

TECHNICAL REPORT OF EFSA

Outcome of Public Consultation on a draft Frequently Asked Questions document (FAQ) related to the EFSA assessment of health claims applications¹

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BACKGROUND

Regulation (EC) No 1924/2006² harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. In 2007 EFSA issued an opinion providing scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim under Article 14/13.5³. In the light of the experience gained with the evaluation of health claims applications, EFSA provided further guidance to applicants for the preparation and presentation of applications for Article 14 and 13.5 claims in the form of a document outlining answers to frequently asked questions (FAQ). The draft FAQ, which is intended to complement the NDA Opinion on guidance published in 2007, was published on the EFSA website in May 2009 for comments and formed the basis for discussion at a technical meeting with experts from industry/applicants for Article 14 and 13.5 health claims, which was held on 15th June, 2009. An updated version of the FAQ, which takes into account the questions/comments received and the discussions at the technical meeting, is published on the EFSA website.

COMMENTS RECEIVED

In addition to the comments made at the technical meeting, EFSA received 47 submissions with comments from interested parties, including applicants for health claims, non-governmental organisations, industry organisations and individuals. A summary of the comments received is given below. Comments which were not related to the Article 14 and 13.5 health claims, or comments related to policy or risk management aspects were considered to be outside the scope of the consultation and are not covered in this report.

¹ On request from EFSA, Question No EFSA-Q-2009-00826 finalised on 30 September 2009.

² European Parliament and Council (2006). 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.

³ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm

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MAIN ISSUES

The main issues raised in the comments received were the following:

1. *Substantiation of claims*

- How many studies are needed for claim substantiation; could one well designed study be sufficient to substantiate the claim?
- What is a suitable study design?
- Is there a need for strict repetition of studies?
- How does EFSA deal with observational studies and tradition of use?
- How important are human data?
- How does EFSA weigh the evidence?
- EFSA is applying a too high standard of proof and level of proof should be adjusted to foods.
- EFSA should take into consideration the fact that most of the knowledge in nutrition science is based on 'probable' or 'possible' evidence.
- Is there a possibility to rank/grade the evidence?
- EFSA is giving more attention to inconsistencies between data and studies than to consistencies of presented data and studies.
- EFSA is not giving due consideration to *in vitro* or *in vivo* mechanistic studies.
- There is a lack of clarity on the criteria used for substantiation of a claim.
- What does the "overall strength" of the pertinent studies mean?
- EFSA does not differentiate between generally available science and newly developed scientific evidence.
- Does EFSA consider a strong body of epidemiological evidence to be sufficient for making health claims on food categories and food?

2. *Pertinent studies for substantiation of a claim*

- What are the criteria needed to judge whether a study group is representative/can be extrapolated to the target population, e.g. data on infants below 6 months, studies in diseased population?
- There is a need for more transparency on inclusion/exclusion criteria for studies to be considered pertinent.
- EFSA is applying a too strict judgement on the relevance of endpoint measured.

3. *Totality of the available scientific data*

- EFSA's criteria for the totality of available data is not clear.
- EFSA does not take into account the totality of the evidence.

4. *Characterisation of food/constituent*

- Why is the food matrix important for the claim?
- Does a modification in manufacturing process require a new claim submission?
- What is an acceptable range of variation for foods?
- How to characterise a probiotic food product?
- How to characterise a complex food product (acceptable range of variation in food)?
- What is the level of evidence needed for bioavailability in a matrix?
- The need to provide a rationale for the role of each constituent in the claimed effect for specific formulation or combinations is considered as too restrictive
- How should food categories, such as dairy, be characterised?
- Does EFSA has a remit to state that 'characterisation should be also sufficient to allow control authorities to verify that the food/constituent which bears the claim is the same one that was the subject of a community authorisation?

5. *Beneficial nature of the claimed effect*

- Would EFSA consider “cosmetic”/beauty claims as beneficial to human health?
- In nutritional intervention studies EFSA should review all endpoints and consider whether they are relevant.
- Remark that evidence from observational evidence does not allow a claimed effect to be testable/measurable.
- How does EFSA take into account causality for a benefit where multiple targets are involved, e.g. natural defence system?
- Statement in draft FAQ that the claimed effect has to be testable and measurable by general accepted methods was questioned.
- How does EFSA decide that the claimed effect is beneficial to health?

