
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, implement Article 9 of Council Directive [89/398/EEC](#) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive [1999/41/EC](#) of the European Parliament and of the Council (“the Directive”).

The Regulations cover foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption and which are marketed as suitable for categories of consumers with disturbed digestive processes or metabolism or in a special physiological condition, or for infants or young children in good health, but which are neither covered, nor to be covered, by other Directives on specific types of foodstuffs for particular nutritional uses (definition of “PNU food” in regulation 2(1)).

Article 9 of the Directive requires notification (followed, where necessary, by provision of supplementary material) to competent authorities of placing on the market of such products; the requirement applies when the product is manufactured or imported, and regulation 3 of these Regulations prohibits sale of products of that type by manufacturers and importers covered by the requirement unless they have complied with the notification requirements. “Sell” is given an extended meaning (regulations 2(1) and 6(a)). In the case of products manufactured in Scotland, or imported into Scotland from outside the United Kingdom, the Food Standards Agency is the competent authority.

Enforcement responsibilities, offences and penalties and application of provisions of the Food Safety Act 1990 are set out in regulations 4, 5 and 6 of these Regulations.

Labelling provisions of the Directive are implemented in the Food Labelling Regulations 1996 (S.I.1996/1499).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect which these Regulations would have on business costs, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.