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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

(Text with EEA relevance)

(OJ L 136, 25.5.2012, p. 1)

Amended by:

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Official Journal

		No	page	date
► <u>M1</u>	Commission Regulation (EU) No 536/2013 of 11 June 2013	L 160	4	12.6.2013
► <u>M2</u>	Commission Regulation (EU) No 851/2013 of 3 September 2013	L 235	3	4.9.2013
► <u>M3</u>	Commission Regulation (EU) No 1018/2013 of 23 October 2013	L 282	43	24.10.2013
<u>M4</u>	Commission Regulation (EU) No 40/2014 of 17 January 2014	L 14	8	18.1.2014
<u>M5</u>	Commission Regulation (EU) No 274/2014 of 14 March 2014	L 83	1	20.3.2014
<u>M6</u>	Commission Regulation (EU) 2015/7 of 6 January 2015	L 3	3	7.1.2015
<u>M7</u>	Commission Regulation (EU) 2015/539 of 31 March 2015	L 88	7	1.4.2015
►M8	Commission Regulation (EU) 2015/2314 of 7 December 2015	L 328	46	12.12.2015

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

(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) 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).
- (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

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ http://www.efsa.europa.eu/en/ndaclaims13/docs/ndaclaims13.zip

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 (1).

- (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.

⁽¹⁾ 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 (1) and may continue to be used pursuant to Article 28(5) and (6) of Regulation (EC) No 1924/2006.
- 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 (2) on the effect of fats on the normal absorption of fat soluble vitamins and another claim (3) 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 and 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.

 $^{(^1) \} http://ec.europa.eu/food/food/labelling nutrition/claims/index_en.htm$

⁽²⁾ Corresponding to entries ID 670 and ID 2902 in the consolidated list.

⁽³⁾ Corresponding to entry ID 359 in the consolidated list.

- (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.
- (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 food-stuffs 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 food-stuff
- (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 14 December 2012.

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

LIST OF PERMITTED HEALTH CLAIMS

	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
	Activated charcoal	Activated charcoal contrib- utes to reducing excessive flatulence after eating	The claim may be used only for food which contains 1 g of activated charcoal per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with 1 g which should be taken at least 30 minutes before and 1 g shortly after the meal.		2011;9(4):2049	1938
▼ <u>M1</u>	Alpha-cyclodextrin	Consumption of alphacyclodextrin 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
	Alpha-linolenic acid (ALA)	ALA contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which is at least a source of ALA as referred to in the claim SOURCE OF OMEGA-3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA.		2009; 7(9):1252 2011;9(6):2203	493, 568
	Arabinoxylan produced from wheat endosperm	Consumption of arabinoxylan as part of a meal contributes to a reduction of the blood glucose rise after that meal	The claim may be used only for food which contains at least 8 g of arabinoxylan (AX)-rich fibre produced from wheat endosperm (at least 60 % AX by weight) per 100 g of available carbohydrates 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 arabinoxylan (AX)-rich fibre produced from wheat endosperm as part of the meal.		2011;9(6):2205	830

▼M3

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	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
▼ <u>M6</u>	Carbohydrates	Carbohydrates contribute to the recovery of normal muscle function (contraction) after highly intensive and/or longlasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle	The claim may be used only for food which provides carbohydrates which are metabolised by humans (excluding polyols). Information shall be given to the consumer that the beneficial effect is obtained with the consumption of carbohydrates, from all sources, at a total intake of 4 g per kg body weight, at doses, within the first 4 hours and no later than 6 hours, following highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.	2013;11(10):3409	
<u>▼</u> B	Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged endurance exercise	In order to bear the claim carbohydrate-electrolyte solutions should contain 80-350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200-330 mOsm/kg water.		2011;9(6):2211	466, 469
	Carbohydrate-electrolyte solutions	Carbohydrate-electrolyte solutions enhance the absorption of water during physical exercise	In order to bear the claim carbohydrate-electrolyte solutions should contain 80-350 kcal/L from carbohydrates, and at least 75 % of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, these beverages should contain between 20 mmol/L (460 mg/L) and 50 mmol/L (1,150 mg/L) of sodium, and have an osmolality between 200-330 mOsm/kg water.		2011;9(6):2211	314, 315, 316, 317, 319, 322, 325, 332, 408, 465, 473, 1168, 1574, 1593, 1618, 4302, 4309

