EUROPEAN COMMUNITIES (ADDITIVES IN FEEDINGSTUFFS) (AMENDMENT) REGULATIONS 1995

I, IVAN YATES, Minister for Agriculture, Food and Forestry, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purposes of giving effect to Council Directive No. 93/114/EC of 14 December 19931 and Commission Directive No. 94/40/EC2 of 22 July 1994 and for the purpose of giving further effect to Council Directive No. 70/524/EEC of 23 November, 19703, as amended, hereby make the following Regulations:

REG 1

1. (1) These Regulations may be cited as the European Communities (Additives in Feedingstuffs) (Amendment) Regulations, 1995.
(2) The European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1995, and these Regulations may be cited together as the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1995.

REG 2

2. In these Regulations "the Regulations of 1989" means the European Communities (Additives in Feedingstuffs) Regulations, 1989 (S.I. No. 49 of 1989).

REG 3

3. The Regulations of 1989 are hereby amended by—
(a) the substitution in Regulation 2 (1) for the definition of "Council Directive" of the definition set out in the First Schedule to these Regulations,
(b) the substitution of the following Regulation for Regulation 11:
"11. (1) A person shall not market any of the additives specified in the First or Second Schedule to these Regulations or, in the case of a medicinal additive, specified in the additive licence, unless the particulars (which shall be clearly visible, readily legible and indelible) set out in paragraph (2) in the case of such additives with the exception of enzymes and micro-organisms or, in the case of enzymes or microorganisms, in paragraph (3) of this Regulation, are set out on the package or container in which they are packed or on a label attached thereto and, in addition to the said particulars, the relevant particulars (which shall be clearly visible, readily legible and indelible) set out in paragraph (4) of this Regulation are set out on the package or container in which the additives are packed or on a label attached thereto.
1O.J. No. L 334, 31.12.1993, p.24.
2O.J. No. L 208, 11.8.1994, p.15.
3O.J. No. L 270, 14.12.1970, p.1.
(2) The particulars referred to in paragraph (1) of this Regulation to be displayaed in respect of all additives, with the exception of enzymes and microorganisms, shall be—

(a) the specific name of the additive being the name used in the First or Second Schedule to these Regulations or, in the case of medicinal additives, in accordance with the additive licence;
(b) the name or business name and the address or registered place of business of the person responsible for the particulars specified in this paragraph and paragraph (4) of this Regulation; and
(c) the net weight and, in the case of liquid additives, either the net volume or the net weight.
(3) The particulars referred to in paragraph (1) of this Regulation to be displayed in respect of enzymes and microorganisms shall be in respect of—
(a) enzymes:
(i) the specific name of all active components according to their enzymatic activities in accordance with the First or Second Schedule to these Regulations,
(ii) the identification number according to the International Union of Biochemistry,
(iii) the activity units, expressed as μmole of product released per minute per gram or per mililitre of enxymatic preparation,
(iv) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph and the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,
(v) the expiry date of the guarantee of the activity units in the preparation or the storage life from the date of manufacture,
(vi) the batch reference number and the date of manufacture,
(vii) the words 'to be used exclusively in the manufacture of feedingstuffs',
(viii) the directions for use and, where appropriate, the safety recommendation where the column entitled 'Other provisions', in the First or Second Schedule to these Regulations, contains special provisions concerning the additives,
(ix) the net weight and, for liquid additives, either the net volume or the net weight, and
(x) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations;
(b) microorganisms:
(i) the identification of the strain(s) in accordance with the First or Second Schedule to these Regulations,
(ii) the file number of the strain(s),
(iii) the number of colony-forming units (per gram of product),
(iv) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph and the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,
(v) the expiry date of the guarantee of the number of colony-forming units (per gram of product) or the storage life from the date of manufacture,
(vi) the batch reference number and the date of manufacture,
(vii) the words 'to be used exclusively in the manufacture of

