
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision to enforce, in England, Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific information and compositional requirements for food for special medical purposes (“the Delegated Regulation”). They do this by amending the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688) (“the 2016 Regulations”), which make provision to enforce the requirements of Regulation (EU) No. 609/2013 of the European Parliament and of the Council on the provisions of food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (“the EU Regulation”). The EU Regulation sets out the general information and compositional requirements for certain categories of food and the 2016 Regulations provide for the enforcement of those requirements by applying, with modifications, certain provisions of the Food Safety Act 1990. The Delegated Regulation sets out the specific information and compositional requirements for food for special medical purposes.

Regulation 4 amends the 2016 Regulations so that specified provisions of the Delegated Regulation become ‘specified EU requirements’, to which the modified provisions of the Food Safety Act 1990 apply. This enables an improvement notice to be served requiring compliance. Failure to comply with an improvement notice is a criminal offence.

References to the provisions of the Delegated Regulation are to be read as references to those provisions as amended from time to time.

A definition of food for special medical purposes is contained in the EU Regulation and this includes such food for infants. However, from 22 February 2019 the Delegated Regulation applies only to food for special medical purposes other than that developed to satisfy the nutritional needs of infants. Regulation 3(2)(b) therefore ensures that enforcement of the Delegated Regulation is similarly limited. Regulation 5 amends the definition of medical food in the Medical Food (England) Regulations 2000 (S.I. 2000/845) (“the 2000 Regulations”), which will continue to apply to medical food developed to satisfy the nutritional needs of infants, so that they only apply to such food.

Regulation 3(3) includes transitional provisions for medical food that is labelled or placed on the market before 22 February 2019. Such food may continue to be marketed until stocks are exhausted as long as they are sold in compliance with specified requirements of the EU Regulation and regulation 3(1) and (2) of the 2000 Regulations.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.