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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 [1], and in particular Article 15(4) thereof,

Having consulted the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1924/2006 establishes rules for the use of claims in the labelling, presentation and advertising of foods.

(2) Applications for authorisation of health claims should adequately and sufficiently demonstrate that the health claim is based on and substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data and by weighing the evidence.

(3) As provided by Article 15(4) of Regulation (EC) No 1924/2006, it is necessary to establish implementing rules concerning health claims applications submitted in accordance with that Regulation, including rules for the preparation and presentation of applications.

(4) The implementing rules should ensure that the application dossier is compiled in a way which defines and classifies the scientific data needed with a view to assessment of the applications by the European Food Safety Authority.

(5) The implementing rules are intended primarily as a general guide, and, depending on the nature of the claim, the nature and extent of the studies necessary to evaluate its scientific merit may vary.

(6) Applications for health claims should take account of the requirements laid down in Regulation (EC) No 1924/2006, particularly the general principles and conditions set out in Articles 3 and 5 thereof. Separate applications should be made for individual health claims and characterise the type of claim.

(7) Particulars and documents to be provided in accordance with this Regulation should be without prejudice to any supplementary information that the European Food Safety Authority (the Authority) may request where appropriate, as laid down in Article 16(2) of Regulation (EC) No 1924/2006.

(8) At the request of the Commission, the Authority has issued an opinion on scientific and technical guidance on the preparation and the presentation of applications concerning health claims [2]. Applications should follow the Authority guidance in conjunction with the implementing rules to ensure the harmonised submission of applications to the Authority.

(9) In order to benefit from data protection, as laid down in Article 21 of Regulation (EC) No 1924/2006, requests for protection of proprietary data must be justified and all data kept in a separate part of the application.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes implementing rules for the following applications:

(a) applications for authorisation, submitted in accordance with Article 15 of Regulation (EC) No 1924/2006; and

[1] OJ L 404, 30.12.2006, p. 9, as corrected by OJ L 12, 18.1.2007, p. 3. Regulation as last amended by Regulation (EC) No 109/2008 (OJ L 39, 13.2.2008, p. 14).

[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592471.htm

(b) applications for the inclusion of a claim in the list provided for in Article 13(3) submitted in accordance with Article 18 of Regulation (EC) No 1924/2006.

Article 2

Scope of the application

Each application shall cover only one relationship between a nutrient or other substance, or food or category of food, and a single claimed effect.

Article 3

Specification of the type of health claim

The application shall specify which type of health claim is concerned among those listed in Articles 13 and 14 of Regulation (EC) No 1924/2006.

Article 4

Proprietary data

The indication of information which should be regarded as proprietary data and verifiable justification thereof, as referred to in Article 15(3)(d) of Regulation (EC) No 1924/2006, shall be included in a separate part of the application.

Article 5

Scientific studies

The studies and other material referred to Article 15(3)(c) and (e) of Regulation (EC) No 1924/2006:

(a) shall consist primarily of studies in humans and, in the case of claims referring to children's development and health, from studies in children;

(b) shall be presented according to a hierarchy of study designs, reflecting the relative strength of evidence which may be obtained from different types of studies.

Article 6

Conditions for use

In accordance with Article 15(3)(f) of Regulation (EC) No 1924/2006, and in addition to the proposal for the wording of the health claim, the conditions of use shall include:

(a) the target population for the intended health claim;

(b) the quantity of the nutrient or other substance, or food or category of food, and the pattern of consumption required to obtain the claimed beneficial effect;

(c) where appropriate, a statement addressed to persons who should avoid using the nutrient or other substance, or food or category of food, for which the health claim is made;

(d) a warning for the nutrient or other substance, or food or category of food, that is likely to present a health risk if consumed to excess;

(e) any other restrictions of use and directions for preparation and/or use.

Article 7

Technical rules

The application shall be prepared and presented in accordance with the technical rules as set out in the Annex.

Article 8

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 April 2008.

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

Technical rules for the preparation and presentation of the application for health claims

INTRODUCTION

1. This Annex applies to health claims related to the consumption of a food category, a food, or its constituents (including a nutrient or other substance, or a combination of nutrients/other substances), hereafter referred to as 'food'.

2. In cases where some of the data that are required as described in this Annex are omitted by the applicant, assuming that they do not apply to the application concerned, reasons shall be given for the absence of such data in the application.

3. The term 'application' hereafter means a stand-alone dossier containing the information and the scientific data submitted for authorisation of the health claim in question.

4. One application shall be prepared for each individual health claim; this means that only a relationship between a food and a single claimed effect can be the object of each application. However, multiple formulations of a food can be proposed by the applicant as candidates to bear the health claim in the same application, provided the scientific evidence is valid for all proposed formulations of a food bearing that same health claim.

5. The application shall indicate whether health claim concerned or a similar one has been scientifically evaluated, by a competent national authority of either a Member State or a third country. If so, a copy of the scientific evaluation shall be provided.

6. Pertinent scientific data are all human and non-human studies, published or unpublished, that are relevant for the substantiation of health claim applied for, by addressing the relationship between the food and the claimed effect, including data in favour and data not in favour of such relationship. Pertinent published human data shall be identified through a comprehensive review.

