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COMMISSION REGULATION (EU) No …/..

of XXX

authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012

(Text with EEA relevance)

COMMISSION REGULATION (EU) No …/..

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authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012

(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(4) and 19 thereof,

Whereas:

(1) Regulation (EC) No 1924/2006 provides that 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) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006, Commission Regulation (EU) No 432/2012[2] was adopted, which establishes 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.

(3) Regulation (EC) No 1924/2006 provides that applications for authorisations of health claims are to 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', for a scientific assessment, as well as to the Commission and the Member States for information.

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

(5) In order to stimulate innovation, health claims which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data shall undergo an accelerated type of authorisation.

(6) Following an application from Barry Callebaut Belgium NV submitted pursuant to Article 19(1) of Regulation (EC) No 1924/2006 and including a request for protection of proprietary data, the Authority was required to deliver an opinion on the modification of the authorisation of health claim “cocoa flavanols help maintain the

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

[2] Commission Regulation (EU) No 432/2012 of 16 May 2012 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 (OJ L 136, 25.5.2012, p. 1.).

elasticity of blood vessels, which contributes to normal blood flow". That health claim was authorised, pursuant to Article 13(5) of Regulation (EC) No 1924/2006, by Commission Regulation (EU) No 851/2013[3]. The applicant requested an extension of the authorised conditions of use of the claim to a high-flavanols (HF) cocoa extract to be consumed in capsules, tablets or added to "other foods, including beverages".

(7) On 5 May 2014, the Commission and the Member States received a scientific opinion from the Authority (Question No EFSA-Q-2013-00832)[4] which concluded that on the basis of the data submitted, a cause and effect relationship had been established between the consumption of cocoa flavanols in the HF cocoa extract (i.e. in capsules or tablets) and the claimed effect.

(8) The Authority indicated in its opinion that its conclusions could not have been reached without considering one human intervention study claimed by the applicant as proprietary.[5]

(9) All the justifiable information provided by the applicant has been assessed by the Commission and it is considered that the requirements laid down in Article 21(1) of Regulation (EC) No 1924/2006 are fulfilled for the study claimed as proprietary. Accordingly, the scientific data and other information included in that study may not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation, under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

(10) One of the objectives of Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that the wording and the presentation are taken into account in that respect. Therefore, where the wording of claims used by the applicant has the same meaning for consumers as that of an authorised health claim, because they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, they should be subject to the same conditions of use as those listed in the Annex to this Regulation.

(11) In accordance with Article 20 of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims should be updated in order to take into account this Regulation.

(12) Since the applicant claims protection of proprietary data, it is considered appropriate to restrict the use of this claim in favour of the applicant for a period of five years. However, the authorisation of this claim restricted for the use of an individual operator should not prevent other applicants from applying for authorisation to use the same claim in case the application is based on data and studies other than those protected under Article 21 of Regulation (EC) No 1924/2006.

(13) The comments from the applicant 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.

(14) Regulation (EU) No 432/2012 should therefore be amended accordingly.

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[3] Commission Regulation (EU) No 851/2013 of 3 September 2013 authorising certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and amending Regulation (EU) No 432/2012 (OJ L 235, 4.9.2013, p. 3).

[4] EFSA Journal 2014;12(5):3654.

[5] ProDigest, 2012. Pharmacokinetic study to assess the bioavailability of the cocoa flavanol epicatechin from different matrices. ProDigest Report nr. PD-2015009/C1-11.

(15) The Member States have been consulted,

HAS ADOPTED THIS REGULATION:

Article 1

1. The health claim set out in the Annex to this Regulation shall be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

2. The use of the health claim referred to in the first paragraph shall be restricted to the applicant for a period of five years from the date of entry into force of this Regulation. After the expiry of that period, that health claim may be used, in conformity with the conditions applying to it, by any food business operator.

Article 2

The scientific data and other information included in the application, which is claimed by the applicant as proprietary and without the submission of which the health claim could not have been authorised is restricted for use for the benefit of the applicant for a period of five years from the date of entry into force of this Regulation under the conditions laid down in Article 21(1) of Regulation (EC) No 1924/2006.

Article 3

The Annex to Regulation (EU) No 432/2012 is amended in accordance with the Annex to this Regulation.

Article 4

This Regulation shall enter into force on the twentieth 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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER