II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2017/1522

of 2 June 2017

supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 11(1)(a), (c) and (d) thereof,

Whereas:

(1) Commission Directive 96/8/EC ([2]) lays down harmonised rules on foods intended for use in energy-restricted diets for weight reduction and includes within its scope products defined in Regulation (EU) No 609/2013 as total diet replacement for weight control products.

(2) Regulation (EU) No 609/2013 repeals Directive 96/8/EC and lays down general compositional and information requirements for different categories of food including products defined as total diet replacement for weight control. In order for the Commission to comply with its obligation to adopt specific compositional and information requirements for total diet replacement for weight control products, it is appropriate to build on the provisions of Directive 96/8/EC as those provisions have ensured the free movement of foods presented as total diet replacement for weight control in a satisfactory manner while ensuring a high level of protection of public health.

(3) Total diet replacement for weight control is a complex product that is specially formulated for overweight or obese adults who intend to achieve weight reduction. The essential composition of total diet replacement for weight control products must satisfy the daily nutritional requirements of overweight or obese adults in good health, in the context of energy-restricted diets for weight reduction, as established by generally accepted scientific data.

([1]) OJ L 181, 29.6.2013, p. 35.
([2]) Commission Directive 96/8/EC of 26 February 1996 on food intended for use in energy restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22).

(4) In order to ensure the safety and suitability of total diet replacement for weight control products, detailed requirements should be laid down on their composition, including requirements on energy value, macronutrient and micronutrient content. Those requirements should be based on the latest scientific advice of the European Food Safety Authority ('the Authority') ([1]) on the matter.

(5) In order to ensure innovation and product development, the voluntary addition to total diet replacement for weight control products of ingredients not covered by specific requirements of this Regulation, with particular attention to dietary fibre, should be possible. All ingredients used in the manufacture of total diet replacement for weight control products should be suitable for healthy overweight or obese adults and their suitability should have been demonstrated, when necessary, by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities to consider, on a case by case basis, whether this is the case.

(6) Total diet replacement for weight control products have to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council ([2]). In order to take account of the specific nature of total diet replacement for weight control products, additions and exceptions to those general rules should be laid down, where appropriate.

(7) It is essential that the nutrition declaration of total diet replacement for weight control products is declared in order to guarantee it is used appropriately by both healthy overweight or obese adults consuming that food and by healthcare professionals who can advise on its appropriateness in certain cases. In order therefore to provide more complete information, the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, the obligation to declare the nutrition declaration should be mandatory for all total diet replacement for weight control products irrespective of the package or container size, therefore the exemption provided for in point 18 of Annex V to Regulation (EU) No 1169/2011 should not apply.

(8) In order to provide appropriate information and to facilitate product comparisons, the nutrition declaration for total diet replacement for weight control products should be expressed per portion and/or per consumption unit as well as per total daily ration. In addition, such information should refer to the product ready for use after preparation in accordance with the manufacturer's instructions.

(9) Article 30(2) of Regulation (EU) No 1169/2011 lists a limited number of nutrients that may be included on a voluntary basis in the nutrition declaration for food. The Annex to Regulation (EU) No 609/2013 lists a series of substances that may be added to total diet replacement for weight control products, some of which are not covered by Article 30(2) of Regulation (EU) No 1169/2011. In order to ensure legal clarity, it should be laid down explicitly that the nutrition declaration for total diet replacement for weight control products may include such substances. In addition, in certain cases, more detailed information on carbohydrate and fat present in the product could be useful for consumers and healthcare professionals. Food business operators should therefore be allowed to provide such information on a voluntary basis.

(10) Healthy overweight or obese adults may have different nutritional needs than the general population. In addition, total diet replacement for weight control is a food that fully replaces the daily diet. For those reasons, the expression of nutrition information on the energy value and the amount of nutrients of total diet replacement for weight control products as a percentage of daily reference intake values set out for the general population in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed.

(11) Statements relating to the 'very low' or 'low' calorie content of total diet replacement for weight control products can provide useful information to consumers. Therefore it is appropriate to lay down rules on such voluntary statements.

([1]) EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific Opinion on the essential composition of total diet replacement for weight control, *EFSA Journal* 2015;13(1):3957, and EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Scientific Opinion on the Dietary Reference Values for choline, *EFSA Journal* 2016;14(8):4484.

([2]) 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 Regulations (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).