7. Journal abstracts and articles published in newspapers, magazines, newsletters or handouts that have not been peer-reviewed shall not be cited. Books or chapters of books for consumers or the general public shall not be cited.

GENERAL PRINCIPLES FOR THE SCIENTIFIC SUBSTANTIATION

1. The application shall contain all scientific data, published and unpublished, in favour and not in favour that are pertinent to the health claim, together with a comprehensive review of the data from human studies in order to demonstrate that the health claim is substantiated by the totality of the scientific data and by weighing the evidence. Data from studies in humans addressing the relationship between consumption of the food and the claimed effect is required for substantiation of a health claim.

2. The application shall contain a comprehensive review of the data from human studies addressing the specific relationship between the food and the claimed effect. This review, and the identification of data considered pertinent to the health claim, should be performed in a systematic and transparent manner in order to demonstrate that the application reflects adequately the balance of all the evidence available.

3. The substantiation of health claims shall take into account the totality of the available scientific data and, by weighing the evidence, shall demonstrate the extent to which:

   (a) the claimed effect of the food is beneficial for human health;

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as the strength, consistency, specificity, dose-response, and biological plausibility of the relationship);

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet;

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

FOOD CHARACTERISTICS

The following information shall be given with regard to the food constituent, the food or the food category for which the health claim is made.

1. For a food constituent:

(a) the source and specifications [1], such as physical and chemical properties, composition; and

(b) where applicable, the microbiological constituents of the food constituent.

2. For a food or category of food:

(a) the description of the food or food category, including characterisation of the food matrix and the overall composition including the nutrient content of the food;

(b) the source and specifications of the food or food category and, in particular, the content of the constituent(s) related to the health claim.

3. In all cases:

(a) where applicable, the variability from batch to batch;

(b) analytical methods applied;

(c) where applicable, a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, and of the results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life;

(d) where applicable, the relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body;

(e) if absorption is not necessary to produce the claimed effect, such as for plant sterols, fibres, lactic acid bacteria, the relevant data and rationale that the constituent reaches the target site;

(f) all available data on factors that could affect the absorption or utilisation in the body of the constituent for which the health claim is made.

[1] Where appropriate internationally recognised specifications may be cited.

ORGANISATION OF PERTINENT SCIENTIFIC DATA

1. Scientific data identified shall be organised in the following order: human data, followed by non-human data if appropriate.

2. Human data shall be classified according to a hierarchy of study design in the following order:

   (a) human intervention studies, randomised controlled studies, other randomised studies (non-controlled), controlled (non-randomised) studies, other intervention studies;

   (b) human observational studies, cohort studies, case-control studies, cross-sectional studies, other observational studies, such as case reports;

   (c) other human studies dealing with the mechanisms by which the food could be responsible for the claimed effect, including the studies on bioavailability.

3. Non-human data shall consist in:

   (a) animal data including studies investigating aspects related to absorption, distribution, metabolism, excretion of the food, mechanistic studies, and other studies;

   (b) *ex vivo* or *in vitro* data, based on either human or animal biological samples related to the mechanisms of action by which the food could be responsible for the claimed effect, and other non-human studies.

SUMMARY OF PERTINENT SCIENTIFIC DATA

In addition to the requirement of Article 15(3)(g) of Regulation (EC) No 1924/2006 for a summary of the application, applicants shall provide a summary of the pertinent scientific data, which shall contain the following information:

1. the summary of data from pertinent human studies, indicating to what extent the relationship between the food and the claimed effect is supported by the totality of human data;

2. the summary of data from pertinent non-human studies, indicating how, and to what extent, the pertinent non-human studies may help to support the relationship between the food and the claimed effect in humans;

3. the overall conclusions, by taking into account the totality of the data, including evidence in favour and not in favour and by weighing the evidence. The overall conclusions should clearly define to what extent:

   (a) the claimed effect of the food is beneficial for human health;

   (b) a cause and effect relationship is established between the consumption of the food and the claimed effect in humans (such as the strength, consistency, specificity, dose-response, and biological plausibility of the relationship);

   (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be consumed as part of a balanced diet;

   (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

STRUCTURE OF THE APPLICATION

Applications shall be structured as follows. If justification is provided by the applicant certain parts can be omitted.

Part 1 — Administrative and Technical Data

1.1. Table of contents

1.2. Application form

1.3. General information

1.4. Health claim particulars

1.5. Summary of the application

1.6. References

Part 2 — Food/Constituent Characteristics

2.1. Food constituent

2.2. Food or category of food

2.3. References

Part 3 — Overall Summary of Pertinent Scientific Data

3.1. Tabulated summary of all pertinent studies identified

3.2. Tabulated summary of data from pertinent human studies

3.3. Written summary of data from pertinent human studies

3.4. Written summary of data from pertinent non-human studies

3.5. Overall conclusions

Part 4 — Body of Pertinent Scientific Data Identified

4.1. Identification of pertinent scientific data

4.2. Pertinent data identified

Part 5 — Annexes to the Application

5.1. Glossary/abbreviations

5.2. Copies/reprints of pertinent published data

5.3. Full study reports of pertinent unpublished data

5.4. Other