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The European Commission establishes the specific compositional and information requirements for “total diet replacement for weight control products”: Commission Delegated Regulation (EU) 2017/1798

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The European Commission establishes the specific compositional and information requirements for “total diet replacement for weight control products”: Commission Delegated Regulation (EU) 2017/1798

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«Val més menjar poc i pair bé»
Catalan saying

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1. Introduction: Regulation (EU) No 609/2013 and total diet replacement for weight control

The objective of 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 is to establish the compositional and information requirements for various food categories, including those for total diet replacement for weight control (article 1.d). It is also aimed at providing greater legal security for companies operating in the sector and for the national authorities that apply the corresponding regulations.

This category of products has been included since, as indicated in recital no. 16 of Regulation No 609/2013, due to the growing rates of people with problems related to being overweight or obese an increasing number of foods are being placed on the market as a total diet replacement for weight control:

«Currently [2013], for such foods present in the market a distinction can be made between products intended for low calorie diets, which contain between 3,360 kJ (800 kcal) and 5,040 kJ (1,200 kcal), and products intended for very low-calorie diets, which normally contain fewer than 3,360 kJ (800 kcal). Given the nature of the foods in question it is appropriate to lay down certain specific provisions for them. Experience has shown that the relevant provisions laid down in Directive 96/8/EC ensure 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. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for foods intended to replace the whole of the daily diet including foods of which the energy content is very low, taking into account the relevant provisions of [the aforementioned] Directive 96/8/EC».

Specifically, «meal replacements for weight control» aimed at replacing part of the daily diet were considered food for specific nutritional use as stated in the

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4 Commission Directive of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22). This Community regulation only regulates the composition and labelling requirements for total diet replacement for weight control products with an energy content of between 800 and 1200 kcal. With regard to products with an energy content of less than 800 kcal, the sixth and seventh recitals states that the energy content of some products intended to replace the whole of the daily diet is very low and, therefore, «specific rules for these very low energy products will be adopted at a later date».
rules established in Directive 96/8/CE. «However, more and more foods intended for the general population have appeared on the market carrying similar statements which are presented as health claims for weight control». Therefore, to eliminate any possible confusion within this group of foods aimed at weight control, and for the sake of legal security and for consistency among the Union’s legislative acts, it was considered that such a claim should be regulated only under Regulation (EC) No 1924/2006 and should meet the requirements established therein.

Article 2.2(h) of Regulation No 609/2013 defines total diet replacement for weight control as «food that is specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet».


Article 11 of Regulation No 609/2013 empowers the European Commission to adopt, inter alia, delegated acts to establish specific compositional and information requirements applicable to total diet replacement for weight control and, in this context, the Commission approved, in June 2017, the Commission Delegated Regulation (EU) 2017/1522 of 2 June 2017 supplementing Regulation

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5 See recital no. 43 of Regulation No 609/2013. We can ask whether it considers that, legally, the claim “Glucomannan in the context of an energy restricted diet contributes to weight loss” is allowed for Glucomannan - konjac mannan [see 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)]; furthermore, this Regulation authorises the use of a similar claim for other products…


7 See also recital no. 43 of Regulation No 609/2013.
(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. Surprisingly, on page 7 of OJ L 234 of 12 September of the same year it published the following “Corrigendum”:

«The publication of Commission Delegated Regulation (EU) 2017/1522 is to be considered null and void».

Such an unusual correction should be understood, in our opinion, as an annulment of the Regulation in question, since publication is a sine qua non condition for the validity and applicability of a legal regulation. The annulment appears to have been due to a hasty action by the European Commission, since it did not take into account that the “Draft Motion for a Resolution pursuant to Rule 105(3) of the Rules of Procedure” regarding said Regulation proposed by MEPs Julie Girling and Annie Schreijer-Pierik, first rejected on 31 August in the Committee on the Environment, Public Health and Food Safety, was transferred by Julie Girling to the Plenary of the European Parliament during which, on 13 September, it failed, by only five votes, to reach the qualified majority required to reject the Commission’s proposal. This resulted in its publication in the interim period between votes.


The Commission surprised us again in October 2017 with the (re-) publication of Delegated Regulation (EU) 2017/1798, also based on article 11 of Regulation No 609/2013 which, as we have mentioned, empowered the European Commission to adopt certain delegated acts and especially considering that recital 27 of the latter Regulation states that this «requires the Commission to take into account, when adopting such rules, Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy restricted diets for weight reduction».

