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)

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

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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

(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.

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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.

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[F1 Article 7a

Verification of the validity of applications by the Member States

1 In accordance with Article 15(2)(a) and Article 18(3) of Regulation (EC) No 1924/2006, Member States shall verify the validity of applications before making them available to the Authority.

2 For the purposes of paragraph 1, the national competent authority shall verify that applications submitted under Article 15 or 18 of Regulation (EC) No 1924/2006 include the data as referred to in Article 15(3) of that Regulation.

3 The national competent authority shall also verify that:

(i) for applications submitted under Article 15 of Regulation (EC) No 1924/2006 the health claim is a health claim concerning the reduction of disease risk claims or referring to children's development and health;

(ii) for applications submitted under Article 18 of Regulation (EC) No 1924/2006 the health claim is any health claim as referred to in Article 13(5) of that Regulation with the exception of health claims referring to children's development and health.**]**

Textual Amendments

F1 Inserted by Commission Regulation (EC) No 1169/2009 of 30 November 2009 amending 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 of the European Parliament and of the Council (Text with EEA relevance).

[F1 Article 7b

Withdrawal of applications

1 An application submitted under Article 15 or 18 of Regulation (EC) No 1924/2006 may be withdrawn by the applicant up to the moment the Authority adopts its opinion pursuant to Article 16(1) or Article 18(3) of Regulation (EC) No 1924/2006.

2 A request for withdrawal of an application must be submitted to the national competent authority of a Member State, to which the application was submitted in accordance with Article 15(2) or Article 18(2) of Regulation (EC) No 1924/2006.

3 The national competent authority shall, without delay, inform the Authority, the Commission and the other Member States of the withdrawal. Only the withdrawal of the application under the conditions mentioned in paragraph 1 and in this paragraph puts an end to the procedure.**]**

Textual Amendments

F1 Inserted by Commission Regulation (EC) No 1169/2009 of 30 November 2009 amending Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims

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as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (Text with EEA relevance).

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.