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**COMMISSION REGULATION (EU) No .../..**

**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) No .../..

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<sup>1</sup>, and in particular Article 13(3) thereof,

Whereas:

- (1) Pursuant to Article 13(3) of Regulation (EC) No 1924/2006, the Commission adopted 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<sup>2</sup>. The list as established by Regulation (EU) No 432/2012 contains 222 permitted health claims, corresponding to 497 entries in the consolidated list<sup>3</sup> submitted to the European Food Safety Authority ('the Authority') for a scientific assessment.
- (2) 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 Authority or consideration by the Commission was not finalised<sup>4</sup>.
- (3) For health claims on micro-organisms which, in its initial assessment, the Authority considered insufficiently characterised and health claims for which it concluded that 'the evidence provided is insufficient to establish a cause and effect relationship', the Commission and Member States agreed that they would not be able to consider their inclusion or non-inclusion in the list of permitted claims unless a further assessment was carried out by the Authority. The Authority finalised its assessments on health claims and published its opinions on 5 June and 7 August 2012<sup>5</sup> concluding 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 for two health claims<sup>6</sup>.
- (4) The Commission has finalised its consideration of all health claims submitted for evaluation except for two categories of claims made on two specific groups of food or

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<sup>1</sup> OJ L 404, 30.12.2006, p. 9.

<sup>2</sup> OJ L 136, 25.5.2012, p. 1.

<sup>3</sup> <http://www.efsa.europa.eu/en/topics/topic/article13.htm>

<sup>4</sup> Corresponding to 2232 entries ID in the consolidated list.

<sup>5</sup> <http://www.efsa.europa.eu/en/publications.htm>

<sup>6</sup> Corresponding to entries ID 2926 and ID 1164 in the consolidated list.

one of their constituents. Those groups of food are composed on the one hand of plant or herbal substances, commonly known as 'botanical substances'<sup>7</sup> and on the other hand of certain specific foodstuffs, namely very low calorie diets and foods with reduced lactose content which are under consideration in the context of the revision of the legislation on foodstuffs for particular nutritional uses<sup>8</sup>.

- (5) As regards botanical substances, Member States and stakeholders expressed concerns as regards the difference in consideration given to the evidence based on 'traditional use' on the one hand under Regulation (EC) No 1924/2006 in relation to health claims and on the other hand under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>9</sup> concerning the use as traditional herbal medicinal products. Since the Commission considers that these concerns are relevant and require further reflection and consultation, a decision on claims relating to botanical substances should only be taken once those steps have been completed.
- (6) As regards the health claims referring to the effects of very low calorie diets<sup>10</sup> and foods with reduced lactose content<sup>11</sup>, the current revision of the legislation on foodstuffs for particular nutritional uses might have an impact on those health claims. In order to avoid potential inconsistencies with that legislation, a decision on the health claims referring to those foodstuffs should only be taken once that revision has been finalised.
- (7) In order to ensure transparency and legal security for all interested parties, claims the consideration of which has not yet been completed will remain published on the website of the Commission<sup>12</sup> and may continue to be used pursuant to paragraphs 5 and 6 of Article 28 of Regulation (EC) No 1924/2006.
- ~~(8)~~ 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<sup>13</sup>.
- ~~(9)~~ 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.
- (10) Pursuant to Article 6(1) and Article 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

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<sup>7</sup> Corresponding to 2078 entries ID in the consolidated list.

<sup>8</sup> COM (2011)353final.

<sup>9</sup> OJ L 311, 28.11.2001, p. 67.

<sup>10</sup> Corresponding to entry ID 1410 in the consolidated list.

<sup>11</sup> Corresponding to entries ID 646, 1224, 1238, 1339 in the consolidated list.

<sup>12</sup> [http://ec.europa.eu/food/food/labellingnutrition/claims/index\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm)

<sup>13</sup> Corresponding to 30 entries IDs in the consolidated list, as they appear in the Annex to this Regulation.

the Authority during either the initial assessment or during the 'further assessment' process, should not be authorised.