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The terms of Delegated Regulation (EU) 2017/1798 coincide with those of Delegated Regulation (EU) 2017/1522 (annulled through revocation of its publication). Therefore, in this article we will focus on the study and analysis of the content and effects of the former. It is worth remembering that the drafting of both these regulations was not improvised:

- The Commission consulted the European Food Safety Authority (EFSA) on the matter: the «EFSA’s Scientific Opinion on the essential composition of total diet replacement for weight control» constitutes the scientific basis for the requirements [of the] delegated Regulation.

- Specialists in Member States were consulted during the Expert Group meetings on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.

- Other stakeholders were consulted in the context of the Advisory Group on the Food Chain and Animal and Plant Health, which held a Working Group on the subject on 18 June 2015: «the possibility to provide written comments was granted to all interested parties and comments were taken into account where relevant [and] bilateral meetings were also held with all interested parties, as appropriate».

A four-week public consultation was held during which nine feedbacks were provided by means of electronic form on the “Better Regulation Portal” by ten interested parties, including food business operators and industry. The comments received mostly reflected the positions already expressed by the interested parties during the consultation phase mentioned above regarding the compositional requirements and the prohibition of the use of nutrition and health claims. However, the conclusion was that, «given the particular role of total diet replacement for weight control in the diet of people consuming them, such products should not be actively marketed with claims likely to attract the general public».

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12 See the second subsection (“Consultations Prior to the Adoption of the Act”) of the Explanatory Memorandum of preparatory document C/2017/3664 final.

13 Reference E02893 in the Register of Commission Expert Groups and other similar entities (see also the second subsection of the Explanatory Memorandum of preparatory document C/2017/3664 final).

14 Reference E00860 in the Register of Commission Expert Groups and other similar entities.


16 See also the second subsection of the Explanatory Memorandum of preparatory document C/2017/3664 final.
population». Likewise, comments related to the compositional requirements laid down in this delegated Regulation were not taken into account as they did not follow the EFSA's Scientific Opinion, with respect to the safety aspects of the products concerned. It seems that the European Commission, despite the explanations received from the industry regarding the difficulty of producing these foods with the composition required by the EFSA in an organoleptically pleasing form, with acceptable durability (no premature rancidity) and at a reasonable price, it ignored these comments and strictly followed the position expressed in the aforementioned EFSA's Scientific Opinion.


In Article 1 ("Subject matter") it states that Commission Delegated Regulation (EU) 2017/1798 «... 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 2.1 ("Placing on the market") specifies that the product name under which food covered by article 2.2(h) of Regulation no.609/2013 is sold, shall be «total diet replacement for weight control». Article 2.2 establishes the basic general rule of Commission Delegated Regulation (EU) 2017/1798:

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

Compositional requirements include:

- 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 (see: https://app.box.com/s/sp0dxpil22rsbrbe3gabf3zkde9cd4kc):

« 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.

17 Ibidem.

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\(^\text{19}\).

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\(^\text{20}\).

4. LIPIDS

4.1. Linoleic acid

The linoleic acid contained in total diet replacement for weight control products shall not be less than 11 g for the total daily ration [in Directive 96/8/EC the minimum is 4.5 g: 11 g represents an increase of 144%].

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 [Directive 96/8/EC specifies no minimum: a high minimum of linoleic acids and alpha linoleic acid increases the risk of premature rancidity].

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.

\(^{19}\) Comment provided by Antonio García Gabarra: «Directive 96/8/CE, which regulates only total diet replacement for weight control products of 800 to 1200 kcal, establishes a contribution of between 25 and 50% of daily energy for proteins, up to a maximum of 125 g a day. Thus, 25% of 800 kcal is 200 kcal, equivalent to 50 g of protein. Regulation 1169/2011 establishes a reference intake of 50 g for protein. The hike to a minimum of 75 g represents an increase of 50% over 50 g.».

\(^{20}\) Comment provided by Antonio García Gabarra: «The EFSA proposed a minimum of 550 mg, which corresponds to the adequate intake for adults recommended by the Food and Nutrition Board – NAS (1998). However, the EFSA recommended an adequate intake for adults of 400 mg (EFSA J 2016;14(8):4484) for which the Commission, at the request of the industry, required confirmation from the EFSA for these replacement products.». 
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 [see: https://e-contrast.blogspot.com.es/2018/01/commission-delegated-regulation-eu.html] 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.«

- The compositional requirements established in Annex I shall be applicable to those products ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

- Lastly, it includes a somewhat imprecise provision: «total diet replacement for weight control products may contain ingredients other than the substances listed in Annex I only if their suitability has been established by generally accepted scientific data».