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	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
	Chromium	Chromium contributes to the maintenance of normal blood glucose levels	The claim may be used only for food which is at least a source of trivalent chromium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1732 2011;9(6):2203	262, 4667 4698
▼ M7						
	Cocoa flavanols	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow (*****) (******)	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 200 mg of cocoa flavanols. The claim can be used only for cocoa beverages (with cocoa powder) or for dark chocolate which provide at least a daily intake of 200 mg of cocoa flavanols with a degree of polymerisation 1-10 (*****). The claim can be used only for capsules or tablets containing high-flavanol cocoa extract which provide at least a daily intake of 200 mg of cocoa flavanols with a degree of polymerisation 1-10 (******).	_	2012;10(7): 2809 (*****) 2014;12(5): 3654 (******)	_
▼ B						
_	Copper	Copper contributes to maintenance of normal connective tissues	The claim may be used only for food which is at least a source of copper as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1211	265, 271, 1722
	Copper	Copper contributes to normal energy-yielding metabolism	The claim may be used only for food which is at least a source of copper as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1211 2011;9(4):2079	266, 1729

▼<u>M1</u>

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Copper	Copper contributes to the protection of cells from oxidative stress	The claim may be used only for food which is at least a source of copper as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1211	263, 1726
Creatine	Creatine increases physical performance in successive bursts of short-term, high intensity exercise	The claim may be used only for food which provides a daily intake of 3 g of creatine. 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 creatine.	The claim may be used only for foods targeting adults performing high intensity exercise	2011;9(7):2303	739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924
Docosahexaenoic acid (DHA)	DHA contributes to maintenance of normal brain function	The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.		2010;8(10):1734 2011;9(4):2078	565, 626, 631, 689, 704, 742, 3148, 690, 3151, 497, 501, 510, 513, 519, 521, 534, 540, 688, 1323, 1360, 4294
Docosahexaenoic acid (DHA)	DHA contributes to the maintenance of normal vision	The claim may be used only for food which contains at least 40 mg of DHA per 100 g and per 100 kcal. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.		2010;8(10):1734 2011;9(4):2078	627, 632, 743, 3149, 2905, 508, 510, 513, 519, 529, 540, 688, 4294
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 eicosapentaenoic acid (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. When the claim is used on food supplements and/or fortified foods information shall also be given to consumers not to exceed a supplemental 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

▼<u>M1</u>

▼<u>B</u>

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
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. When the claim is used on food supplements and/or fortified foods information shall also be given to consumers not to exceed a supplemental 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 levels	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. When the claim is used on food supplements and/or fortified foods information shall also be given to consumers not to exceed a supplemental 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
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
Eicosapentaenoic acid and docosahexaenoic acid (EPA/DHA)	EPA and DHA contribute to the normal function of the heart	The claim may be used only for food which is at least a source of EPA and DHA as referred to in the claim SOURCE OF OMEGA-3 FATTY ACIDS as listed in the Annex to Regulation (EC) No 1924/2006. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of EPA and DHA.		2010;8(10):1796 2011;9(4):2078	504, 506, 516, 527, 538, 703, 1128, 1317, 1324, 1325, 510, 688, 1360

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Fluoride	Fluoride contributes to the maintenance of tooth mineralisation	The claim may be used only for food which is at least a source of fluoride as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1212 2010;8(10):1797	275, 276, 338, 4238,
Folate	Folate contributes to maternal tissue growth during pregnancy	The claim may be used only for food which is at least a source of folate as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1213	2882
Folate	Folate contributes to normal amino acid synthesis	The claim may be used only for food which is at least a source of folate as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1760	195, 2881
Folate	Folate contributes to normal blood formation	The claim may be used only for food which is at least a source of folate as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1213	79
Folate	Folate contributes to normal homocysteine metabolism	The claim may be used only for food which is at least a source of folate as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1213	80

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	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
	Foods with a low or reduced content of sodium	Reducing consumption of sodium contributes to the maintenance of normal blood pressure	The claim may be used only for food which is at least low in sodium/salt as referred to in the claim LOW SODIUM/SALT or reduced in sodium/salt as referred to in the claim REDUCED [NAME OF NUTRIENT] as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(6):2237	336, 705, 1148, 1178, 1185, 1420
<u>₩1</u>	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 in content of glucose and/or sucrose, in these foods or drinks, is at least 30 %.		2011; 9(6):2223	558
▼ <u>B</u>	Glucomannan (konjac mannan)	Glucomannan contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which provides a daily intake of 4 g of glucomannan. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 4 g of glucomannan.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking with plenty of water to ensure substance reaches stomach.	2009; 7(9):1258 2010;8(10):1798	836, 1560, 3100, 3217
	Glucomannan (konjac mannan)	Glucomannan in the context of an energy restricted diet contributes to weight loss	The claim may be used only for food which contains 1 g of glucomannan 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 3 g of glucomannan in three doses of 1 g each, together with 1-2 glasses of water, before meals and in the context of an energy-restricted diet.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking with plenty of water to ensure substance reaches stomach.	2010;8(10):1798	854, 1556, 3725,

