

**COMMISSION REGULATION (EU) 2016/1413****of 24 August 2016****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(4) thereof,

Whereas:

- (1) Regulation (EC) No 1924/2006 provides that health claims made on food 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 <sup>(2)</sup> 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) The list of permitted health claims and their conditions of use are set out in the Annex to Regulation (EU) No 432/2012. Two claims have been authorised for meal replacement for weight control. The conditions of use of those claims require that in order to bear them, the food should comply with specifications laid down in Commission Directive 96/8/EC <sup>(3)</sup>.
- (4) Those claims were included in the list of permitted health claims pursuant to the favourable Opinion of the European Food Safety Authority (hereinafter 'the Authority') of 2010 (Question EFSA-Q-2008-2154, EFSA-Q-2008-2155 <sup>(4)</sup>) which found that a cause and effect relationship had been established between the consumption of meal replacements in substitution of regular meals and the maintenance of body weight after weight loss and also between the consumption of meal replacements in substitution of regular meals in the context of energy restricted diets and reduction in body weight. It stated that in order to bear the claims a food should contain a maximum of 250 kcal per serving and comply with specifications laid down in Directive 96/8/EC.
- (5) Directive 96/8/EC lays down compositional requirements for foods for use in energy-restricted diets for weight reduction which replace the whole or part of the total daily diet and specifies mandatory particulars which shall appear on the labelling of those products. It provides that as regards products which are presented as a replacement for one or more meals of the daily diet, the name under which they are sold is 'Meal replacement for weight control'.
- (6) Regulation (EU) No 609/2013 of the European Parliament and of the Council <sup>(5)</sup> revises the legal framework applicable to foods for particular nutritional uses. It provides that Directive 96/8/EC shall not apply from 20 July 2016 to foods presented as a replacement for one or more meals of the daily diet, which should in future be regulated under Regulation (EC) No 1924/2006 and should comply with requirements set out therein.

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

<sup>(2)</sup> 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).

<sup>(3)</sup> Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).

<sup>(4)</sup> EFSA Journal 2010; 8(2):1466.

<sup>(5)</sup> Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

- (7) Therefore, the references to Directive 96/8/EC regarding health claims which may be made on meal replacement for weight control need to be replaced by setting out the conditions of use of those claims in the Annex to Regulation (EC) No 432/2012.
- (8) Article 13(4) of Regulation (EC) No 1924/2006 empowers the Commission, after consulting the Authority, to adopt changes to the list of permitted health claims based on generally accepted scientific evidence.
- (9) When introducing the necessary technical adaptations regarding the health claims for meal replacement for weight control the requirements as regards the amounts of vitamins and minerals in food set out in Directive 96/8/EC should be taken into account.
- (10) Regulation (EU) No 1169/2011 of the European Parliament and of the Council <sup>(1)</sup> lays down rules on the provision of food information to consumers. Part A of Annex XIII sets out nutrient reference values for vitamins and minerals on the basis of recent scientific advices.
- (11) Accordingly, the Commission requested the Authority to provide scientific advice on whether a change in the conditions of use for claims on meal replacements for weight control regarding their vitamin and mineral composition (30 % of the nutrient reference values of vitamins and minerals laid down in Regulation (EU) No 1169/2011 instead of the 30 % of values of vitamins and minerals laid down in Directive 96/8/EC) would affect the conclusions reached in the Authority's Opinion of 2010 with respect to the scientific substantiation of health claims related to meal replacement for weight control.
- (12) The Authority adopted an Opinion on 28 October 2015 (Question EFSA-Q-2015-00579) <sup>(2)</sup> and concluded that the differences in the micronutrient composition of meal replacements which would derive from changing the conditions of use from Directive 96/8/EC to Regulation (EU) No 1169/2011 do not affect the scientific substantiation of health claims related to meal replacements for weight control and reduction in body weight and maintenance of body weight after weight loss.
- (13) Nutrient reference values for fluoride, chromium, chloride and molybdenum are provided in Annex XIII to Regulation (EU) No 1169/2011. Directive 96/8/EC does not require the addition of these micronutrients to meal replacement for weight control. Taking into account that the claimed effects of meal replacement for weight control are related to the controlled energy content and the relatively high protein/low fat content, there is no need to require that meal replacement for weight control provides at least 30 % of the nutrient reference values of fluoride, chromium, chloride and molybdenum per meal as laid down in Regulation (EU) No 1169/2011.
- (14) Annex XIII to Regulation (EU) No 1169/2011 does not set nutrient reference value for sodium. However, taking into account the intended use of meal replacement for weight control products, the requirement to provide 30 % of the sodium amount per meal as laid down in Annex I to Directive 96/8/EC should be further maintained in the conditions of use of those health claims.
- (15) Nutrient reference value for potassium is set at 2000 milligrams in PART A of Annex XIII to Regulation (EU) No 1169/2011. Directive 96/8/EC does not require for meal replacement for weight control to provide 30 % of the potassium value, but sets a minimum amount at 500 milligram per meal. This value should be further maintained.
- (16) Since the Authority's Opinion of 2015 confirmed the conclusions of its Opinion of 2010 as regards the energy content of the products concerned a maximum of 250 kcal per serving should be set. The requirements set out in Directive 96/8/EC on fat, protein and amino acids should be maintained.
- (17) As regards mandatory particulars which should appear on the labelling of meal replacement for weight control food information requirements included in Directive 96/8/EC should be maintained in the conditions of use of the relevant health claims.