(12) Nutrition and health claims are promotional tools that are used on a voluntary basis by food business operators in commercial communication, in line with the rules of Regulation (EC) No 1924/2006 of the European Parliament and of the Council ([1]). Given the particular role of total diet replacement for weight control products in the diet of people consuming them, the use of nutrition and health claims should not be allowed for such products. Taking however into account that information on the presence of dietary fibre in total diet replacement for weight control products can be useful for consumers, provision should be made to allow nutrition claims to be made on the addition of dietary fibre under certain conditions.

(13) Directive 96/8/EC required dietary fibre to be added to total diet replacement for weight control products. Due to the lack of scientific evidence in its regard the Authority could not establish a minimum content for dietary fibre in its latest opinion. For these reasons, it is appropriate to maintain the minimum amount for dietary fibre required under Directive 96/8/EC, if it is added to total diet replacement for weight control products.

(14) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([2]) requires Member States to enforce food law and to monitor and verify that the requirements are fulfilled by food and feed business operators at all stages of production, processing and distribution. In this context, in order to facilitate the efficient official monitoring of total diet replacement for weight control food, business operators placing such products on the market should provide the national competent authorities with a model of the label used and all relevant information considered necessary by the competent authorities for the purposes of verifying compliance with this Regulation, unless Member States have a different efficient monitoring system.

(15) In order to enable food business operators to adapt to the new requirements that may involve technical adaptation to the manufacturing process of the products concerned, this Regulation should apply from a date that is 5 years after its entry into force,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down the following specific requirements with regard to total diet replacement for weight control products:

(a) compositional requirements;

(b) requirements for labelling, presentation and advertising;

(c) notification requirements for placing the product on the market.

Article 2

Placing on the market

1. The product name under which food covered by Article 2(2)(h) of Regulation (EU) No 609/2013 is sold shall be 'total diet replacement for weight control'.

2. Total diet replacement for weight control products may only be placed on the market where they comply with this Regulation.

([1]) 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 (OJ L 404, 30.12.2006, p. 9).

([2]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Article 3

Compositional requirements

1. Total diet replacement for weight control products shall comply with the compositional requirements set out in Annex I, taking into account the specifications in Annex II.

2. The compositional requirements set out in Annex I shall apply to the food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

3. Total diet replacement for weight control products may contain other ingredients than the substances listed in Annex I only if their suitability has been established by generally accepted scientific data.

Article 4

Specific requirements concerning food information

1. In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for total diet replacement for weight control products:

(a) a statement that the product is only intended for healthy overweight or obese adults who intend to achieve weight reduction;

(b) a statement that the product should be not used by pregnant or lactating women, adolescents or by individuals suffering from a medical condition without the advice of a healthcare professional;

(c) a statement on the importance of maintaining an adequate daily fluid intake;

(d) a statement that the product provides adequate daily amounts of all essential nutrients when used in accordance with the instructions for use;

(e) a statement that the product should not be used for more than 8 weeks, or repeatedly for shorter periods than this, by healthy overweight or obese adults without the advice of a healthcare professional;

(f) instructions for appropriate preparation, where necessary, and a statement as to the importance of following those instructions;

(g) if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, a statement that the food may have a laxative effect;

(h) if dietary fibre is not added to the product, a statement that the advice of a healthcare professional must be sought regarding the possibility of supplementing the product with dietary fibre.

2. When appearing on the package or on the label attached thereto, the mandatory particulars listed in paragraph 1 shall be indicated in such a way as to meet requirements laid down in Article 13(2) and (3) of Regulation (EU) No 1169/2011.

3. The labelling, presentation and advertising of total diet replacement for weight control products shall not make any reference to the rate or amount of weight reduction which may result from its use.

Article 5

Specific requirements concerning the nutrition declaration

1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for total diet replacement for weight control products shall include the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation that are present in the product.

The mandatory nutrition declaration for total diet replacement for weight control products shall also include the amount of choline present, and if added, of dietary fibre.

2. In addition to the information referred to in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, the content of the mandatory nutrition declaration for total diet replacement for weight control products may be supplemented, with:

(a) the amounts of components of fat and carbohydrates;

(b) the amounts of any of the substances listed in the Annex to Regulation (EU) No 609/2013, where such an indication is not covered by paragraph 1 of this Article;

(c) the amount of any of the substances added to the product pursuant to Article 3(3).

3. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for total diet replacement for weight control products shall not be repeated on the labelling.

4. The nutrition declaration shall be mandatory for all total diet replacement for weight control products, irrespective of the size of the largest surface of the packaging or container.

5. All the nutrients included in the nutrition declaration for total diet replacement for weight control products shall meet requirements laid down in Article 31 to 35 of Regulation (EU) No 1169/2011.

