EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 ("the principal Regulations").

These Regulations implement–

(a) Commission Directive 2004/5/EC (O.J. No. L 14, 21.1.04, p.19) amending Directive 2001/15/EC to include certain substances in the Annex; and

(b) Commission Directive 2004/6/EC (O.J. No. L 15, 22.1.04, p.31) derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products.

The principal Regulations apply to food for most particular nutritional uses ("designated PNU foods"). Such foods are defined in regulation 2(1) of the principal Regulations but do not include infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children. Where there has been added to a designated PNU food a substance falling within one of the following categories: vitamins; minerals; amino acids; carnitine and taurine; nucleotides; choline and inositol for a specific nutritional purpose, the principal Regulations prohibit (in most cases from 1st April 2004) the sale of such food unless the substance is listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, Schedule 1 or 2.

These Regulations–

(a) allow until 1st January 2007, subject to conditions, the sale of designated PNU foods to which there has been added a substance listed in new Schedule 3 to the principal Regulations (regulations 4(c) and 7 and Schedule 2);

(b) add another substance to the list of substances in the category carnitine and taurine which may be added for specific nutritional purposes in designated PNU foods (regulation 5);

(c) add six substances to the list of substances in the category amino acids which may be added for specific nutritional purposes in foods for specific medical purposes (regulation 6 and Schedule 1); impose a condition of use in the case of one of these substances (regulation 4(a) and Schedule 1);

(d) in implementation of the Annex to Directive 2001/15/EC (O.J. No. L 52, 22.2.01, p.19) provide that for amino acids also the sodium, potassium, calcium and magnesium salts, as well as their hydrochlorides may be used (regulation 6 and Schedule 1); and

(e) update the definition of "Directive 2001/15" (regulation 3).

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, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.