EUROPEAN COMMISSION

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COMMISSION REGULATION (EU) No …/..

of XXX

establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 13(3) thereof,

Whereas:

(1) Pursuant to Article 10(1) of Regulation (EC) No 1924/2006, health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.

(2) Article 13(2) of Regulation (EC) No 1924/2006 provides that Member States shall submit national lists of health claims made on foods, as referred to in Article 13(1) of that Regulation to the Commission, by 31 January 2008 at the latest. The national lists of claims must be accompanied by the conditions applying to them and by references to the relevant scientific justification.

(3) Article 13(3) of Regulation (EC) No 1924/2006 provides that, after consulting the European Food Safety Authority (hereinafter referred to as 'the Authority'), the Commission shall adopt a list of permitted health claims made on foods, as referred to in Article 13(1) of that Regulation, and all necessary conditions for the use of those claims by 31 January 2010 at the latest.

(4) On 31 January 2008 the Commission received lists with more than 44.000 health claims from the Member States. An examination of the national lists showed that due to many duplications and following discussions with Member States, it was necessary to compile the national lists into a consolidated list of the claims for which the Authority should give scientific advice, hereinafter referred to as the 'consolidated list'[2].

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[1] OJ L 404, 30.12.2006, p. 9.

[2] http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaclaims13.zip

(5) On 24 July 2008, the Commission formally transmitted to the Authority the request for a scientific opinion pursuant to Article 13(3) of Regulation (EC) No 1924/2006, together with terms of reference and a first part of the consolidated list. Subsequent parts of the consolidated list were transmitted in November and December 2008. The consolidated list was finalised by the Commission by an addendum, which was forwarded to the Authority on 12 March 2010. Some claims in the consolidated list were subsequently withdrawn by Member States before their evaluation by the Authority. The scientific evaluation by the Authority concluded in the publication of its opinions between October 2009 and July 2011[3].

(6) In its evaluation the Authority found that some submissions covered different claimed effects or brought together the same claimed effect. Therefore, a health claim considered in this Regulation may represent one or more of the entries on the consolidated list.

(7) For a number of health claims the Authority concluded that, on the basis of the data submitted, a cause and effect relationship has been established between a food category, a food or one of its constituents and the claimed effect. Health claims corresponding to those conclusions and complying with the requirements of Regulation (EC) No 1924/2006 should be authorised under Article 13(3) of Regulation (EC) No 1924/2006, and included in a list of permitted claims.

(8) Article 13(3) of Regulation (EC) No 1924/2006 provides that permitted health claims must be accompanied with all necessary conditions (including restrictions) for their use. Accordingly, the list of permitted claims should include the wording of the claims and specific conditions of use of the claims, and where applicable, conditions or restrictions of use and/or an additional statement or warning, in accordance with the rules laid down in Regulation (EC) No 1924/2006 and in line with the opinions of the Authority.

(9) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear, reliable and useful to the consumer. In that respect, the wording and presentation of such claims have to be taken into account. Where the wording of claims has the same meaning for consumers as that of a permitted health claim, because it demonstrates the same relationship that exists between a food category, a food or one of its constituents and health, the claims should be subject to the same conditions of use indicated for the permitted health claims.

(10) The Commission has identified a number of claims submitted for evaluation, referring to effects of plant or herbal substances, commonly known as 'botanical' substances, for which the Authority has yet to complete a scientific evaluation. In addition, there are a number of health claims for which either a further evaluation is required before the Commission is able to consider their inclusion or otherwise in the list of permitted claims, or which have been evaluated, but due to other legitimate factors consideration cannot be completed by the Commission at this time.

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[3] http://www.efsa.europa.eu/en/topics/topic/article13.htm

(11) Claims whose evaluation by the Authority or whose consideration by the Commission has not yet been completed will be published on the website of the Commission[4] and may continue to be used pursuant to Articles 28(5) and (6) of Regulation (EC) No 1924/2006.

(12) Pursuant to Articles 6(1) and 13(1) of Regulation (EC) No 1924/2006 health claims need to be based on generally accepted scientific evidence. Accordingly, health claims that did not receive a favourable assessment on their scientific substantiation by the Authority, as it was not concluded that a cause and effect relationship had been established between a food category, a food or one of its constituents and the claimed effect, should not be authorised. Authorisation may also legitimately be withheld if health claims do not comply with other general and specific requirements of Regulation (EC) No 1924/2006, even in the case of a favourable scientific assessment by the Authority. Health claims inconsistent with generally accepted nutrition and health principles should not be made. The Authority concluded that for one claim[5] on the effect of fats on the normal absorption of fat soluble vitamins and another claim[6] on the effect of sodium on the maintenance of normal muscle function a cause and effect relationship has been established. However, the use of these health claims would convey a conflicting and confusing message to consumers, because it would encourage consumption of those nutrients for which, on the basis of generally accepted scientific advice, European, national and international authorities inform the consumer that their intake should be reduced. Therefore, these two claims do not comply with point (a) of the second paragraph of Article 3 of Regulation (EC) No 1924/2006 which foresees that the use of claims shall not be ambiguous or misleading. Furthermore, even if the health claims concerned were to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claims should not be authorised.

(13) This Regulation should apply six months after the date of its entry into force to enable food business operators to adapt to its requirements, including the prohibition according to Article 10(1) of Regulation (EC) No 1924/2006 of those health claims whose evaluation by the Authority or whose consideration by the Commission has been completed.

(14) Article 20(1) of Regulation (EC) No 1924/2006 provides for the Commission to establish and maintain a Union Register of nutrition and health claims made on foods, hereinafter referred to as 'the Register'. The Register will contain all the authorised claims and, *inter alia,* the conditions of use applying to them. The Register will also contain a list of rejected health claims and the reasons for their rejection.

(15) Health claims that have been withdrawn by the Member States will not be included in the list of rejected claims in the Union Register. The Register will be updated periodically and, as the case may be, following progress on health claims for which the evaluation by the Authority and/or consideration by the Commission has not yet been completed.

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4 http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

5 Corresponding to entries ID 670 and ID 2902 in the consolidated list.

6 Corresponding to entry ID 359 in the consolidated list.

(16) Comments and positions from the members of the public and interested stakeholders, received by the Commission have been adequately considered when setting the measures provided for in this Regulation.

(17) The addition of substances to or the use of substances in foodstuffs is governed by specific Union and national legislation, as is the classification of products as foodstuffs or medicinal products. Any decision on a health claim in accordance with Regulation (EC) No 1924/2006 such as inclusion in the list of permitted claims referred to in Article 13(3) thereof does not constitute an authorisation to the marketing of the substance on which the claim is made, a decision on whether the substance can be used in foodstuffs, or a classification of a certain product as a foodstuff.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council have opposed them,

HAS ADOPTED THIS REGULATION:

Article 1
Permitted health claims

1. The list of health claims which may be made on foods, as referred to in Article 13(3) of Regulation (EC) No 1924/2006, is set out in the Annex to this Regulation.

2. Health claims referred to in paragraph 1 may be made on foods in compliance with the conditions set out in the Annex.

Article 2
Entry into force and application

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

It shall apply from … *[six months after the date of its entry into force]*.

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

Done at Brussels,

For the Commission
The President
José Manuel BARROSO