8. How should the claimed effect be shown to be beneficial?**

According to Regulation (EC) No 1924/2006, the use of health claims shall only be permitted if the food/constituent, for which the claim is made, has been shown to have a beneficial physiological effect.

In assessing each claim, the NDA Panel makes a scientific judgement on whether the claimed effect is considered to be a beneficial physiological effect in the context of the specific claim, as described in the information provided and taking into account the population group for whom the claim is intended.

For function claims, a beneficial effect may relate to maintenance or improvement of a function.

For reduction of disease risk claims, 'beneficial' refers to whether the claimed effect relates to the reduction (or beneficial alteration) of a risk factor for the development of a human disease (not reduction of the risk of disease).

The NDA Panel considers whether the claimed effect is sufficiently defined, to establish that the studies identified for substantiation of the claim were performed with (an) appropriate outcome measure(s) of that claimed effect. Thus, it may be necessary to distinguish between different possible effects or interpretations.

For health claim applications, one application should be prepared for each individual health claim; this means that only a relationship between a food/constituent and a single claimed effect can be the subject of each application.

The NDA Panel considers whether the claimed effect refers to a specific health claim (and is not general and non-specific) as required by Regulation (EC) No 1924/2006. The claimed effect needs to be specific enough to be testable and measurable by generally accepted methods. For example, "gut health" is too general (unclear what measure can be used) but "transit time" is specific (measurable by generally accepted methods).

For claims for which the information in the Article 13 list is unclear as to the definition of the claimed effect, the NDA Panel will use its best judgement to identify the claimed effect, e.g. by reference to the proposed wordings as well as the health relationship. The NDA Panel will also use its best judgement to identify the appropriate target group for the claim when this information is not provided. In its evaluation, the NDA Panel considers that where a health claim relates to a function which may be associated with a disease, subjects with the disease are not the target for the claim.

In the preparation of an application, a rationale/evidence should be provided that the claimed effect is beneficial in the context of the specific claim.

## 9. What is a risk factor for the development of a human disease?

Regulation (EC) No 1924/2006 defines reduction of disease risk claims as ‘significantly reduces a risk factor in the development of a human disease’. Thus, for reduction of disease risk claims, the beneficial physiological effect (which the Regulation requires to be shown for the claim to be permitted) is the reduction (or beneficial alteration) of a risk factor for the development of a human disease (not reduction of the risk of disease).

For the purpose of classifying disease, the World Health Organization (WHO) International Statistical Classification of Diseases and Related Health<sup>18</sup> should be used.

A risk factor is a factor associated with the risk of a disease, and which may serve as a predictor for the development of that disease. To date, the NDA Panel has considered a limited number of disease risk factors, all of which are physiological factors that (potentially) may be beneficially altered by diet. Dietary behaviour (e.g. diets with a low content of a specific category of foods or nutrients) would not be acceptable as a risk factor in this context as the beneficial alteration of the factor (increased consumption of a specific category of foods or nutrients) is not a beneficial physiological effect as required by the Regulation.

Whether or not the alteration of a factor is considered to be beneficial in the context of a reduction of disease risk claim depends on the extent to which it is established that:

- The factor is an independent predictor of disease risk (such a predictor may be established from intervention and/or observational studies);
- The relationship of the factor to the development of the disease is biologically plausible.

For some factors, there is strong evidence that they meet both criteria. For example, elevated blood LDL-cholesterol concentrations are associated with increased risk of coronary heart disease (CHD), for which there is strong evidence for the biological basis through which it can contribute to the development of atherosclerosis (one pathway to CHD). There is also strong evidence that there is an independent association between this factor and incidence of CHD, including evidence that a reduction in blood LDL-cholesterol concentrations (by dietary modification and drugs) generally reduces the risk of development of CHD. Reduction in blood LDL-cholesterol concentrations, therefore, may be considered beneficial in the context of a reduction of disease risk claim for CHD.

Similarly, reduction in systolic blood pressure may be considered beneficial in the context of a reduction of disease risk claim for CHD or stroke.