However, we do not want to overload our review with technical data, especially considering that these are included in Commission Delegated Regulation (EU) 2017/1798 and can be easily consulted, so we will now list the specific requirements concerning food information.

5. Information for the consumer

As is logical, in addition to the mandatory particulars specified in article 9.1 of Regulation (EU) No 1169/2011 on the provision of food information to consumers, total diet replacement for weight control products must include the

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21 Comment provided also by Antonio García Gabarra: «The Commission reiterates the maximum recommended by the EFSA. However, as recognised by the Food Safety Authority, this maximum was established by the Scientific Committee for Food in 2001 as a “Tolerable Upper Safe Level” for magnesium added to food in the form of easily dissociable salts due to the risk of causing diarrhoea. However, this maximum should not include magnesium that is naturally present in other ingredients (milk, soy, nuts, etc.) as it does not cause diarrhoea. Thus, the content of magnesium in these replacement products ranges from between 150 and 250 mg, well below the 375 mg reference intake of Regulation 1169/2011, which seems rather inconsistent.».

22 See a contrary opinion in: Vidreras, C., “Ventajas e inconvenientes de los productos sustitutivos de la dieta completa para el control de peso”, BoDIA/Co, No. 26, 2017, 24-25 [the author justifies such an open regulation in order to avoid hindering innovation, and refers to the fifth recital of Commission Delegated Regulation (EU) 2017/1798].

following *additional mandatory particulars* (article 4 of Commission Delegated Regulation (EU) 2017/1798):

«[1.] 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 not be 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; [and]

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 fibre²⁴.

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 use²⁵.*

22.11.2011, p. 18). See the sixth recital of Commission Delegated Regulation (EU) 2017/1798 which specifies that the «total diet replacement for weight control products must comply with Regulation (EU) No 1169/2011…» and that «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 ».

²⁴ Directive 96/8 set a contribution of 10 to 30 g daily. We are surprised by the elimination of the minimum amount, as the lack of fibre in these diets causes constipation, without considering the benefits of fibre for illnesses often associated with excess weight.

²⁵ Emphasis added by the authors.
Article 5 of the Commission Delegated Regulation (EU) 2017/1798 includes the “specific requirements concerning the nutrition declaration”. This information is highly important as it is essential that it be declared explicitly and in detail in order to guarantee the appropriate use of total diet replacement for weight control products by healthy obese or overweight adults who consume them, without forgetting health professionals, who can advise on their suitability in certain cases. Therefore, for the information to be more complete, the nutrition information must include the particulars required by Regulation No. 1169/2011 (excluding application of the exemption specified in point 18 of Annex V of said Regulation; in this way, the obligation to provide nutrition information for all total diet replacement for weight control products, regardless of the size of the packaging or container, is reiterated).

In this regard, the aforementioned article 5 of Delegated Regulation states that, as well as the particulars referred to in article 30.1 of Regulation No. 1169/2011, the mandatory nutrition information for total diet replacement for weight control products shall include the quantity of each mineral substance and each vitamin mentioned in Annex I of the Commission Delegated Regulation (EU) 2017/1798 that is present in the product: “the mandatory nutrition declaration for total diet replacement for weight control products shall also include the amount of choline present\(^{26}\), and if added, of dietary fibre\(^{27}\).”

According to the same article of Delegated Regulation, 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 [in article 5];

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

The often-cited article 5 of Commission Delegated Regulation (EU) 2017/1798 contains other provisions:

● Notwithstanding the provisions of article 30.3 of Regulation (EU) No. 1169/2011, the information included in nutritional information for total diet replacement for weight control products shall not be repeated on the labelling (article 5.3).

\(^{26}\) Idem.

\(^{27}\) Idem.
● Furthermore, nutritional information shall be mandatory for all total diet replacement for weight control products, regardless of the size of the maximum surface area of its packaging or container (article 5.4).

● All the nutrients included in the nutrition declaration for total diet replacement for weight control products shall comply with the requirements established in articles 31 to 35 of Regulation (EU) No 1169/2011 (article 5.5).

● «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» (article 5.6). In any case, where appropriate, information may in addition refer to 100 g or 100 ml of the food as sold (ibidem).

● «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 Regulation28»29 (article 5.7).

● The particulars included in the information for the total diet replacement for weight control products that do not appear in Annex XV of Regulation (EU) No. 1169/2011 will be presented after the corresponding entry in said Annex to which they belong or form part of (article 5.830).

28 Idem.


30 This article also states that the «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» and that «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)’». 
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)\(^{31}\) (article 5.9).

The aforementioned declaration of «very low calorie diet» can be used for all total diet replacement for weight control products\(^{32}\) (article 5.10).

