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Delegations will find attached document D044599/02.

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COMMISSION

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[…](2016) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 432/2012 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

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EU) No 432/2012 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

(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 13(3) 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 the Commission adopted Regulation (EU) No 432/2012 of 16 May 2012[2] 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) However, at the time of the adoption of the list of permitted health claims, there were a number of health claims whose evaluation by the European Food Safety Authority ('the Authority') or consideration by the Commission was not finalised[3].

(4) Among those claims there were five health claims on caffeine[4] which received a favourable assessment from the Authority. Two health claims were for the general adult population relating to increased attention and to increased alertness with 'at least 75 mg caffeine per serving' as proposed conditions of use[5]. Three health claims were for adults performing endurance exercise with two of the claimed effects relating to an

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).

3 Corresponding to 2232 entries (IDs) in the consolidated list (http://www.efsa.europa.eu/en/topics/topic/article13).

4 Corresponding to entries ID 737, ID 1486, ID 1488, ID 1490, ID 736, ID 1101, ID 1187, ID 1485, ID 1491, ID 2063, ID 2103 and ID 2375 in the consolidated list (http://www.efsa.europa.eu/en/topics/topic/article13).

5 EFSA Journal 2011;9(4):2054.

increase in endurance performance and to an increase in endurance capacity, with caffeine intake of '3 mg/kg body weight one hour prior to exercise' as proposed conditions of use, and a claimed effect relating to the reduction in the rated perceived exertion/effort during exercise, with caffeine intake of '4 mg/kg body weight one hour prior to exercise' as proposed conditions of use[6].

(5) However, a number of Member States raised concerns about the value of safe daily intake of caffeine for the general population and the potential health risks of caffeine consumption for people performing exercise. Therefore, the Commission requested the Authority to provide scientific advice. The Authority published its scientific opinion on the safety of caffeine (EFSA-Q-2013-00220[7]) on 27 May 2015. The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.

(6) As regards the health claim on the effect of caffeine on perceived exertion/effort during exercise[8], the Authority concluded that in order to obtain the claimed effect, caffeine should be consumed at doses of 4 mg/kg body weight one hour prior to exercise. As regards the safety of caffeine intake, the Authority recommended that single doses up to 200 mg, corresponding to 3 mg/kg body weight, from all sources, do not raise safety concerns for the general adult population, even if consumed less than 2 hours prior to intense physical exercise under normal environmental conditions. Given that the proposed conditions of use exceed the limit of 3 mg/kg body weight recommended by the Authority as a safe caffeine intake, the health claim on the effect of caffeine on perceived exertion/effort during exercise should not be authorised for safety reasons.

(7) Health claims corresponding to the conclusions of the Authority that a cause and effect relationship has been established between a food category, a food or one of its constituents and the claimed effect and which comply with the requirements of Regulation (EC) No 1924/2006 should be authorised under Article 13(3) of that Regulation, and included in the list of permitted claims established by Regulation (EU) No 432/2012. Accordingly, the health claims on caffeine relating to an increase in endurance performance, to an increase in endurance capacity, to increased alertness and to increased attention[9] which do not raise safety concerns should be considered as complying with the requirements of Regulation (EC) No 1924/2006, and should be included in the Union 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 their conditions of use, and where applicable, conditions or restrictions of use

6 EFSA Journal 2011;9(4):2053.

7 EFSA Journal 2015;13(5):4102.

8 Corresponding to entries ID 1488 and ID 1490 in the consolidated list (http://www.efsa.europa.eu/en/topics/topic/article13).

9 Corresponding to entries ID 736, ID 1101, ID 1187, ID 1485, ID 1491, ID 2063, ID 2103, ID 736, ID 1485, ID 1491, ID 2375, ID 737, ID 1486 and ID 1488 in the consolidated list (http://www.efsa.europa.eu/en/topics/topic/article13).

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) 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 and whose consideration by the Commission has been completed.

(10) In line with Article 20(1) of Regulation (EC) No 1924/2006, the Register of nutrition and health claims containing all authorised health claims and those rejected and the reasons for their rejection should be updated in the light of the present Regulation and its deferred application.

(11) 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.

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

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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
Jean-Claude JUNCKER