For other proposed risk factors, the evidence may not be as strong. For example, increased dental plaque is a factor associated with increased risk of dental caries, for which there is strong evidence for the biological basis through which it can contribute to the development of dental caries. However, while there is evidence that there is an independent association between the amount of dental plaque and incidence of dental caries, it is not generally established that lowering the amount of dental plaque can lower the risk of development of the disease. Nevertheless, if evidence is provided that decreasing dental plaque by a specific dietary intervention is accompanied by reduced incidence of dental caries, then such a reduction in dental plaque might be considered beneficial in the context of a reduction of disease risk claim for dental caries for that specific dietary intervention.

Except for factors for which changes are generally predictive of the development of diseases (e.g. elevated LDL-cholesterol concentrations for CHD, or elevated blood pressure for CHD or stroke), the extent to which a change in a factor is beneficial in the context of a reduction of disease risk claim needs to be considered on a case-by-case basis.

<sup>18</sup> <http://www.who.int/classifications/icd/en/>

## 10. Comparative health claims

Claims for a beneficial effect of the absence (or reduced content) of a food/constituent in a food or category of foods are evaluated as comparative claims. Substantiation may be based on evidence for an independent role of the food/constituent in an adverse effect. For example, for claims related to a reduced content of saturated fatty acids (SFAs) in relation to blood LDL-cholesterol concentrations, SFAs have been shown to increase blood LDL-cholesterol concentrations when compared to carbohydrates, which have a neutral effect on LDL-cholesterol concentrations, and therefore SFAs have an independent role in the adverse effect.

Claims for a beneficial effect of a food/constituent when used in replacement of a food/constituent with an independent role in an adverse effect are also evaluated as comparative claims. Substantiation may be based on evidence for an independent role in an adverse effect of the food/constituent which is being replaced, together with evidence for the lack of an effect or a reduced effect of the food/constituent which is used for replacement. Examples include claims for unsaturated fats and reduced blood LDL-cholesterol concentrations when replacing saturated fats, for low-fermentable carbohydrates and maintenance of tooth mineralisation ('non-cariogenic') when replacing fermentable sugars, and for low-digestible carbohydrates and reduced post-prandial blood glucose when replacing digestible carbohydrates.

In presenting such claims, applicants should take into account the Commission guidance on the implementation of Regulation (EC) No 1924/2006, of December 2007<sup>19</sup> for the use of comparative claims, including characterisation of the appropriate reference or comparator food/constituent.

## 11. Compliance/eligibility issues for health claims

### 11.1. Compliance with the criteria laid down in the Regulation

EFSA is requested to consider the claimed effect on the function, and provide advice on the extent to which the wording used to express the claimed effect complies with the criteria laid down in the Regulation.

Such criteria include:

- General, non-specific claims - reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14 (Article 10.3).
- Claims which encourage excess consumption of a food – the use of health claims shall not encourage or condone excess consumption of a food (Article 3c and Recital 18).
- The claimed effect must be beneficial - the use of health claims shall only be permitted if the food/constituent for which the claim is made has been shown to have a beneficial physiological effect (Article 5.1(a)).

### 11.2. Borderline issues with respect to the Regulation

*Maintenance claims on risk factors* - In the Article 13 list, there are some claims which refer to the maintenance of a function, but for which the scientific evidence is based on a reduction of a (well established) risk factor for a disease (e.g. maintenance of normal blood cholesterol concentrations, based on evidence of reduction of LDL-cholesterol concentrations). The NDA Panel notes the

<sup>19</sup> [http://ec.europa.eu/food/food/labellingnutrition/claims/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm)

Commission guidance on the implementation of Regulation (EC) No 1924/2006, of December 2007<sup>20</sup>: ‘when the claim mentions a disease risk factor generally recognised by scientific evidence, it should be considered as an Article 14 claim only when a reduction of this risk factor is stated, suggested or implied’, and ‘when a claim refers to a risk factor of a disease, without stating, suggesting or implying its reduction it is considered an Article 13 claim’.

The NDA Panel has evaluated claims for the maintenance of normal blood cholesterol concentrations under Article 13 even when the evidence for substantiation of the claimed effect is based on studies showing a reduction of blood cholesterol concentrations. Such evaluations have also been done for claims related to the maintenance of normal blood pressure.

*Claims related to children’s health and development* - In accordance with the Commission guidance on the implementation of Regulation (EC) No 1924/2006, of December 2007, claims which the NDA Panel considers to be only scientifically justified for children are considered as Article 14, and are not evaluated in the context of the Article 13 claims list.

*Target group* - The NDA Panel considers that the population group for which health claims are intended is the general (healthy) population or specific subgroups thereof, for example, elderly people, physically active subjects and pregnant women. In its evaluation, the NDA Panel considers that where a health claim relates to a function/effect, which may be associated with a disease, subjects with the disease are not the target population for the claim, for example, joint health and osteoarthritis patients. Applications for claims which specify target groups other than the general (healthy) population are the subject of ongoing discussions with the European Commission and Member States with regard to their admissibility.

## 12. Procedural aspects for Article 13.1, 13.5 and 14 health claims

### 12.1. Article 13.1 health claims

A consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 submitted by Member States via the European Commission to EFSA (in July 2008, November 2008, December 2008, March 2010) contains 4,637 main health claim entries. Around 10,500 similar health claims/health relationships have been clustered within these main health claim entries. These health claims/relationships describe similar effects of a substance on the body, and include the conditions of use and the literature which EFSA took into account in its scientific evaluation. EFSA has screened all health claims which were 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<sup>21</sup>. In June 2009, EFSA also referred back to the European Commission/Member States a number of so-called product specific claims and comparative claims for consideration of their eligibility. With its letters of 9 November 2009 and 12 March 2010 the European Commission provided clarification on the health claims sent back. Clarification was provided for the majority of

<sup>20</sup> [http://ec.europa.eu/food/food/labellingnutrition/claims/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm)

<sup>21</sup> **Screening criteria**

1. Claims where clarification on legal scope is needed (e.g. claims referring to risk reduction or referring to children’s development and health, or medicinal claims).
2. General well-being claims where the health relationship is not clear, e.g. “Compound X supplementation to sustain vitality while aging”.
3. Claims which are too vague (claimed effect not specified/measurable), e.g. Compound X and “energy and vitality”. Proposed wording: Compound X is “necessary to maintain energy and general vitality”.
4. Foods which are not sufficiently characterised or conditions of use are not sufficiently specified.
5. Combination constituents that are not sufficiently defined.
6. Claims in languages other than English (to be returned for translation). If EFSA is asked to carry out the translations, EFSA will send translated claims back to Member States for validation of the translation.

main entry claims, but for 621 main entry claims no clarification has been given. With respect to comparative claims the European Commission indicated that EFSA should proceed with their assessment. As product specific claims are not eligible under the Article 13 claims procedure, in March 2010 EFSA received back those claims which could be transferred to a generic food/food constituent.

The clarifications on the claims have been included in the consolidated list, and were taken into account by the NDA Panel in its evaluation as clarification to the originally provided information.

On 20 October 2010 EFSA was asked by the European Commission to reprioritise the work of the NDA Panel and to put on hold 1,549 so called “botanical claims”.

The updated consolidated list of health claims, including evaluation status, can be found at: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

The consolidated list of Article 13.1 health claims published on the EFSA website constitutes an EFSA working document for internal use. This list is not, and cannot be interpreted as being, representative of the final Community list of permitted health claims to be adopted by the European Commission in accordance with Article 13(3) of Regulation (EC) No 1924/2006.

EFSA is not accountable for the content of the list as the content lies solely within the responsibility of the European Commission/Member States. Therefore questions related to this (updated) list should be directed to the respective National Competent Authority or the European Commission.

Taking into account the high number of claims evaluated, and in order to comply with requirements for transparency<sup>22</sup> and to keep the workload manageable, the NDA Panel has adopted claim opinions in series, with subsequent publication in the EFSA Journal. In this context, EFSA has been trying to be as efficient as possible in combining claims into series of opinions.

EFSA envisages completing the evaluation of Article 13.1 claims by June 2011, except for the 1,549 so called “botanical claims”, which EFSA was asked to put on hold.