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Guar Gum	Guar gum contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which provides a daily intake of 10 g of guar gum. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 10 g of guar gum.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking with plenty of water to ensure substance reaches stomach.	2010;8(2):1464	808
Hydroxypropyl methyl- cellulose (HPMC)	Consumption of Hydroxy- propyl methylcellulose with a meal contributes to a reduction in the blood glucose rise after that meal	The claim may be used only for food which contains 4 g of HPMC per 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 4 g of HPMC as part of the meal.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking with plenty of water to ensure substance reaches stomach.	2010;8(10):1739	814
Hydroxypropyl methyl- cellulose (HPMC)	Hydroxypropyl methylcel- lulose contributes to the maintenance of normal blood cholesterol levels	The claim may be used only for food which provides a daily intake of 5 g of HPMC. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 5 g of HPMC.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking with plenty of water to ensure substance reaches stomach.	2010;8(10):1739	815
Iodine	Iodine contributes to normal cognitive function	The claim may be used only for food which is at least a source of iodine as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1800	273

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Melatonin	Melatonin contributes to the alleviation of subjective feelings of jet lag	The claim may be used only for food which contains at least 0,5 mg of melatonin per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a minimum intake of 0,5 mg to be taken close to bedtime on the first day of travel and on the following few days after arrival at the destination.		2010; 8(2):1467	1953
Melatonin	Melatonin contributes to the reduction of time taken to fall asleep	The claim may be used only for food which contains 1 mg of melatonin per quantified portion. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained by consuming 1 mg of melatonin close to bedtime.		2011;9(6):2241	1698, 1780, 4080
Molybdenum	Molybdenum contributes to normal sulphur amino acid metabolism	The claim may be used only for food which is at least a source of molybdenum as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1745	313
Monascus purpureus (red yeast rice)	Monacolin K from red yeast rice contributes to the main- tenance of normal blood cholesterol levels	The claim may be used only for food which provides a daily intake of 10 mg of monacolin K from red yeast rice. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 10 mg of monacolin K from fermented red yeast rice preparations.		2011;9(7):2304	1648, 1700
Monounsaturated and/ or polyunsaturated fatty acids	Replacing saturated fats with unsaturated fats in the diet contributes to the main- tenance of normal blood cholesterol levels [MUFA and PUFA are unsaturated fats]	The claim may be used only for food which is high in unsaturated fatty acids, as referred to in the claim HIGH UNSATURATED FAT as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(4):2069 2011;9(6):2203	621, 1190, 1203, 2906, 2910, 3065 674, 4335

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	Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
	Selenium	Selenium contributes to the protection of cells from oxidative stress	The claim may be used only for food which is at least a source of selenium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1220 2010;8(10):1727	277, 283, 286, 1289, 1290, 1291, 1293, 1751, 410, 1292
▼ <u>M2</u>	Slowly digestible starch	Consumption of products high in slowly digestible starch (SDS) raises blood glucose concentration less after a meal compared to products low in SDS (****)	The claim may be used only on food where the digestible carbohydrates provide at least 60 % of the total energy and where at least 55 % of those carbohydrates is digestible starch, of which at least 40 % is SDS	_	2011;9(7):2292	_
▼ <u>M4</u>	Sugar beet fibre	Sugar beet fibre contributes to an increase in faecal bulk	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(12):2468	
▼ <u>B</u>	Sugar replacers, i.e. intense sweeteners; xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, sucralose and polydextrose; D-tagatose and isomaltulose	Consumption of foods/drinks containing <name of="" replacer="" sugar=""> instead of sugar (*) induces a lower blood glucose rise after their consumption compared to sugar-containing foods/drinks</name>	In order to bear the claim, sugars should be replaced in foods or drinks by sugar replacers, i.e. intense sweeteners, xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, erythritol, sucralose or polydextrose, or a combination of them, so that foods or drinks contain reduced amounts of sugars by at least the amount referred to in the claim REDUCED [NAME OF NUTRIENT] as listed in the Annex to Regulation (EC) No 1924/2006. In the case of D-tagatose and isomaltulose, they should replace equivalent amounts of other sugars in the same proportion as that referred to in the claim REDUCED [NAME OF NUTRIENT] as listed in the Annex to Regulation (EC) No 1924/2006.		2011;9(4):2076 2011;9(6):2229	617, 619, 669, 1590, 1762, 2903, 2908, 2920 4298

