
EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations implement Commission Directive [1999/21/EC](#) on dietary foods for special medical purposes (O.J. No. L91, 7.4.99, p. 29).

Article 1(2) of the Directive classifies such foods as foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet, and regulation 2 defines medical food as food within that classification.

Article 2 of the Directive calls for member States to ensure that such food may only be marketed if it complies with the Directive, and Articles 3 and 4 of the Directive lay down requirements for formulation, composition and instructions for use of such food, and for its naming and labelling; regulation 3(1) prohibits the sale of medical food unless those requirements are met.

Article 5 of the Directive requires notification to competent authorities of the placing on the market of products covered by the Directive when manufactured in, or imported from outside, the European Community, and regulation 3(2) and (3) prohibits the sale of medical foods by manufacturers and importers covered by a notification requirement unless they have complied with it, and specifies the Food Standards Agency to be the recipient of the notification.

Enforcement responsibilities, offences and penalties, and application of provisions of the Food Safety (Northern Ireland) Order 1991 are set out in regulations 4, 5 and 7. The Regulations also provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive [89/397/EEC](#) (O.J. No. L186, 30.6.89, p. 23) on the official control of foodstuffs (regulation 6).