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)

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[(1)], 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[(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) 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[(3)].

(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[(4)]) 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1413. (See end of Document for details)*

(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[(5)] 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.

(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[(6)] 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)[(7)] 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.

(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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1413. (See end of Document for details)*

Done at Brussels, 24 August 2016.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1413. (See end of Document for details)*

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
a 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).					
b 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_6	(mg)	1,5
Folate	(µg)	200
Vitamin B_{12}	(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.'