Based on Regulation (EC) No 1924/2006, the list of claims was submitted to EFSA by Member States via the European Commission. Therefore, EFSA’s contact point for any issues related to the Article 13.1 list is the European Commission/Member States.

A more detailed description of the procedural aspects of Article 13.1 health claims is provided in the Appendix.

## **12.2. Article 13.5 and 14 applications**

Procedural aspects for the authorisation of Article 13.5 and Article 14 claims are laid down in Articles 15-18 of the Health Claims Regulation (Regulation (EC) No 1924/2006), and in Commission Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims.

---

<sup>22</sup> Regulation (EC) No 178/2002 requires EFSA to make public without delay the opinions of the Scientific Panels

Additional procedural aspects for EFSA concern:

### 12.2.1. Communication with applicants

All communication between EFSA and the applicant is through the staff of the NDA Unit (not the Panel experts). There are five points during the procedure where direct or indirect communication between EFSA and the applicant may occur.

1. *Indirect* - during the admissibility check carried out by the Member State through which the application is submitted. EFSA liaises with the Member State regarding whether the application fulfils the criteria for the health claim classification under which it was submitted (i.e. Article 14 for claims related to children's development and health or the reduction of disease risk, or Article 13.5 for newly developed science/proprietary data).

2. *Direct* - before EFSA considers the application complete, EFSA communicates with the applicant regarding completeness of the application and compliance with administrative procedures. Completeness checking includes administrative completeness, clear identification of the food/constituent for which the claim is made (consistency throughout the application), clear definition of the claimed effect (a defined claimed effect including identification of endpoint(s) and methods of measurement, identification of (a) risk factor(s) for disease risk reduction claims), and definition of conditions of use. Identification of the food/constituent, the claimed effect and the conditions of use are key decision points for the evaluation.

3. *During evaluation* - EFSA may request the applicant to provide supplementary information on the application ('stop the clock' procedure). Requests from EFSA to applicants for supplementary information are made based on a case-by-case judgement by the NDA Panel. In addition to requests for clarification of aspects of data presented in the application, EFSA uses the 'stop the clock' procedure to request, when the NDA Panel considers appropriate, supplementary information from applicants related to the definition of the claim, for example, the proposed food/constituent, the claimed effect, risk factors for disease, or conditions of use. The experience of the NDA Panel has shown that issues relating to the definition of these aspects of claims, and which become apparent only during assessment of the application, can have a significant bearing on the evaluation. Therefore, EFSA considers that this communication procedure is helpful both to applicants and the NDA Panel.

If the applicant fails to provide the supplementary information within the time limit specified by EFSA, the NDA Panel will issue an opinion based on the data provided in the application.

4. *Notification* - before publication of the adopted opinion EFSA sends applicants a copy of the adopted opinion in advance of publication, for their information and to give them the possibility to indicate any errors and to check that no confidential data are disclosed unnecessarily. No re-opening of the scientific evaluation is foreseen at this step.

5. *Indirect* - after publication of the opinion, EFSA replies to requests from the European Commission in relation to scientific comments on the opinion submitted during the public comment period (30 days following publication of the opinion) provided for in Regulation (EC) No 1924/2006. Such comments may be from applicants (amongst others). In addition, as appropriate, EFSA may be asked by the Commission for additional advice, for example, in relation to the conditions of use of the claim, or scientific aspects of the wording of the claim.

### 12.2.2. Use of proprietary data

Where evidence for substantiation includes a request for the protection of proprietary data, the NDA Panel considers whether the claim could not have been substantiated without the data claimed

proprietary by the applicant. In such cases, applicants should ensure that, in addition to all proprietary data, all non-proprietary data pertinent to the claim are included in the application.

The decision on the protection of proprietary data falls within the responsibility of the European Commission.

### **12.2.3. Use of confidential data**

The applicant should keep the designation of confidential information to a minimum.

For transparency reasons, those data and information which are considered essential for the scientific assessment are released in the opinion, for example, a broad description of the study and the main outcome.