<sup>(1)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulation (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

<sup>(2)</sup> EFSA Journal 2015; 13(11): 4287.

- (18) To enable food business operators to adapt to the necessary changes regarding the conditions of use of health claims for meal replacement for weight control in particular regarding the energy content and the vitamin and mineral content, a transitional period *should be provided*.
- (19) Regulation (EU) No 432/2012 should therefore be amended accordingly.
- (20) 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*.

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

Done at Brussels, 24 August 2016.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

In the Annex to Regulation (EU) No 432/2012 the entries for food categories 'Meal replacement for weight control' are replaced by the following:

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						
Meal replacement for weight control	Substituting one of the main daily meals of an energy restricted diet with a meal replacement contributes to the maintenance of weight after weight loss	<p>In order to bear the claim, a food should comply with the following requirements:</p> <p><b>1. Energy content</b></p> <p>The energy content shall not be less than 200 kcal (840 kJ) and shall not exceed 250 kcal (1 046 KJ) per meal (*).</p> <p><b>2. Fat content and composition</b></p> <p>The energy derived from fat shall not exceed 30 % of total available energy content of the product.</p> <p>The linoleic acid (in the form of glycerides) shall not be less than 1 g.</p> <p><b>3. Protein content and composition</b></p> <p>The protein contained in the food shall provide not less than 25 % and not more than 50 % of the total energy content of the product.</p> <p>The chemical index of protein shall be equal to that set by the World Health Organization in "Energy and protein requirements". Report of a Joint WHO/FAO/UNU Meeting. Geneva: World Health Organisation, 1985 (WHO Technical Report Series, 724):</p> <p><b>Amino acid requirement pattern (g/100 g protein)</b></p> <table border="1" data-bbox="640 1294 1249 1453"> <tbody> <tr> <td>Cystine + methionine</td> <td>1,7</td> </tr> <tr> <td>Histidine</td> <td>1,6</td> </tr> <tr> <td>Isoleucine</td> <td>1,3</td> </tr> </tbody> </table>	Cystine + methionine	1,7	Histidine	1,6	Isoleucine	1,3	<p>In order to bear the claim, information shall be provided to the consumer on the importance of maintaining an adequate daily fluid intake and on the fact that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.</p> <p>In order to achieve the claimed effect, one main meal should be substituted with one meal replacement daily.</p>	2010; 8(2):1466 2015; 13(11):4287	1418
Cystine + methionine	1,7										
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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												
		<table border="1" data-bbox="640 252 1249 564"> <tr> <td data-bbox="640 252 1043 300">Leucine</td> <td data-bbox="1043 252 1249 300">1,9</td> </tr> <tr> <td data-bbox="640 300 1043 347">Lysine</td> <td data-bbox="1043 300 1249 347">1,6</td> </tr> <tr> <td data-bbox="640 347 1043 395">Phenylalanine + tyrosine</td> <td data-bbox="1043 347 1249 395">1,9</td> </tr> <tr> <td data-bbox="640 395 1043 443">Threonine</td> <td data-bbox="1043 395 1249 443">0,9</td> </tr> <tr> <td data-bbox="640 443 1043 491">Tryptophan</td> <td data-bbox="1043 443 1249 491">0,5</td> </tr> <tr> <td data-bbox="640 491 1043 564">Valine</td> <td data-bbox="1043 491 1249 564">1,3</td> </tr> </table> <p data-bbox="640 628 1249 740">The “chemical index” shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.</p> <p data-bbox="640 778 1249 922">If the chemical index is lower than 100 % of the reference protein, the minimum protein levels shall be correspondingly increased. In any case the chemical index of the protein shall at least be equal to 80 % of that of the reference protein.