

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY  
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT  
POLICY

Voluntary  Public

**Date:** 10/25/2017

**GAIN Report Number:** E17067

## EU-28

**Post:** Brussels USEU

### **The Skinny on New EU Rules for Weight Loss Products**

**Report Categories:**

FAIRS Subject Report

**Approved By:**

Jennifer Lappin

**Prepared By:**

Hilde Brans

**Report Highlights:**

New EU rules for "total diet replacement for weight control" will become applicable on October 27, 2022. Commission Delegated Regulation 2017/1798 sets out specific compositional and labeling requirements as well as a notification procedure under which food business operators are required to send copies of their product labels to the competent authority of each Member State where the product will be marketed.

## New EU Rules on Weight Loss Products

New EU rules for “total diet replacement (TDR) for weight control” will become applicable on October 27, 2022. [Commission Delegated Regulation 2017/1798](#), published on October 7, 2017, sets out specific compositional and labeling requirements for TDRs. A new notification procedure requires food business operators to send a copy of the product label to the competent Member State authorities in order to verify compliance with the new rules. The regulation provides for a 5-year transitional period. From October 27, 2022, non-compliant weight loss products may not be marketed in the EU.

### Labeling Requirements

Under regulation 2017/1798, TDRs may only be marketed under the name “total diet replacement for weight control”. TDRs must comply with the EU’s general food labeling rules set out in the Food Information to Consumers (FIC) regulation 1169/2011. However, regulation 2017/1798 introduces a set of additional mandatory labeling requirements and exceptions to the FIC regulation. Specific labeling requirements set out in [Article 4 of regulation 2017/1798](#) include:

- A statement that the product is **only intended for healthy overweight or obese adults who intend to lose weight**
- A statement that the product **should not be used by pregnant or lactating women, adolescents or individuals suffering from a medical condition without the advice of a healthcare professional**
- A statement on **the importance of maintaining an adequate daily fluid intake**
- A statement that the product **provides adequate daily amounts of essential nutrients when used in accordance with the instructions for use**
- A statement that the product **should not be used for more than 8 weeks or repeatedly for shorter periods without the advice of a healthcare professional**
- **Instructions for appropriate preparation**, and where necessary a statement as to the importance of following those instructions
- For products with a **polyols content exceeding 20 g per day**, a statement that **the food may have a laxative effect**
- If dietary fiber is not added, a statement **that the advice of a healthcare professional must be sought regarding the possibility of supplementing the product with dietary fiber**

Mandatory information must be presented in a minimum font size of 1.2 mm or 0.9 mm for packages or containers with a labeling surface smaller than 80 cm<sup>2</sup>. It will be prohibited to make any reference on the label, or packaging of a TDR to the rate or amount of weight reduction that may result from its use.

### Nutrition Declaration

The nutrition declaration is mandatory for all TDRs, irrespective of the size of the package or container. The FIC regulation requires the declaration of the energy value and the amounts of fat, saturates,

carbohydrates, sugars, protein and salt. Under Article 5 of regulation 2017/1798, the nutrition declaration must also include the amount of each mineral substance and of each vitamin listed in Annex I, the amount of choline and, if added, of dietary fiber. Information provided in the nutrition declaration may not be repeated on the label.

Derogating from the FIC regulation, the energy value and the amounts of nutrients must be given per total daily ration as well as per portion and/or consumption unit rather than per 100 g or 100 ml. The energy value and the amount of nutrients may not be expressed as a percentage of reference intakes set out in Annex XII to the FIC regulation.

The statement “**very low calorie diet**” may be used provided that the energy content is lower than 800 kcal per day. The statement “**low calorie diet**” may be used when the energy content is between 800 kcal and 1200 kcal per day.

### **Nutrition and Health Claims**

Nutrition and health claims are NOT allowed on TDRs, except for “added fiber” if the TDR contains minimum 10 g fiber.

### **Compositional Requirements**

Compositional requirements per daily ration set out in Annex I to regulation 2017/1798 include:

- Energy provided by TDRs must be at least 600 kcal and may not exceed 1200 kcal
- Protein content must be minimum 75 g and maximum 105 g
- Choline content must be minimum 400 g
- Linoleic acid content must be minimum 11 g
- Alpha-linoleic acid content must be minimum 1.4 g
- Carbohydrates content must be minimum 30 g
- Minimum amounts for vitamins and minerals (Table 1)
- Maximum magnesium content is 250 g

### **Notification Requirement**

Food business operators must notify the competent authority of each Member State where the TDR is marketed by sending a copy of the product label and any other information the competent authority “may reasonably request to establish compliance with the regulation”. Member States with an efficient national monitoring system in place may exempt food business operators from the notification obligation.

### **EU Industry Criticizes New Rules**

Following the publication of the new TDR regulation 2017/1798, Specialized Nutrition Europe (SNE) and Very Low Calorie Diet Industry Group (VLCDIG), stated in a [news release](#) that the new law “does

not take into account current food technology or commercial considerations, or how consumers make food choices and, most importantly, consumer safety.” Both organizations are concerned that the new rules will impose an unnecessary and disproportionate burden on the sector and could ultimately result in a category of products, which has been on the market safely for decades, ceasing to exist.

### **Related Reports**

- [EU FAIRS Report](#)
- [New EU Dietetic Rules](#)
- [New EU Rules on Sports Food](#)