feedingstuffs',
(viii) the directions for use and, where appropriate, a safety recommendation where the column entitled 'Other provisions', in the First or Second Schedule to these Regulations, contains special provisions concerning the additives,
(ix) the net weight and, for liquid additives, either the net volume or the net weight, and
(x) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations;
(4) The particulars referred to in paragraph (1) of this Regulation shall be in respect of—
(a) antibiotics, growth promoters, coccidiostats and other medicinal substances:
(i) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label,
(ii) the active substance level,
(iii) the expiry date of the guarantee of the active substance level of the product or the storage life from the date of manufacture,
(iv) batch reference number,
(v) date of manufacture,
(vi) the indication 'to be used exclusively by manufacturers of pre-mixtures for compound feedingstuffs',
(vii) directions for use, and
(viii) where appropriate, a safety recommendation regarding use in the case of additives which are the subject of special provisions in the additive licence;
(b) vitamin E: the alpha-tocopherol level and expiry date of the guarantee of the alpha-tocopherol level or the storage life from the date of manufacture;
(c) vitamins (other than vitamin E), provitamins and substances having a similar effect: the active substance level and expiry date of the guarantee of the active substance level or the storage life from the date of manufacture;
(d) trace elements, colorants including pigments, preservatives and other additives with the exception of those belonging to the groups of enzymes and microorganisms: the active substance level; and
(e) the additives referred to in sub-paragraphs (b), (c) and (d) of this paragraph: the indication 'to be used exclusively in the manufacture of feedingstuffs'.";
(c) the substitution of the following Regulation for Regulation 14:
"14. (1) A person shall not market premixtures unless the particulars (which shall be clearly visible, readily legible and indelible) specified in paragraphs (2) and (3) of this Regulation are given on the package or container in which the premixtures are packed or on a label affixed thereto.
(2) The particulars referred to in paragraph (1) of this Regulation in respect of premixtures shall be—
(a) the description 'premixture';
(b) the indication 'to be used exclusively in the manufacture of

feedingstuffs', except for the premixtures referred to in paragraph (3) (a) of this Regulation;
(c) directions for use, and any safety recommendations regarding the use of the premixture,
(d) the animal species or category of animal for which the premixture is intended;
(e) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph and paragraph (3) of this Regulation; and
(f) the net weight and, in the case of liquids, either the net volume or net weight.
(3) The particulars referred to in paragraph (1) of this Regulation, in addition to those specified in Paragraph (2) of this Regulation, shall be, in respect of premixtures containing—
(a) antibiotics, growth promoters, coccidiostats and other medicinal substances:
(i) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label,
(ii) the specific name of the additive being the name used in the additive licence,
(iii) the active substance level,
(iv) the expiry date of the guarantee of that level or the storage life from the date of manufacture, and
(v) the indication 'to be used exclusively by manufacturers of compound feedingstuffs';
(b) substances having antioxidant effects:
(i) the specific name of the additive being the name used in the First or Second Schedule to these Regulations, and
(ii) the active substance level: provided that a maximum level is fixed for complete feedingstuffs in the First or Second Schedule to these Regulations;
(c) colourants, including pigments:
(i) the specific name of the additive, if any, being the name used in the First or Second Schedule to these Regulations and, if no name is given, the common chemical name of the additive, and
(ii) the active substance level: provided that a maximum level is fixed for complete feedingstuffs in the First or Second Schedule to these Regulations;
(d) vitamin E:
(i) the specific name of the additive, if any, being the name used in the First or Second Schedule to these Regulations and, if no name is given, the common chemical name of the additive,
(ii) the alpha-tocopherol level, and
(iii) the expiry date of the guarantee of that level or the storage life from the date of manufacture;
(e) vitamins (other than vitamin E), provitamins and substances having a similar effect:
(i) the specific name of the additive, if any, being the name used in the First or Second Schedule to these Regulations or the common chemical name of the additive where no such name is given in the said Schedules,
(ii) the active substance level, and
(iii) the expiry date of the guarantee of that level or the

storage life from the date of manufacture;
(f) trace elements:
(i) the specific name of the additive being the name used in the First or Second Schedule to these Regulations, and
(ii) the level of the various elements in so far as a maximum level is fixed for complete feedingstuffs in the First or Second Schedule to these Regulations;
(g) preserving agents:
(i) the specific name of the additive being the name used in the First or Second Schedule to these Regulations, and
(ii) the active substance level, provided that a maximum level is fixed for complete feedingstuffs in the First or Second Schedule to these Regulations;
(h) enzymes:
(i) the specific name of all active components according to their enzymatic activities in accordance with the First or Second Schedule to these Regulations;
(ii) the identification number according to the International Union of Biochemistry;
(iii) the activity units (activity units per g or activity units per ml);
(iv) the expiry date of the guarantee of the activity units (expressed as activity units per gram or per mililitre of premixture) or the storage life from the date of manufacture,
(v) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label; and
(vi) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations;
(i) micro-organisms:
(i) the identification of the strains in accordance with the First or Second Schedule to these Regulations;
(ii) the file number of the strains;
(iii) the number of colony-forming units (CFU/g);
(iv) the expiry date of the guarantee of the number of colony-forming units (CFU) in the premixture expressed as CFU per gram of premixture or the storage life from the date of manufacture,
(v) the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label; and
(vi) where applicable, an indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations;
(j) other additives belonging to the groups referred to in (b) to (i) for which no maximum level is laid down and additives belonging to other groups provided for in the First or Second Schedule to these Regulations: the specific name of the additive in accordance with the First or Second Schedule to these Regulations and the active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by