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Vitamin C	Vitamin C contributes to normal collagen formation for the normal function of bones	The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1226	131, 149
Vitamin C	Vitamin C contributes to normal collagen formation for the normal function of cartilage	The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1226	131, 149
Vitamin C	Vitamin C contributes to normal collagen formation for the normal function of gums	The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1226	131, 136, 149
Vitamin C	Vitamin C contributes to normal collagen formation for the normal function of skin	The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1226	131, 137, 149
Vitamin C	Vitamin C contributes to normal collagen formation for the normal function of teeth	The claim may be used only for food which is at least a source of vitamin C as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1226	131, 149

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Vitamin K	Vitamin K contributes to normal blood clotting	The claim may be used only for food which is at least a source of vitamin K as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7 (9):1228	124, 126
Vitamin K	Vitamin K contributes to the maintenance of normal bones	The claim may be used only for food which is at least a source of vitamin K as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7 (9):1228	123, 127, 128, 2879
Walnuts	Walnuts contribute to the improvement of the elasticity of blood vessels	The claim may be used only for food which provides a daily intake of 30 g of walnuts. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 30 g of walnuts.		2011;9(4):2074	1155, 1157
Water	Water contributes to the maintenance of normal physical and cognitive functions	consumer that in order to obtain the claimed effect, at least	The claim may be used only on water complying with Directives 2009/54/EC and/or 98/83/EC	2011;9(4):2075	1102, 1209, 1294, 1331
Water	Water contributes to the maintenance of normal regulation of the body's temperature	consumer that in order to obtain the claimed effect, at least	The claim may be used only on water complying with Directives 2009/54/EC and/or 98/83/EC	2011;9(4):2075	1208

Nutrient, substance, food or food category	Claim	Conditions of use of the claim	Conditions and/or restrictions of use of the food and/or additional statement or warning	EFSA Journal number	Relevant entry number in the Consolidated List submitted to EFSA for its assessment
Wheat bran fibre	Wheat bran fibre contributes to an acceleration of intestinal transit	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006. In order to bear the claim information shall be given to the consumer that the claimed effect is obtained with a daily intake of at least 10 g of wheat bran fibre.		2010;8(10):1817	828, 839, 3067, 4699
Wheat bran fibre	Wheat bran fibre contributes to an increase in faecal bulk	The claim may be used only for food which is high in that fibre as referred to in the claim HIGH FIBRE as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1817	3066
Zinc	Zinc contributes to normal acid-base metabolism	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	360
Zinc	Zinc contributes to normal carbohydrate metabolism	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2010;8(10):1819	382
Zinc	Zinc contributes to normal cognitive function	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	296

	Conditions of use of the claim	use of the food and/or additional statement or warning	EFSA Journal number	List submitted to EFSA for its assessment
Zinc contributes to the maintenance of normal vision	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	361
Zinc contributes to the normal function of the immune system	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	291, 1757
Zinc contributes to the protection of cells from oxidative stress	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	294, 1758
Zinc has a role in the process of cell division	The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.		2009; 7(9):1229	292, 293, 1759
	maintenance of normal vision Zinc contributes to the normal function of the immune system Zinc contributes to the protection of cells from oxidative stress Zinc has a role in the process of cell division	maintenance of normal vision source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc contributes to the normal function of the immune system The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc contributes to the protection of cells from oxidative stress The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc has a role in the process of cell division The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC)	maintenance of normal vision Source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc contributes to the normal function of the immune system The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc contributes to the protection of cells from oxidative stress The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006. Zinc has a role in the process of cell division The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006.	maintenance of normal vision source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) Zinc contributes to the normal function of the immune system The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) Zinc contributes to the protection of cells from oxidative stress The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) Zinc has a role in the process of cell division The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) The claim may be used only for food which is at least a source of zinc as referred to in the claim SOURCE OF [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) MINERAL/S] as listed in the Annex to Regulation (EC)

^(*) In the case of D-tagatose and isomaltulose this should read 'other sugars'

^(**) In the case of D-tagatose and isomaltulose this should read 'other sugars'

^(***) Authorised on 24.9.2013 restricted to the use of GlaxoSmithKline Services Unlimited and its affiliates, GSK House, 980 Great West Road, Brentford, TW89GS, United Kingdom, for a period of five **►**<u>M2</u>

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