6. By way of derogation from Articles 31(3), 32(2) and 33(1) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of total diet replacement for weight control products shall be expressed per total daily ration as well as, per portion and/or per consumption unit of the food ready for use after preparation in accordance with the manufacturer's instructions. Where appropriate, information may in addition refer to 100 g or 100 ml of the food as sold.

7. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and amount of nutrients of total diet replacement for weight control products shall not be expressed as a percentage of reference intakes set out in Annex XIII to that Regulation.

8. The particulars included in the nutrition declaration for total diet replacement for weight control products that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: 'Salt: X g (of which sodium: Y mg)'.

9. The statement 'very low calorie diet' may be used for total diet replacement for weight control products provided that the energy content of the product is below 3 360 kJ/day (800 kcal/day).

10. The statement 'low calorie diet' may be used for total diet replacement for weight control products provided that the energy content of the products is between 3 360 kJ/day (800 kcal/day) and 5 040 kJ/day (1 200 kcal/day).

Article 6

Nutrition and health claims

1. Nutrition and health claims shall not be made on total diet replacement for weight control products.

2. By way of derogation from paragraph 1, the nutrition claim 'added fibre' may be used for total diet replacement for weight control products provided that the dietary fibre content of the product is not less than 10 g.

Article 7

Notification

When total diet replacement for weight control products are placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.

Article 8

References to Directive 96/8/EC

References to Directive 96/8/EC in other acts shall be construed as references to this Regulation.

Article 9

Entry into force

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 26 September 2022.

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

Done at Brussels, 2 June 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Compositional requirements referred to in Article 3

1. ENERGY

The energy provided by total diet replacement for weight control products shall not be less than 2 510 kJ (600 kcal) and shall not exceed 5 020 kJ (1 200 kcal) for the total daily ration.

2. PROTEIN

2.1. The protein contained in total diet replacement for weight control products shall not be less than 75 g and shall not exceed 105 g for the total daily ration.

2.2. For the purposes of point 2.1, 'protein' shall be understood as protein whose protein digestibility-corrected amino acid score is 1.0 when compared to the reference protein as set out in Annex II.

2.3. The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins contained in total diet replacement for weight control products, and only in the proportions necessary for that purpose.

3. CHOLINE

The choline contained in total diet replacement for weight control products shall not be less than 400 mg for the total daily ration.

4. LIPIDS

4.1. **Linoleic acid**

The linoleic acid contained in in total diet replacement for weight control products shall not be less than 11 g for the total daily ration.

4.2. **Alpha-linolenic acid**

The alpha-linolenic acid contained in total diet replacement for weight control products shall not be less than 1,4 g for the total daily ration.

5. CARBOHYDRATES

The carbohydrates contained in total diet replacement for weight control products shall not be less than 30 g for the total daily ration.

6. VITAMINS AND MINERALS

Total diet replacement for weight control products shall provide at least the amounts of vitamins and minerals specified in Table 1 for the total daily ration.

Total diet replacement for weight control products shall not contain more than 250 mg of magnesium for the total daily ration.

Table 1

Vitamin A	(µg RE [1])	700
Vitamin D	(µg)	10
Vitamin E [2]	(mg)	10

Vitamin C	(mg)	110
Vitamin K	(µg)	70
Thiamin	(mg)	0,8
Riboflavin	(mg)	1,6
Niacin	(mg-NE [3])	17
Vitamin B_6	(mg)	1,6
Folate	(µg-DFE [4])	330
Vitamin B_{12}	(µg)	3
Biotin	(µg)	40
Pantothenic acid	(mg)	5
Calcium	(mg)	950
Phosphorus	(mg)	730
Potassium	(g)	3,1
Iron	(mg)	9
Zinc	(mg)	9,4
Copper	(mg)	1,1
Iodine	(µg)	150
Molybdenum	(µg)	65
Selenium	(µg)	70
Sodium	(mg)	575
Magnesium	(mg)	150
Manganese	(mg)	3
Chloride	(mg)	830

[1] Retinol equivalents
[2] Vitamin E activity of RRR α-tocopherol.
[3] Niacin equivalents
[4] Dietary folate equivalents: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from total diet replacement for weight control.

ANNEX II

Amino acid requirement pattern [1]

	g/100g protein
Cystine + methionine	2,2
Histidine	1,5
Isoleucine	3,0
Leucine	5,9
Lysine	4,5
Phenylalanine + tyrosine	3,8
Threonine	2,3
Tryptophan	0,6
Valine	3,9

[1] World Health Organisation/Food and Agriculture Organisation of the United Nations/United Nations University), 2007. Protein and amino acid requirements in human nutrition. Report of a Joint WHO/FAO/UNU Expert Consultation. (WHO Technical Report Series, 935, 284 pp.).