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

[X1CHAPTER IV

HEALTH CLAIMS

Article 10

Specific conditions

1 Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.

2 Health claims shall only be permitted if the following information is included in the labelling, or if no such labelling exists, in the presentation and advertising:

a a statement indicating the importance of a varied and balanced diet and a healthy lifestyle;

b the quantity of the food and pattern of consumption required to obtain the claimed beneficial effect;

c where appropriate, a statement addressed to persons who should avoid using the food; and

d an appropriate warning for products that are likely to present a health risk if consumed to excess.

3 Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

4 Where appropriate, guidelines on the implementation of this Article shall be adopted in accordance with the procedure referred to in Article 25(2) and, if necessary, in consultation with interested parties, in particular food business operators and consumer groups.

Article 11

National associations of medical, nutrition or dietetic professionals and health-related charities

In the absence of specific Community rules concerning recommendations of or endorsements by national associations of medical, nutrition or dietetic professionals and health-related charities, relevant national rules may apply in compliance with the provisions of the Treaty.

Article 12

Restrictions on the use of certain health claims

The following health claims shall not be allowed:

(a) claims which suggest that health could be affected by not consuming the food;

(b) claims which make reference to the rate or amount of weight loss;

(c) claims which make reference to recommendations of individual doctors or health professionals and other associations not referred to in Article 11.

Article 13

Health claims other than those referring to the reduction of disease risk and to children's development and health

1 Health claims describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body; or

(b) psychological and behavioural functions; or

(c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

2 Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.

[[F1]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.**]**

[[F1]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.**]**

5 Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall be adopted following the procedure laid down in Article 18, except claims referring to children's development and health, which shall be authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19.

Textual Amendments

F1 Substituted by 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.

Article 14

Reduction of disease risk claims and claims referring to children's development and health

[[F2]1 Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, the following claims may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims:

a reduction of disease risk claims;

b claims referring to children's development and health.**]**

2 In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Textual Amendments

F2 Substituted by Regulation (EC) No 109/2008 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.

Article 15

Application for authorisation

1 When reference is made to this Article, an application for authorisation shall be submitted in accordance with the following paragraphs.

2 The application shall be sent to the national competent authority of a Member State.

a The national competent authority shall:

(i) acknowledge receipt of an application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application;

(ii) inform without delay the Authority; and

(iii) make the application and any supplementary information supplied by the applicant available to the Authority;

b The Authority shall:

(i) inform without delay the other Member States and the Commission of the application and shall make the application and any supplementary information supplied by the applicant available to them;

(ii) make the summary of the application referred to in paragraph 3(g) available to the public.

3 The application shall include the following:

a the name and address of the applicant;

b the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;

c a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;

d where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

e a copy of other scientific studies which are relevant to that health claim;

f a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use;

g a summary of the application.

4 The Commission, having first consulted the Authority, shall establish in accordance with the procedure referred to in Article 25(2) implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application.

5 The Commission, in close cooperation with the Authority, shall make available appropriate technical guidance and tools to assist food business operators, in particular SMEs, in the preparation and presentation of the application for scientific assessment.

Article 16

Opinion of the Authority

1 In giving its opinion, the Authority shall respect a time limit of five months from the date of receipt of a valid application. Whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2, such time limit shall be extended by up to two months following the date of receipt of the requested information submitted by the applicant.

2 The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit.

3 In order to prepare its opinion, the Authority shall verify:

a that the health claim is substantiated by scientific evidence;

b that the wording of the health claim complies with the criteria laid down in this Regulation.

4 In the event of an opinion in favour of authorising the health claim, the opinion shall include the following particulars:

a the name and address of the applicant;

b the nutrient or other substance, or the food or the category of food, in respect of which a claim is to be made and its particular characteristics;

c a proposal for the wording of the health claim, including, as the case may be, the specific conditions of use;

d where applicable, conditions or restrictions of use of the food and/or an additional statement or warning that should accompany the health claim on the label and in advertising.

5 The Authority shall forward its opinion to the Commission, the Member States and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based.

6 The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The applicant or members of the public may make comments to the Commission within 30 days from such publication.

Article 17

Community authorisation

1 Within two months after receiving the opinion of the Authority, the Commission shall submit to the Committee referred to in Article 23(2) a draft decision on the lists of permitted health claims, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. Where the draft decision is not in accordance with the opinion of the Authority, the Commission shall provide an explanation for the differences.

2 Any draft decision to amend the lists of permitted health claims shall include the particulars referred to in Article 16(4).

[[F1]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).**]**

4 The Commission shall without delay inform the applicant of the decision taken and publish details of the decision in the *Official Journal of the European Union*.

5 Health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator, if they are not restricted for use in accordance with the provisions of Article 21.

6 The granting of authorisation shall not lessen the general civil and criminal liability of any food business operator in respect of the food concerned.

Textual Amendments

F1 Substituted by 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.

Article 18

Claims referred to in Article 13(5)

1 A food business operator intending to use a health claim not included in the list provided for in Article 13(3) may apply for the inclusion of the claim in that list.

2 The application for this inclusion shall be submitted to the national competent authority of a Member State which shall acknowledge receipt of the application in writing within 14 days of its receipt. The acknowledgement shall state the date of receipt of the application. The application shall include the data provided for in Article 15(3) and the reasons for the request.

3 The valid application, in line with the guidance referred to in Article 15(5), and any information supplied by the applicant shall be sent without delay to the Authority for a scientific assessment as well as to the Commission and the Member States for information. The Authority shall issue its opinion within a time limit of five months from the date of receipt of the request. Such time limit may be extended by up to one month if the Authority considers it necessary to seek supplementary information from the applicant. In such a case the applicant shall submit the requested information within 15 days from the date of receipt of the Authority's request.

The procedure laid down in Article 16(3)(a) and (b), (5) and (6) shall apply mutatis mutandis.

4 Where the Authority, following scientific assessment, issues an opinion in favour of the inclusion of the claim in the list provided for in Article 13(3), the Commission shall take a decision on the application, taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration, after having consulted the Member States and within two months of receiving the opinion of the Authority.

[[F3]. . . . .**]**

[[F4]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).**]**

Textual Amendments

F3 Deleted by 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.

F4 Inserted by 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.

Article 19

Modification, suspension and revocation of authorisations

1 The applicant/user of a claim included in one of the lists provided for in Articles 13 and 14 may apply for a modification of the relevant list. The procedures laid down in Articles 15 to 18 shall apply mutatis mutandis.

2 On its own initiative or following a request from a Member State or from the Commission, the Authority shall issue an opinion on whether a health claim included in the lists provided for in Articles 13 and 14 still meets the conditions laid down in this Regulation.

It shall forthwith transmit its opinion to the Commission, the Member States and, where relevant, to the original applicant of the claim in question. The Authority, in accordance with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public.

The applicant/user or a member of the public may make comments to the Commission within 30 days of such publication.

The Commission shall examine the opinion of the Authority and any comments received as soon as possible. If appropriate, the authorisation shall be modified, suspended or revoked in accordance with the procedures laid down in Articles 17 and 18.**]**

Editorial Information

X1 Substituted by Corrigendum 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 (Official Journal of the European Union L 404 of 30 December 2006).

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Regulation (EC) No 1924/2006 of the european parliament and of the council, CHAPTER IV.