6. *Risk factor for the development of a human disease*

- What are the options if no risk factor can be identified?
- Is EFSA only considering validated risk factors?
- Can risk factor identified in non healthy populations be used for claims targeted to healthy populations?
- Under what circumstances is it possible to treat a non-validated intermediate factor as a risk factor?
- How does EFSA draw the line between disease, symptoms and risk factor?
- Could unhealthy diets be considered as a risk factor?
- Is there a possibility to establish a ‘living’ list of acceptable risk factors?

7. *Wording of claims*

- On what basis does EFSA propose a wording?
- Does EFSA propose alternative wording which would be scientifically substantiated?
- Why can the applicant not propose several wordings for the same claim?
- What is the margin for the Commission/MS to change the scientific wording proposed by EFSA?

8. *Communication with applicants*

- Remark that transparent procedure for requiring additional information is lacking.
- Questions on the possibility to have pre-application advice prior to initiating clinical studies
- Questions on the possibility to have consultation with EFSA during the evaluation, e.g. at mid stage and/or at early stage
- How can an applicant stop a registered request, or an ongoing evaluation?
- Request to have more timely and efficient communication between EFSA and the applicant
- Will EFSA issue a guidance document for the scientific substantiation of claim adjusted to foods?

9. *Proprietary data*

- Who checks that the data are really proprietary to an organisation?

10. *Confidential data*

- How can EFSA ensure that the data and the claim are going to be protected?

11. *Others*

- Some specific comments on the organisation and structure of the EFSA guidance document.

- EFSA should improve the transparency of opinions.
- Which definition of a balanced diet is used by EFSA?
- Are supplements part of a balanced diet?

EFSA CONSIDERATION OF COMMENTS RECEIVED

EFSA has reviewed all comments carefully and has updated the draft FAQ as appropriate. It should be noted that the FAQ is intended to address issues that apply to claims in general and questions/comments of a detailed technical nature cannot be addressed in such a document. Detailed technical issues related to specific applications for claims are more appropriately addressed through communication between EFSA and the applicant when an application is made. The FAQ presumes familiarity with generally accepted science in the relevant research areas, taking into account the accepted norms in the respective research fields.

SUBSTANTIATION OF CLAIMS

The updated FAQ provides further clarification on how the NDA Panel makes a scientific judgement on the extent to which a claim is substantiated. In this regard the following points are made:

- 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. However, the NDA Panel considers what the accepted norms are in the relevant research fields and EFSA consults experts from various disciplines, as appropriate.
- Human data are central for the substantiation of the claim. The hierarchy of different types of data and of study designs, reflecting the relative strength of evidence which may be obtained from different types of studies is outlined in the EFSA scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim under Article 14⁴.
- EFSA is committed to providing a clear explanation in the opinions on how the NDA Panel weighs the evidence in making a scientific judgement on the extent to which a claim is substantiated by 'generally accepted scientific evidence'. A grade is not assigned to the evidence.
- A rationale/evidence on biological plausibility of the claimed effect should be provided to support the substantiation of the claim.

TOTALITY OF THE AVAILABLE SCIENTIFIC DATA

EFSA considers that the totality of data is sufficiently described in the FAQ. EFSA is committed to providing a clear explanation in opinions on the extent to which scientific conclusions can be drawn from individual studies.

PERTINENT STUDIES FOR SUBSTANTIATION

EFSA considers that the criteria applied by the NDA Panel when considering whether studies are pertinent for substantiation of the claim are sufficiently covered in the FAQ. The panel is committed to explain clearly in opinions the basis for its judgement on which studies are pertinent for substantiation of the claim.