In this context, we will emphasise that [as done in the 10th recital of Commission Delegated Regulation (EU) 2017/1798] the nutritional needs of healthy obese or overweight adults may differ from those of the rest of the population and in that, furthermore, the total diet replacement for weight control are foods that completely replace the daily diet: «for those reasons, the expression of nutrition information regarding 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 [...] therefore [is] not [...] allowed».

Although we have tried to avoid an excess of technical data and to analyse thoroughly very detailed or even repetitive provisions, it seemed appropriate to pay special attention to requirements related to information for consumers insofar as the products in question are often consumed indiscriminately, without professional follow-up, etc. In this sense, this section cannot be considered complete without referring to the controversial article 6 ("Nutrition and health claims") which states the following:

«1. Nutrition and health claims shall not be made on total diet replacement for weight control products\(^{33}\).

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.»

The drastic prohibition provided for in article 6.1 is justified by the fact that nutrition and health claims are the promotional tools used voluntarily by food companies in their commercial communication, in accordance with Regulation (EC) No 1924/2006; therefore, and in virtue of the particular purpose of total diet replacement for weight control products in the diet of the people who consume them, the use of nutrition and health claims should not be permitted in these products.

\(^{31}\) That is, it can be used for products that provide equal to or more than 600 kcal, or less than 800 kcal.

\(^{32}\) In other words, it can be used for products with a contribution of between 800 and 1200 kcal.

\(^{33}\) Emphasis added by the authors [our colleague Antonio García Gabarra mentioned that this criterion coincides with that applied in the Commission Delegated Regulation (EU) 2016/128].
The previous prohibition, specific to this category of products, reflects the concern of the legislator regarding the risk that an inadequate consumption (whether excessive or insufficient) may entail for consumers: in particular the fact that, «given that total diet replacement for weight control products may have a significantly reduced energy value, and that they may be consumed as the only source of nutrition for several weeks by healthy obese or overweight adults with the intention of losing weight, without consulting health professionals, under Commission Delegated Regulation (EU) 2017/1798 both the possibility of formulating nutrition claims or health claims have been prohibited for this type of food»\(^{34}\).

In any case, considering that the information about the presence of fibre in the total diet replacement for weight control products can be useful for consumers, it is expected that nutrition statements about the addition of dietary fibre will be allowed provided that the content of this *ingredient* is not less than 10 g\(^{35}\).

### 6. Other provisions

It is worth mentioning that article 7 of Commission Delegated Regulation (EU) 2017/1798 establishes a “notification” system for facilitating the efficient monitoring of this type of product, so that, when total diet replacement for weight control products are introduced into the market the food company operator shall notify the competent authority of each Member State in which the product is sold of the information included in the labelling, by sending a sample of the label and any other information that the competent authority may reasonably request for the purpose of determining compliance with the new Delegated Regulation, unless a Member State is exempted from this obligation under a national system that guarantees official efficient control of the product in question (Directive 96/8/EC does not require notification of total diet replacement for weight control products with contribution of 800 to 1200 kcal but in some Member States it was required for products with a contribution of less than 800 kcal).

It should be added that Commission Delegated Regulation (EU) 2017/1798 came into force «on the twentieth day following that of its publication in the Official Journal of the European Union», but «it shall only apply from 27 October 2022» (article 9\(^{36}\)).

### 7. Conclusions

To summarise:

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36 The reason for such an extended period is to give companies time to adapt to the new requirements, which may involve technical adaptations to the manufacturing process of the products in question [see recital no. 15 of Commission Delegated Regulation (EU) 2017/1798].
- after the events commented on at the beginning of this report, in October 2017 Commission Delegated Regulation (EU) 2017/1798 was finally published, which establishes the specific compositional and information contribution requirements applicable to total diet replacement for weight control products;

- given the important changes introduced in total diet replacement for weight control products, particularly with regard to the increase in the minimum amount of proteins and essential fatty acids, the Community legislator has granted a significant period for adaptation to the new regulation (however, in principle, companies who wish to do so may apply it voluntarily as from now);

- nutrition or health claims shall not be permitted for total diet replacement for weight control products, nor may they refer to the speed or magnitude of weight loss that can be achieved through their use; and

- however, as already mentioned, some specific declarations (for example «low-calorie diet» or «added fibre») may be allowed provided that the conditions laid down by the Regulation are met.

In any case, the objective of this review is to analyse a Community regulation that will still take some time before it is fully applied; therefore, there is still ample opportunity to continue to explore Commission Delegated Regulation (EU) 2017/1798.