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Frequently Asked Questions (FAQ) related to the EFSA assessment of health claims applications

Panel on Dietetic Products, Nutrition and Allergies

FOR COMMENTS

Deadline: 8 June 2009

INTRODUCTION

These frequently asked questions (FAQ) discuss key issues that are addressed by EFSA in assessment of the scientific evidence submitted for substantiation of health claims in order to assist applicants in preparing applications for claims under Articles 13.5 and 14 of Regulation (EC) No 1924/2006 on nutrition and health claims 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. This EFSA opinion formed the basis for a Commission Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006, which applies also to claims submitted under Article 13.5 of the Health Claims Regulation.

Health claims applications are assessed on a case by case basis in the order in which they are received by EFSA. It is intended that this FAQ will complement the EFSA guidance based on the experience gained to date in the assessment of health claims by the NDA Panel. The FAQ will be updated as appropriate as additional issues are addressed.

The following topics are addressed in this FAQ document:

1. **Overview of main issues addressed by the NDA Panel**
2. **To what extent should a food/constituent be characterised?**
3. **How should the claimed effect be shown to be beneficial?**
4. **What is a risk factor for the development of a human disease?**
5. **What are pertinent studies for substantiation of a claim?**
6. **What is the totality of the available scientific data?**
7. **How does the NDA Panel decide whether a claim is substantiated?**
8. **When does EFSA request supplementary information from the applicant?**
9. **On what basis does EFSA propose wordings of claims?**
10. **How does EFSA treat proprietary data?**
11. **How does EFSA treat confidential data?**

1. Overview of main issues addressed by the NDA Panel

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

- the food/constituent is defined and characterised
- the claimed effect is defined and is a beneficial nutritional or physiological effect ("beneficial to human health")
- 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)

and, if a cause effect relationship is considered to be established, whether:

- the quantity of food/pattern of consumption required to obtain the claimed effect can 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 of use are appropriate
- substantiation was 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.

2. 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) and these are covered under the term "food/constituent".

The specific food/constituent should be sufficiently defined and characterised to establish that the studies provided for substantiation of the claim were performed with the food/constituent in respect of which the claim is made. 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.

Thus, it may be necessary to distinguish between a specific product formulation, a specific constituent or combination of constituents. 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.

If the claim is for an individual constituent, then substantiation of the claim should be based on studies performed with this constituent. However, if the claim is for a specific product formulation or fixed combination of constituents, then studies should be presented on this specific formulation or combination. In the latter case a rationale/evidence should be provided for the role of each constituent in the claimed effect.

For plant products information provided should also include the scientific name, the part used and the preparation procedure.

For microorganisms (e.g. bacteria, yeast), as well as species identification there should be sufficient characterisation (genetic typing) at strain level by internationally accepted molecular methods and strains should be named according to the International Code of Nomenclature. It is also desirable that strains are deposited in an internationally recognized culture collection (with access number) for control purposes.

For manufacturing processes, information should be provided to show consistency in the final product for those characteristics considered pertinent to the claimed effect.

3. How should the claimed effect be shown to be beneficial to human health?

According to Regulation EC (No) 1924/2006, the use of nutrition and health claims shall only be permitted if the substance in respect of which the claim is made has been shown to have a beneficial nutritional or physiological effect.

The claimed effect should be sufficiently defined to establish that the studies provided 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. 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 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).

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 as described in the application.

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 of a risk factor for the development of a human disease.

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

For the purpose of classifying disease, the World Health Organisations (WHO) International Statistical Classification of Diseases and Related Health http://www.who.int/classifications/icd/en/ should be used.

A risk factor is a factor associated with the risk of a disease that may serve as a predictor of development of that disease.

For reduction of a risk factor to be considered beneficial in the context of a reduction of disease risk claim depends on the extent to which it is established that:

- The risk factor is an independent predictor of disease risk (this may be established from intervention and/or observational studies)

- The relationship of the risk factor to the development of the disease is biologically plausible

For some risk factors, there is strong evidence that they meet both criteria. For example, elevated serum LDL cholesterol is a risk factor for 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 the level of the risk factor and the incidence of CHD, including evidence that a reduction in the risk factor (by dietary modification and drugs) generally reduces the risk of development of CHD. Thus, reduction in serum LDL cholesterol 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 risk factors, the evidence is not as strong. For example, elevated dental plaque level is a risk factor for 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 dental plaque and the incidence of dental caries, it is not generally established that lowering plaque level can lower risk for development of the disease. Nevertheless, if there is evidence that lowering 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 well established risk factors (e.g. elevated LDL cholesterol for CHD), the extent to which reduction of a risk factor is beneficial in the context of a reduction of disease risk claim needs to be considered on a case by case basis for each application.

5. What are pertinent studies for substantiation of a claim?

Applicants should provide evidence that shows the extent to which a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect that is applicable to the target group under the proposed conditions of use for the claim. Thus, in presenting studies that are pertinent (i.e. from which scientific conclusions can be drawn) for the substantiation of the claim, applicants should consider the following questions:

- Have the studies been carried out with the food/constituent for which the claim is made?
- Have the human studies used an appropriate outcome measure(s) of the claimed effect?
- How do the conditions under which the human studies were performed relate to the conditions of use (e.g. food/constituent quantity) proposed for the claim?
- Have the human studies been carried out in a study group representative of the population group for which the claim is intended? Can the results obtained from the studied population be extrapolated to the target population?
- For studies in animals/in vitro, to what extent can evidence derived from such

models support the claimed effect in humans?

As human data are central for the substantiation of a claim, particular attention should be given to ensuring that the human studies presented 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 that supports the relationship as well as equivocal evidence and evidence of no effect and/or opposing effects.

6. What is the totality of the available scientific data?

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

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 it is considered pertinent to the claimed effect.

7. How does the NDA Panel decide whether a claim is substantiated?

In assessing each specific food/health relationship that 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 consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use). All of the evidence from the pertinent studies 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 the conditions of use proposed for the claimed effect. While studies in animals or *in vitro* may provide supportive evidence, human data are central for the substantiation of the claim.

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.

8. When does EFSA request supplementary information from the applicant?

Requests from EFSA to applicants for supplementary information are made based on a case by case judgement. Such requests generally relate to clarification of aspects of data presented in the application. If the applicant fails to provide the additional data within a time limit as specified by EFSA, EFSA will issue an opinion based on the data provided.

9. On what basis does EFSA propose wordings of claims?

For claims for which a cause and effect relationship is considered to be established, EFSA 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, EFSA proposes an appropriate wording. For reduction of disease risk claims, the wording should refer to the specific risk factor for disease.

It should be noted that the wording adopted by the Commission during authorisation may need to take into account aspects other than agreement with the scientific evidence, e.g. the understanding of consumers.

10. How does EFSA treat proprietary data?

Where evidence for substantiation includes a request for the protection of proprietary data, EFSA only considers whether the claim could not have been substantiated without the proprietary data claimed by the applicant. In such cases applicants should ensure that all proprietary and non-proprietary data pertinent to the claimed effect are included in the application.

The protection of proprietary data, as appropriate, falls within the responsibility of the European Commission.

11. How does EFSA treat 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, e.g. broad description of the study and main outcome.