⁴ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm

CHARACTERISATION OF FOOD/ CONSTITUENT

The revised FAQ provides further clarification on the criteria applied by the NDA Panel when considering whether a food/constituent is sufficiently defined and characterised. In this regard the following points are emphasised:

- Characterisation should be also sufficient to allow appropriate conditions of use to be defined.
- Although not required for substantiation of a claim, it is in the interests of the applicant that characterisation should also be sufficient to allow control authorities to verify that the food/constituent which bears the claim is the same one that was the subject of a community authorisation.
- The information provided should include those characteristics considered pertinent to the claimed effect, i.e. those that may influence the specific nutritional or physiological effect that is the basis of the claim.
- For specific product formulations or fixed combinations of constituents, a rationale/evidence should be provided for the role of those constituents proposed to have a role in the claimed effect.
- For a food category, information should be provided on variability between individual foods for those characteristics considered pertinent to the claimed effect.
- Although not required for substantiation of a claim, it is in the interests of the applicant that strains are deposited in an internationally recognized culture collection (with access number) for control purposes.

BENEFICIAL NATURE OF THE CLAIMED EFFECT

EFSA considers that the beneficial nature of the claimed effect is sufficiently described in the FAQ.

RISK FACTOR FOR THE DEVELOPMENT OF A HUMAN DISEASE

The revised FAQ provides further clarification on the views of the NDA Panel on how a risk factor may be considered to be beneficial in the context of a reduction of disease risk claim. In this regard the following points are emphasised:

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

WORDING OF CLAIMS

EFSA considers that the wording of claims is sufficiently described in the FAQ. In this regard the following points are emphasised:

- EFSA considers whether the proposed wording reflects the scientific evidence and complies with the criteria laid down in the Regulation.

- The panel does not comment on the wording with respect to consumer understanding. Applicants should address issues related to consumer understanding of the wording of a claim to the Commission following publication of the EFSA opinion.
- EFSA liaises with the Commission as appropriate on scientific aspects of the wording of the claim.

COMMUNICATION WITH APPLICANTS

EFSA is committed to develop further its procedures for communication with applicants during the evaluation stage. Details of procedures for direct and indirect communication between EFSA and applicants are provided in the revised FAQ.

PROPRIETARY/CONFIDENTIAL DATA

EFSA considers that the treatment of proprietary data and confidential data are sufficiently covered in the FAQ.

LIST OF ORGANISATIONS, WHICH HAVE PROVIDED WRITTEN COMMENTS

- AESPG, *Association of the European Self-Medication Industry*
- Alliance 7
- Analyze & Realize
- ANIA, *French National Federation for Food*
- Barilla
- Cantox
- CEFIC, *European Chemical Industry Council*
- Christian Hansen
- CIAA, *Confederation of the Food and Drink Industries of the EU*
- Coldiretti
- COPA-COGECA, *European Farmers & Agri-Cooperatives*
- CPW, *Cereal Partners Worldwide*
- CRN, *Council for Responsible Nutrition (UK)*
- Danone
- DSM, *Nutritional Products Europe*
- EBF, *European Botanical Forum*
- EDA, *European Dairy Association*
- EFFCA, *European Food and Feed Cultures Association and LABIP Lactic Acid Bacteria Industrial Platform*
- EHPM, *European Federation of Associations of Health Product Manufacturers*
- ERNA, *European Responsible Nutrition Alliance*
- FAIA, *Food Additives and Ingredients Association*
- IDACE, *Association of the Food Industries for Particular Nutritional Uses of the European Union*

- IDF, *International Dairy Federation*
- ILSI Europe, *International Life Sciences Institute*
- Ingredia Nutritional
- ISAPP, *International Scientific Association for Probiotics and Prebiotics*
- Kellogg's
- Kraft Foods
- Lactalis Group
- Lallemand
- LR BEVA Nutrition
- Mead Johnson Europe
- Merck Selbstmedikation
- Nestlé Research Center
- Nino Binns
- NMB Consulting
- Oy Foodfiles
- PAGB, *The Proprietary Association of Great Britain*
- PIE, *Platform for Ingredients in Europe*
- Procter & Gamble
- Puratos
- Schwabe
- Tate & Lyle
- TNO Quality of Life, *The Netherlands Organisation*
- UNESDA, *Union of European Beverages Associations*
- V.A.B. Nutrition, *Véronique Azaïs Braesco - Nutrition*
- YLFA-International, *Yogurt and Live Fermented Milks Association*

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