</p> <p data-bbox="640 960 1249 1072">In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins and only in the proportions necessary for that purpose.</p> <p data-bbox="640 1126 922 1152"><b>4. Vitamins and minerals</b></p> <p data-bbox="640 1190 1249 1423">The food shall provide at least 30 % of the amounts of the nutrient reference values of vitamins and minerals per meal as laid down in Annex XIII to Regulation (EU) No 1169/2011. This requirement does not apply to fluoride, chromium, chloride and molybdenum. The amount of sodium per meal provided by the food shall be at least 172,5 mg. The amount of potassium per meal provided by the food shall be at least 500 mg (**).</p>	Leucine	1,9	Lysine	1,6	Phenylalanine + tyrosine	1,9	Threonine	0,9	Tryptophan	0,5	Valine	1,3			
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Meal replacement for weight control	Substituting two of the main daily meals of an energy restricted diet with meal replacements contributes to weight loss	<p>In order to bear the claim, a food should comply with the following requirements:</p> <p><b>1. Energy content</b></p> <p>The energy content shall not be less than 200 kcal (840 kJ) and shall not exceed 250 kcal (1 046 KJ) per meal (*).</p> <p><b>2. Fat content and composition</b></p> <p>The energy derived from fat shall not exceed 30 % of total available energy content of the product.</p> <p>The linoleic acid (in the form of glycerides) shall not be less than 1 g.</p> <p><b>3. Protein content and composition</b></p> <p>The protein contained in the food shall provide not less than 25 % and not more than 50 % of the total energy content of the product.</p> <p>The chemical index of protein shall be equal to that set by the World Health Organization in “Energy and protein requirements”. Report of a Joint WHO/FAO/UNU Meeting, Geneva: World Health Organisation, 1985 (WHO Technical Report Series, 724):</p> <p><b>Amino acid requirement pattern (g/100 g protein)</b></p> <table border="1" data-bbox="640 1123 1249 1441"> <tbody> <tr> <td>Cystine + methionine</td> <td>1,7</td> </tr> <tr> <td>Histidine</td> <td>1,6</td> </tr> <tr> <td>Isoleucine</td> <td>1,3</td> </tr> <tr> <td>Leucine</td> <td>1,9</td> </tr> <tr> <td>Lysine</td> <td>1,6</td> </tr> <tr> <td>Phenylalanine + tyrosine</td> <td>1,9</td> </tr> </tbody> </table>	Cystine + methionine	1,7	Histidine	1,6	Isoleucine	1,3	Leucine	1,9	Lysine	1,6	Phenylalanine + tyrosine	1,9	<p>In order to bear the claim, information shall be provided to the consumer on the importance of maintaining an adequate daily fluid intake and on the fact that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet.</p> <p>In order to achieve the claimed effect, two of the main daily meals should be substituted with meal replacements daily.</p>	2010; 8(2):1466 2015; 13(11):4287	1417
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(\*) From 21 July 2016 until 14 September 2019 the energy content of the food shall not be less than 200 kcal (840 kJ) and shall not exceed 400 kcal (1 680 kJ).

(\*\*) From 21 July 2016 until 14 September 2019 the food shall provide at least 30 % of the amounts of vitamins and minerals specified in the below Table per meal:

Vitamin A	(µg RE)	700
Vitamin D	(µg)	5

Vitamin E	(mg)	10
Vitamin C	(mg)	45
Thiamine	(mg)	1,1
Riboflavin	(mg)	1,6
Niacin	(mg-NE)	18
Vitamin B <sub>6</sub>	(mg)	1,5
Folate	(µg)	200
Vitamin B <sub>12</sub>	(µg)	1,4
Biotin	(µg)	15
Pantothenic acid	(mg)	3
Calcium	(mg)	700
Phosphorus	(mg)	550
Iron	(mg)	16
Zinc	(mg)	9,5
Copper	(mg)	1,1
Iodine	(µg)	130
Selenium	(µg)	55
Sodium	(mg)	575
Magnesium	(mg)	150
Manganese	(mg)	1

From 21 July 2016 until 14 September 2019 the amount of potassium per meal provided by the food shall be at least 500 mg.'