valid scientific methods.";
(d) the insertion of the following Regulation after Regulation 21:
"21.A (1) A person shall not market feedingstuffs incorporating enzymes or microorganisms unless the particulars (which shall be clearly visible and readily legible and indelible) set out in paragraph 2 of this Regulation are given on the package, container or a label attached thereto.
(2) The particulars referred to in paragraph (1) of this Regulation are:
(a) in the case of enzymes:
(ii) the identification number according to the International Union of Biochemistry;
(iii) the activity units (activity units per kg or activity unit per L);
(iv) the expiry date of the guarantee of the activity units in the feedingstuff expressed as activity units per kilogram or per litre of feedingstuff or the storage life from the date of manufacture; and
(v) where applicable, an indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations;
(b) in the case of micro-organisms;
(i) the identification of the strain(s) in accordance with the First or Second Schedule to these Regulations;
(ii) the file number of the strain(s);
(iii) the number of colony-forming units (CFU/kg);
(iv) the expiry date of the guarantee of the number of colony-forming units (CFU) of the feedingstuff expressed as CFU per kilogram or per litre of the feedingstuff or the storage life from the date of manufacture; and
(v) where applicable, an indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the column entitled 'Other provisions' in the First or Second Schedule to these Regulations.";
(e) the substitution of the following Regulation for Regulation 28:
"28. Every person concerned shall comply with the provisions of Council Directive No. 94/40/EC amending Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition4.";
(f) the substitution of the following Regulation for Regulation 37:
"37. In any legal proceedings under these regulations the production by an authorised officer of a certificate in the form set out in the European Communities (Feedingstuffs) (Methods of Analysis) (Amendment) and (Methods of Sampling) Regulations, 1980 (S.I. No. 14 of 1980) and purporting to be signed by the State Chemist shall, without proof of any signature on the certificate or that the signatory was the proper person to sign it, be sufficient evidence of the facts stated in the certificate and of the analysis to which it relates having been carried out in accordance with such of the requirements (if any) specified in the official methods of analysis as applied in the particular case.".

(4)O.J. No. L 208, 11.8.1994, p.15.
(g) the insertion of the following paragraph in Regulation 39:
"(2) A person shall not import or market additives, premixtures or feedingstuffs for use in the State unless the details referred to in Regulations 11 to 27 of these Regulations are given in at least English or Irish.".
(h) the insertion in Regulation 42 (1) of "21.A" after "21".

SCHEDULE.

"FIRST SCHEDULE.
"Council Directive" means Council Directive No. 70/524/EEC of 23 November 19705, as amended by:—
Council Directive No. 73/103/EEC of 28 April, 19736,
Council Directive No. 75/296/EEC of 28 April, 19757,
Council Directive No. 84/587/EEC of 29 November, 19848,
Commission Directive No. 91/248/EEC of 12 April, 19919,
Commission Directive No. 92/249/EEC of 19 April, 199110,
Commission Directive No. 91/336/EEC of 10 June, 199111,
5O.J. No. L 270, 14.12.1970, p.1.
6O.J. No. L 124, 10.5.1973, p.17.
7O.J. No. L 124, 15.5.1975, p.29.
8O.J. No. L 319, 8.12.1984, p.13.
9O.J. No. L 124, 18.5.1991, p.1.
10O.J. No. L124, 18.5.1991, p.43.
11O.J. No. L 185, 11.7.1991, p.31.
Commission Directive No. 91/508/EEC of 9 September, 199112
Commission Directive No. 91/620/EEC of 22 November, 199113,
Commission Directive No. 92/64/EEC of 13 July 199214,
Commission Directive No. 92/99/EEC of 17 November, 199215,
Commission Directive No. 92/113/EEC of 16 December, 199216,
Commission Directive No. 93/27/EEC of 4 June, 199317,
Commission Directive No. 93/55/EEC of 25 June, 199318,
Commission Directive No. 93/107/EEC of 26 November, 199319,
Council Directive No. 93/114/EC of 14 December, 199320, and
Commission Directive No. 94/40/EC of 22 July, 199421.".

GIVEN under my Official Seal, this 23rd day of January, 1995.
IVAN YATES,
Minister for Agriculture, Food and
Forestry.

12O.J. No. L 271,27.9.1991, p.67.
13O.J. No. L 334,5.12.1991, p.62.
14O.J. No. L 221,6.8.1992, p.51.
15O.J. No. L 350,1.12.1992, p.83.
16O.J. No. L 16,25.1.1993, p.2.
17O.J. No. L 179, 22.7.1993, p.5.
18O.J. No. L 206, 18.8.1993, p. 11.
19O.J. No. L 299,4.12.1993, p.44.
20O.J. No. L 334, 31.12.1993, p. 24.
21O.J. No. L 208, 11.8.1994, p.15.