## **CONCLUSIONS**

This general guidance document summarises the general principles applied by the NDA Panel in the evaluation of health claims, and covers issues such as the totality of the available scientific evidence, pertinent studies for substantiation of health claims, wording of claims, the extent to which a food needs to be characterised for the claimed effect, claimed effects which are beneficial physiological effects, definition of a risk factor for the development of a human disease, compliance/eligibility issues for health claims, and procedural aspects. The general guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluations of health claims, and it may be further updated as appropriate as additional issues are addressed.

## APPENDIX

### PROCEDURAL ASPECTS FOR ARTICLE 13.1 HEALTH CLAIMS

#### The Article 13 list of health claims

The updated consolidated database of Article 13.1 health claims published in May 2010 contains the 4,637 main health claim entries submitted to EFSA for evaluation<sup>23</sup>. Around 10,500 similar health claims/health relationships have been clustered within these main health claim entries. These health claims/relationships describe similar effects of a substance on the body, and include the conditions of use and literature that EFSA took into account in its scientific evaluation.

The list can be found at: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

This list incorporates amendments to the earlier version of the Access database published on the EFSA website in January 2009, which were requested by the European Commission and Member States, including:

- re-allocation of a number of similar health claims which had been accidentally placed under a wrong main health claim entry (“misplaced claims”).
- a number of similar health claims identified by Member States which were not submitted to EFSA with the original list (“missing claims”), and which were added to the database under the appropriate main health claim entry.

Detailed information on each claim, including evaluation status, question number and proposed deadline for completion of evaluation, is also available through the EFSA Register of Questions<sup>24</sup>.

The list of Article 13 health claims published on the EFSA website constitutes an EFSA working document for internal use. This list is not, and cannot be interpreted as being, representative of the final Community list of permitted health claims to be adopted by the European Commission in accordance with Article 13(3) of Regulation (EC) No 1924/2006.

EFSA is not accountable for the content of the list as the content lies solely within the responsibility of the European Commission/Member States. Therefore, questions related to this (updated) list should be directed to the respective National Competent Authority or the European Commission.

#### Screening of 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

---

<sup>23</sup> Lists of Article 13 health claims received by EFSA from the Commission:

- July 2008: draft list with 2870 main entries and about 7000 similar health relationships in 9 separate Access files including 885 botanicals). This was a consolidated list of Article 13 claims submitted by Member States to the European Commission (about 44,000 claims in total, accompanied by the conditions of use and by references for the scientific substantiation).
- November 2008: list with 3,138 main entries and over 8,000 similar health relationships in 9 separate Access files (health claims for botanicals not included). This was a revision of the draft list received in July 2008.
- December 2008: list of health claims (mainly for botanicals) with 4,185 main entries and about 10,000 similar health relationships in 9 separate Access files. This was a revision of the draft list received in July 2008.
- March 2010: addendum to the list with 452 main entry claims (single entries with no additional similar health relationships). This was an addition to the lists received in July, November and December 2008.

<sup>24</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>

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<sup>25</sup>.

Approximately 2,000 main health claims entries were referred back to the European Commission/Member States in January 2009 for further information or clarification. The outcome of this screening is indicated for each claim (main entry) in the list. The European Commission agreed to coordinate with Member States the provision of the information or clarification needed by the NDA Panel in order to carry out the evaluation of these claims. For the remaining claims, the NDA Panel proceeded with the evaluation.

This screening was based on the information provided in the list, i.e. the name of the food, the proposed health relationship, the proposed conditions of use and examples of wordings. Screening was applied to all claims in the same way. For example, 94 claims (main entries) were considered to require more information or clarification with respect to criterion 4: 'foods which are not sufficiently characterised or conditions of use are not sufficiently specified'. This procedure was undertaken because the screening step showed that the information provided in the list (the name of the food and/or the proposed conditions of use) for the food/constituent was not properly identified for assessment purposes (e.g. 'dairy products' or 'soups'). Therefore, scientific evaluation of the claim was not started and the claim was referred back to the European Commission for more information or clarification with regard to criterion 4.

