
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive [2002/46/EC](#) of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (“the Directive”).

The Regulations concern the sale (as defined in regulation 2(1)) of food supplements which are sold as food and presented as such (regulation 3). A food supplement is defined as a food sold in dose form whose purpose is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination (regulation 2(1)).

With effect from 1st August 2005, the Regulations—

- (i) prohibit the sale of a food supplement to the ultimate consumer unless it is prepacked (regulations 4 and 2(2));
- (ii) prohibit the sale of a food supplement in the manufacture of which a vitamin or mineral has been used, unless certain compositional requirements are met, subject to a transitional provision (regulation 5 and Schedules 1 and 2);
- (iii) prohibit the sale of a food supplement which is ready for delivery to the ultimate consumer or a catering establishment unless certain requirements as to labelling, presentation and advertising of the product are met (regulations 6 and 7).

The prohibition in Article 6(2) of the Directive (labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties) is already implemented in the Food Labelling Regulations 1996 (S.I. [1996/1499](#)) (regulation 40(1) and Schedule 6, Part I, paragraph 2).

The Regulations make provision as to responsibilities for enforcement (regulation 8); create offences and penalties (regulation 9) and apply certain provisions of the Food Safety Act 1990 (regulation 11). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive [89/397/EEC](#) (O.J. No. L 186, 30.6.89, p.23) on the official control of foodstuffs (regulation 10).

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 Labelling and Standards Division of the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.