Commission Regulation (EU) No 666/2011 of 11 July 2011 refusing to authorise certain 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)

COMMISSION REGULATION (EU) No 666/2011

of 11 July 2011

refusing to authorise certain 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)

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 18(5) thereof,

Whereas:

(1) Pursuant to 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) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority'.

(3) Following receipt of an application the Authority is to inform without delay the other Member States and the Commission thereof and to deliver an opinion on the health claim concerned.

(4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(5) Following an application from Synbiotec S.r.l., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Synbio on maintenance and improvement of intestinal well-being (Question No EFSA-Q-2009-00889)[(2)]. The claim proposed by the applicant was worded as follows: 'Synbio persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being'.

(6) On 27 September 2010, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of

Synbio and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(7) Following an application from MILTE ITALIA SpA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to the effects of Silymarin BIO-C® on increase in production of breast milk (Question No EFSA-Q-2009-00957)[(3)]. The claim proposed by the applicant was worded, inter alia, as follows: 'Suggested for improving the physiological production of breast milk during breast feeding'.

(8) On 28 September 2010, the Commission and the Member States received the scientific opinion from the Authority, which concluded that on the basis of the data presented, a cause and effect relationship had not been established between the consumption of Silymarin BIO-C® and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

(9) All the health claims subject to this Regulation are health claims as referred to in point (a) of Article 13(1) of Regulation (EC) No 1924/2006 and may benefit from the transition period laid down in Article 28(5) of that Regulation. As the Authority concluded that cause and effect relationships have not been established between the foods and the respective claimed effects, the two claims do not comply with Regulation (EC) No 1924/2006, and therefore they may not benefit from the transition period provided for in that Article.

(10) In order to ensure that this Regulation is fully complied with, both food business operators and the national competent authorities should take the necessary actions to ensure that, at the latest 6 months following the entry into force of this Regulation, products bearing the health claims listed in its Annex are no longer present on the market.

(11) The comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.

(12) 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

1 The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

2 However, products bearing these health claims placed on the market or labelled prior to the date of entry into force of this Regulation may remain on the market for a maximum period of 6 months after that date.

Article 2

This Regulation shall enter into force on the 20th day following 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, 11 July 2011.

For the Commission

The President

José Manuel BARROSO

ANNEX

REJECTED HEALTH CLAIMS

Application – Relevant provisions of Regulation (EC) No 1924/2006	**Nutrient, substance, food or food category**	**Claim**	**EFSA opinion reference**
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Synbio	Synbio persists in the intestinal tract and favours the natural regularity contributing to maintain and improve human intestinal well-being	Q-2009-00889
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Silymarin BIO-C®	Suggested for improving the physiological production of breast milk during breast feeding	Q-2009-00957

(**1**) OJ L 404, 30.12.2006, p. 9.

(**2**) The EFSA Journal 2010; 8(9):1773.

(**3**) The EFSA Journal 2010; 8(9):1774.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EU) No 666/2011. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Art. 1 word omitted by S.I. 2019/651 reg. 39(2)(a)
- Art. 1 words substituted by S.I. 2019/651 reg. 39(2)(b)
- Art. 1(2) omitted by S.I. 2019/651 reg. 39(2)(c)
- Art. 2 omitted by S.I. 2019/651 reg. 39(3)