Many claims (main entries) were considered to require more information or clarification with respect to criterion 2: 'general well-being claims where the health relationship is not clear' and 3: 'claims which are too vague (claimed effect not specified/measurable)'; this means that based on the screening of the information provided on the list (the proposed health relationship and examples of wordings), a specific claim could not be identified due to lack of definition of the claim, or that the only claims defined were of a general, non-specific nature (e.g. 'sustain vitality while ageing'). Therefore, evaluation of the claim was not started and the claim was referred back to the European Commission for further information or clarification with regard to criteria 2 or 3. Claims were not referred back to the European Commission under criterion 2 or 3 if any specific claim could be identified from either the health relationship or the proposed wordings.

In June 2009 EFSA also referred back to the European Commission/Member States a number of so-called product specific claims and comparative health claims for consideration of their eligibility. In its letter of 9 November 2009 the European Commission indicated that the assessment of comparative health claims should proceed.

As product specific claims are not eligible under the Article 13 claims procedure, in March 2010 EFSA received back only those claims which could be transferred to a generic food/food constituent.

The clarifications on the claims have been included in the consolidated list and have been taken into account by the NDA Panel in its evaluation as clarification to the originally provided information.

---

<sup>25</sup> **Screening criteria**

1. Claims where clarification on legal scope is needed (e.g. claims referring to risk reduction or referring to children's development and health, or medicinal claims).
2. General well-being claims where the health relationship is not clear, e.g. "Compound X supplementation to sustain vitality while aging".
3. Claims which are too vague (claimed effect not specified/measurable), e.g. Compound X and "energy and vitality". Proposed wording: Compound X is "necessary to maintain energy and general vitality".
4. Foods which are not sufficiently characterised or conditions of use are not sufficiently specified.
5. Combination constituents that are not sufficiently defined.
6. Claims in languages other than English (to be returned for translation). If EFSA is asked to carry out the translations, EFSA will send translated claims back to Member States for validation of the translation.

## References

The references provided by Member States were either included in the Access database or were submitted in separate files. In addition, full-text copies of references were provided directly to EFSA by some stakeholders. The deadline for submission of full-text copies of references was at the end of 2008. In some instances, references provided to EFSA referred to papers which were submitted for publication. In the case of subsequent publication in the public domain, EFSA has endeavoured to include the correct citation in the list of references, and this inclusion may result in some references carrying a 2009 publication date.

A compilation of the references for all claims which have been prioritised for scientific evaluation by the European Commission is published on the EFSA website<sup>26</sup>.

Some other issues related to the references provided are covered in section 4.

## Overview of Article 13 claims

In total, EFSA has received 4,637 health claims, sent to EFSA in July 2008, November 2008, December 2008 and March 2011. Out of these, by 18 March 2011 EFSA has registered as withdrawn a total of 320 claims. In addition, on 20 October 2010 EFSA was asked by the European Commission to reprioritise the work of the NDA Panel and to put on hold 1,549 so called “botanical claims”. This leaves EFSA with 2,768 claims to be evaluated by June 2011 based on the information received. The NDA Panel evaluates the claims on the list by taking into account the clarifications EFSA has received from the European Commission via its correspondence of 9 November 2009, in relation to those claims in the consolidated list for which EFSA had asked for further information in January 2009, as well as the conditions of use and the literature provided in similar health claims clustered under a main health claim entry.

Taking into account the high number of claims evaluated, and in order to comply with requirements for transparency<sup>27</sup> and to keep the workload manageable, the NDA Panel has adopted claim opinions in series, with subsequent publication in the EFSA Journal. In this context, EFSA has been trying to be as efficient as possible in combining claims into series of opinions. EFSA envisages completing the evaluation of Article 13.1 claims by June 2011, except for the 1,549 so called “botanical claims”, which EFSA was asked to put on hold.

## EFSA’s contact point for further clarification on claims

Based on Regulation (EC) No 1924/2006, the list of claims was submitted to EFSA by Member States via the European Commission. Therefore, EFSA’s contact point for any issues related to the Article 13 list is the European Commission/Member States.

---

<sup>26</sup> <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>

<sup>27</sup> Regulation (EC) No 178/2002 requires EFSA to make public without delay the opinions of the Scientific Panels

## **GLOSSARY AND ABBREVIATIONS**

CHD	Coronary heart disease
FAQ	Frequently asked questions
LDL	Low-density lipoproteins
SFA	Saturated fatty acid
WHO	World Health Organization