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)

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2017/1522. (See end of Document for details)*

(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')[3] 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[4]. 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2017/1522. (See end of Document for details)*

(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.

(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[(5)]. 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[(6)] 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:

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2017/1522. (See end of Document for details)*

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.

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