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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations implement in Wales 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.

2. 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)).

3. The Regulations — with effect from 1st August 2005 —

- (a) prohibit the sale of a food supplement to the ultimate consumer unless it is prepacked (regulations 4 and 2(2)),
- (b) 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(3) and Schedules),
- (c) 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).

4. 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 (regulation 40(1) and Schedule 6, Part I, paragraph 2).

5. 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](#) (OJNo. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 10).

6. A Regulatory appraisal for these Regulations has been prepared and placed in the Library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff CF10 1EW.