- (11) 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. The Authority concluded that for one claim on the effect of L-arginine on the maintenance of normal ammonia clearance and for another claim on the effect of L-tyrosine on the normal synthesis of catecholamines a cause and effect relationship has been established. The Commission and the Member States have considered whether health claims reflecting those conclusions should be authorised. On the basis of the data submitted and of the current scientific knowledge, the Authority concluded that no conditions of use can be defined which would accompany the health claim on L-arginine<sup>14</sup>, while for the health claim on L-tyrosine, the Authority proposed as appropriate conditions of use that 'a food should be at least a source of protein *as per* Annex to Regulation (EC) No 1924/2006'<sup>15</sup>. In the Authority's response of 9 November 2012 to the request of the Commission for clarification, the Authority noted that its conclusions for those claims were based on the known biochemical role of the two amino acids, as contained in protein. It added that it could not provide a quantitative indication of the necessary daily intake of L-tyrosine and L-arginine *per se* to produce the respective beneficial physiological effects. Accordingly, it is not possible to establish specific conditions for the use of those claims to ensure that the amino acids are contained in the final product in a quantity that will produce the respective beneficial physiological effects in accordance with point (i) of Article 5(1)(b) of Regulation (EC) No 1924/2006. In the absence of such specific conditions of use the beneficial effect of the substance to which the claim relates cannot be assured. Therefore, those claims could be misleading the consumer and should not be included in the lists of permitted health claims.
- (12) 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.
- (13) 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.
- (14) 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.
- (15) Regulation (EU) No 432/2012 should therefore be amended accordingly.
- (16) 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,

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<sup>14</sup> <http://www.efsa.europa.eu/en/efsajournal/doc/2051.pdf>

<sup>15</sup> <http://www.efsa.europa.eu/en/efsajournal/doc/2270.pdf>

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*  
*José Manuel BARROSO*

## **ANNEX**

Regulation (EU) No 432/2012 is amended as follows:

In the Annex, the following entries of permitted health claims are inserted in an alphabetical order:

<b>Nutrient, substance, food or food category</b>	<b>Claim</b>	<b>Conditions of use of the claim</b>	<b>Conditions and/or restrictions of use of the food and/or additional statement or warning</b>	<b>EFSA Journal number</b>	<b>Relevant entry number in the Consolidated List submitted to EFSA for its assessment</b>
alpha-Cyclodextrin	Consumption of alpha-cyclodextrin as part of a starch-containing meal contributes to the reduction of the blood glucose rise after that meal	The claim may be used for food which contains at least 5 g of alpha-cyclodextrin per 50 g of starch in a quantified portion as part of the meal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained by consuming the alpha-Cyclodextrin as part of the meal.		2012;10(6):2713	2926
Caffeine	Caffeine contributes to an increase in endurance performance	In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with caffeine consumption at doses of 3 mg/kg body weight at least one hour prior to exercise and only if any other caffeine consumption is avoided for at least 12 hours prior to consumption of the product in habitual caffeine consumers.	The claim may be used only for foods targeting adults performing endurance exercise.	2011;9(4):2053	737, 1486

<b>Nutrient, substance, food or food category</b>	<b>Claim</b>	<b>Conditions of use of the claim</b>	<b>Conditions and/or restrictions of use of the food and/or additional statement or warning</b>	<b>EFSA Journal number</b>	<b>Relevant entry number in the Consolidated List submitted to EFSA for its assessment</b>
Caffeine	Caffeine contributes to an increase in endurance capacity	In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with caffeine consumption at doses of 3 mg/kg body weight at least one hour prior to exercise and only if any other caffeine consumption is avoided for at least 12 hours prior to consumption of the product in habitual caffeine consumers.	The claim may be used only for foods targeting adults performing endurance exercise.	2011;9(4):2053	1488
Caffeine	Caffeine contributes to a reduction in the rated perceived exertion/effort during endurance exercise	In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with caffeine consumption at doses of 4 mg/kg body weight at least one hour prior to exercise and only if any other caffeine consumption is avoided for at least 12 hours prior to consumption of the product in habitual caffeine consumers.	The claim may be used only for foods targeting adults performing endurance exercise.	2011;9(4):2053	1488, 1490
Caffeine	Caffeine helps to increase alertness	The claim may be used only for food which contains at least 75 mg caffeine per quantified portion. In order to bear the claim information shall be given to the consumer not to exceed a daily intake of 300 mg of caffeine.	The claim shall not be used for foods targeting children.	2011;9(4):2054	736, 1101, 1187, 1485, 1491, 2063, 2103
Caffeine	Caffeine helps to improve concentration	The claim may be used only for food which contains at least 75 mg caffeine per quantified portion. In order to bear the claim information shall be given to the consumer not to exceed a daily intake of 300 mg of caffeine.	The claim shall not be used for foods targeting children.	2011;9(4):2054	736, 1485, 1491, 2375

