Regulation (EC) No 107/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission

REGULATION (EC) No 107/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

Whereas:

(1) Regulation (EC) No 1924/2006 of the European Parliament and of the Council[(3)] provides that the regulatory procedure established by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(4)] is to be applied for the adoption of implementing measures concerning that Regulation.

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, inter alia, by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(3) The Commission should be empowered to adopt Community measures concerning the labelling, presentation and advertising of certain foods; to establish derogations from certain provisions of Regulation (EC) No 1924/2006; to establish and update nutrient profiles and the conditions and exemptions under which they can be used; to establish and/or amend lists of nutrition and health claims; and to amend the list of foods in respect of which the making of claims is restricted or prohibited. Since those measures are of general scope and are designed to amend non-essential elements of that Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(4) When data protection provisions apply, the authorisation restricted to use by an individual operator should not prevent other applicants from applying for authorisation to use the same claim.

(5) Regulation (EC) No 1924/2006 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1924/2006 is hereby amended as follows:

1. Article 1 shall be amended as follows:

   (a) in paragraph 2, the second subparagraph shall be replaced by the following:

   > In the case of non-prepackaged foodstuffs (including fresh products such as fruit, vegetables or bread) put up for sale to the final consumer or to mass caterers and foodstuffs packed at the point of sale at the request of the purchaser or pre-packaged with a view to immediate sale, Article 7 and Article 10(2)(a) and (b) shall not apply. National provisions may apply until the eventual adoption of Community measures designed to amend non-essential elements of this Regulation, inter alia, by supplementing it, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).;

   (b) paragraph 4 shall be replaced by the following:

   > 4. For generic descriptors (denominations) which have traditionally been used to indicate a particularity of a class of foods or beverages which could imply an effect on human health, a derogation from paragraph 3 designed to amend non-essential elements of this Regulation by supplementing it may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), on application by the food business operators concerned. The application shall be sent to the national competent authority of a Member State which will forward it to the Commission without delay. The Commission shall adopt and make public the rules for food business operators according to which such applications shall be made, so as to ensure that the application is dealt with transparently and within a reasonable time.;

2. in Article 3, second paragraph, point (d) shall be replaced by the following:

   (d) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. Derogations in the case of nutrients for which sufficient quantities cannot be provided by a balanced and varied diet, including the conditions for their application, and designed to amend non-essential elements of this Regulation by supplementing it may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), taking into account the special conditions present in Member States;

3. Article 4 shall be amended as follows:

   (a) paragraph 1 shall be amended as follows:

(i) the first subparagraph shall be replaced by the following:

1. By 19 January 2009, the Commission shall establish specific nutrient profiles, including exemptions, which food or certain categories of food must comply with in order to bear nutrition or health claims and the conditions for the use of nutrition or health claims for foods or categories of foods with respect to the nutrient profiles. Such measures, designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).;

(ii) the sixth subparagraph shall be replaced by the following:

Nutrient profiles and their conditions of use designed to amend non-essential elements of this Regulation by supplementing it shall be updated to take into account relevant scientific developments in accordance with the regulatory procedure with scrutiny referred to in Article 25(3) and after consultation of interested parties, in particular food business operators and consumer groups.;

(b) paragraph 5 shall be replaced by the following:

5. Measures determining the foods or categories of foods other than those referred to in paragraph 3 for which nutrition or health claims are to be restricted or prohibited and designed to amend non-essential elements of this Regulation may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3) and in the light of scientific evidence.;

4. Article 8(2) shall be replaced by the following:

2. Amendments to the Annex shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3) and, where appropriate, after consulting the Authority. Where appropriate, the Commission shall involve interested parties, in particular food business operators and consumer groups, in order to evaluate the perception and understanding of the claims in question.;

5. Article 13 shall be amended as follows:

(a) paragraph 3 shall be replaced by the following:

3. After consulting the Authority, the Commission shall adopt, in accordance with the regulatory procedure with scrutiny referred to in Article 25(3), a Community list, designed to amend non-essential elements of this Regulation by supplementing it, of permitted claims as referred to in paragraph 1 and all necessary conditions for the use of these claims by 31 January 2010 at the latest.;

(b) paragraph 4 shall be replaced by the following:

4. Any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence and designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in

Article 25(3), after consulting the Authority, on the Commission's own initiative or following a request by a Member State.;

6. Article 17(3) shall be replaced by the following:

3. A final decision on the application, designed to amend non essential elements of this Regulation by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

However, where at the applicant's request for the protection of proprietary data, the Commission proposes to restrict the use of the claim in favour of the applicant:

a a decision on the authorisation of the claim shall be taken in accordance with the regulatory procedure referred to in Article 25(2). In such case, the authorisation, if granted, shall expire after five years;

b before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the Commission shall submit a draft of measures designed to amend non-essential elements of this Regulation by supplementing it for authorisation of the claim without restriction for use which shall be decided on in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).;

7. in Article 18(4), the second subparagraph shall be replaced by the following:

5. Where the Authority issues an opinion that does not support the inclusion of the claim in the list referred to in paragraph 4, a decision on the application designed to amend non-essential elements of this Regulation by supplementing it shall be taken in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).

However, where at the applicant's request for the protection of proprietary data the Commission proposes to restrict the use of the claim in favour of the applicant:

a a decision on the authorisation of the claim shall be taken in accordance with the regulatory procedure referred to in Article 25(2). In such case, the authorisation, if granted, shall expire after five years;

b before the expiry of the five-year period, if the claim still meets the conditions laid down in this Regulation, the Commission shall submit a draft of measures designed to amend non-essential elements of this Regulation by supplementing it for authorisation of the claim without restriction of use which shall be decided on in accordance with the regulatory procedure with scrutiny referred to in Article 25(3).;

8. in Article 20(2), second subparagraph, points 2 and 3 shall be replaced by the following:

2. the fact that the Commission authorised the health claim on the basis of proprietary data and restricted use;

3. in the cases referred to in Article 17(3), second subparagraph, and Article 18(5), second subparagraph, the fact that the health claim is authorised for a limited duration.;

9. Article 25 shall be replaced by the following: