

**COMMISSION DELEGATED REGULATION (EU) 2017/1798****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)***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.

*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.

▼B

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.

▼B

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 27 October 2022.

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

▼B*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

▼M1**▼B**

4.2. Alpha-linolenic acid

▼M1

The alpha-linolenic acid contained in total diet replacement for weight control products shall not be less than 0,8 g for the total daily ration.

▼B

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.

▼M1

Total diet replacement for weight control products shall not contain more than 350 mg of magnesium for the total daily ration.

▼B*Table 1*

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

▼B

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.

▼B*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.).