<b>Nutrient, substance, food or food category</b>	<b>Claim</b>	<b>Conditions of use of the claim</b>	<b>Conditions and/or restrictions of use of the food and/or additional statement or warning</b>	<b>EFSA Journal number</b>	<b>Relevant entry number in the Consolidated List submitted to EFSA for its assessment</b>
Docosahexaenoic acid (DHA)	DHA contributes to the maintenance of normal blood triglyceride levels	The claim may be used only for food which provides a daily intake of 2 g of DHA and which contains DHA in combination with EPA. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of DHA. Information shall also be given to consumers not to exceed a daily intake of 5 g of EPA and DHA combined.	The claim shall not be used for foods targeting children.	2010;8(10):1734	533, 691, 3150
Docosahexaenoic acid and Eicosapentaenoic acid (DHA/EPA)	DHA and EPA contribute to the maintenance of normal blood pressure	The claim may be used only for food which provides a daily intake of 3 g of EPA and DHA. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of EPA and DHA. Information shall also be given to consumers not to exceed a daily intake of 5 g of EPA and DHA combined.	The claim shall not be used for foods targeting children.	2009; 7(9):1263 2010;8(10):1796	502, 506, 516, 703, 1317, 1324
Docosahexaenoic acid and Eicosapentaenoic acid (DHA/EPA)	DHA and EPA contribute to the maintenance of normal blood triglyceride concentrations	The claim may be used only for food which provides a daily intake of 2 g of EPA and DHA. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of EPA and DHA. Information shall also be given to consumers not to exceed a daily intake of 5 g of EPA and DHA combined.	The claim shall not be used for foods targeting children.	2009; 7(9):1263 2010;8(10):1796	506, 517, 527, 538, 1317, 1324, 1325



<b>Nutrient, substance, food or food category</b>	<b>Claim</b>	<b>Conditions of use of the claim</b>	<b>Conditions and/or restrictions of use of the food and/or additional statement or warning</b>	<b>EFSA Journal number</b>	<b>Relevant entry number in the Consolidated List submitted to EFSA for its assessment</b>
Dried plums of "prune" cultivars ( <i>Prunus domestica</i> L.)	Dried plums/prunes contribute to normal bowel function	The claim may be used only for food which provides a daily intake of 100 g of dried plums (prunes). In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 100 g of dried plums (prunes).		2012;10(6):2712	1164
Fructose	Consumption of foods containing fructose leads to a lower blood glucose rise compared to foods containing sucrose or glucose	In order to bear the claim, glucose and/or sucrose should be replaced by fructose in sugar-sweetened foods or drinks so that the reduction of glucose and/or sucrose in these foods or drinks complies with the claim REDUCED [NAME OF THE NUTRIENT] as listed in the Annex of Regulation (EC) No 1924/2006.		2011;9(6):2223	558
Glycaemic carbohydrates	Glycaemic carbohydrates contribute to the maintenance of normal brain function	The claim may be used only for food which contains at least 19.5 g glycaemic carbohydrates per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 130 g of glycaemic carbohydrates. When the claim is used on foods with added sugars, information shall also be given to the consumer that intake of added sugars shall not exceed 10% of the total daily energy intake (=50g/day).		2011;9(6):2226	603, 653