



News on food products intended for specific groups of the population

Royal Decree 1412/2018 regulating the communication procedure of placing food products intended for certain population groups on the Spanish market

Background

Since the mid-seventies, food products intended for dietary purposes and/or for particular nutritional uses have been regulated in Spain by Royal Decree 2685/1976. By means of such Royal Decree, the technical-healthcare regulations applicable to these products were approved. Thereafter, several modifications and further regulations on this matter have taken place. The considerable period of time elapsed, the scientific developments, and the gradual regulation of these products by EU regulations, have made Spanish legislation on this matter partially obsolete. For that reason, Spanish lawmakers have considered it necessary to simplify such Spanish legislation and adapt it to the control mechanisms provided by European regulations, in particular, 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 delegated acts adopted pursuant to this Regulation.

Communication of placing on the market

The new Royal Decree 1412/2018 repeals the old one from 1976, and reorders these products, which are now called "food products destined for certain population groups" and which are grouped into the following categories: (a) infant formula, (b) follow-on formula based on protein hydrolysates, (c) follow-on formula based on substances other than those incorporated in the previous formulas, (d) foods for special medical

purposes, and (e) total diet replacement for weight control.

Prior or simultaneous to the placing of any of these products on the Spanish market, the entity whose name and address appears on the label must send a notification using electronic means to the competent authorities. Such competent authorities are either ones of the Autonomous Region where the company has its registered offices or, in case such company is not registered in Spain, the Spanish Agency for Food Safety and Nutrition. The notification must include a copy of the product's label and, if applicable, the EU Member State(s) where such product is already being legally marketed. Moreover, the authorities may request further information when they consider it necessary for effective control purposes. The inaccuracy, falsification or omission of essential data will imply that the product cannot continue being marketed. Labeling modifications as well as termination of placing on the market must also be notified.

Public provision of dietary products

The new Royal Decree includes provisions regarding how the National Health System will work when it comes to dietary products. The inclusion of foods for special medical purposes in the National Health System, therefore, their financing with public funds, will require a favorable decision of the competent authority responsible for receiving the notification of placing on the market of the relevant product. In case the authorities are regional, they must communicate their favorable decision to the Spanish Agency for Food Safety and Nutrition.