EUROPEAN COMMUNITIES (MARKETING OF ENZYMES, MICROORGANISMS AND THEIR PREPARATIONS IN ANIMAL NUTRITION) 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 purpose of giving effect to Council Directive 93/113/EC of 14th December, 19931 hereby make the following Regulations:

REG 1

1. These Regulations may be cited as the European Communities (Marketing of Enzymes, Microorganisms and their Preparations in Animal Nutrition) Regulations, 1995.

REG 2

2. Without prejudice to the European Communities (Additives in Feedingstuffs) Regulations, 1989 to 1994, these Regulations shall apply to the marketing and use of enzymes, microorganisms and their preparations in animal nutrition.

REG 3

3. A person shall not market any enzyme, microorganism or preparation thereof for use in animal nutrition or administer any enzyme, microorganisms or preparations thereof to an animal unless such enzyme, microorganism or preparation thereof is listed in the Schedule to these Regulations and the enzyme, microorganism or preparation thereof complies with the specifications, if any, specified in the Schedule to these Regulations.

REG 4

4. (1) A person shall not market any of the enzymes, microorganisms or preparations thereof listed in the Schedule to these Regulations or any premixtures or compound feedingstuffs in which they have been incorporated unless,

(a) in the case of enzymes and their preparations, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (2), are set out on the package in which they are packed or on a label attached thereto,

10.J. No. L334, 31.12.1993, p17.

(b) in the case of microorganisms and their preparations, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (3), are set out on the package in which they are packed or on a label attached thereto,

(c) in the case of premixtures containing enzymes, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (4), are set out on the package in which they are packed or on a label attached thereto,

(d) in the case of premixtures containing microorganisms, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (5), are set out on the package in which they are packed or on a label attached thereto,

(e) in the case of compound feedingstuffs into which enzymes have been incorporated, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (6), are set out on the package in which they are packed or on a label attached thereto,

(f) in the case of compound feedingstuffs into which microorganisms have been incorporated, the particulars (which shall be clearly visible, legible and indelible) set out in paragraph (7), are set out on the package in which they are packed or on a label attached thereto.

(2) The particulars to be set out in respect of enzymes and their preparations are:

(a) the specific name of the active constituent according to their enzymatic activity and the identification number in accordance with the Schedule to these Regulations;

(b) the activity units (activity units (being units of activity expressed as µmole of product released per minute per gram of enzymatic preparation) per g or activity units per ml);

(c) the name or business name and the address or registered place of business of the person responsible for the particulars in this paragraph;

(d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

(e) the expiry date of the guarantee of the activity units in the product or the storage life from the date of manufacture;

(f) the batch reference number and the date of manufacture;

(g) directions for use and, where appropriate, a safety recommendation;

(h) the net weight and for liquid additives either the net volume or the net weight;

(i) the indication "to be used exclusively for the manufacture of feedingstuffs".

(3) The particulars to be set out in respect of microorganisms and their preparations are:

(a) the identification of the strain and the deposit number of the strain in accordance with the Schedule to these Regulations;(b) the number of colony- forming units (CFU/g);

(c) the name or business name and address or registered place of business of the person responsible for the particulars referred to in this paragraph;

(d) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

(e) the expiry date of the guarantee of the CFU/g of the product or the storage life from the date of manufacture;

 $(\ f\)$ the batch reference number and the date of manufacture;

(g) the directions for use and, where appropriate, a safety recommendation;

(h) the net weight and for liquid additives either the net volume or the net weight;

(i) the indication "to be used exclusively in the manufacture of feedingstuffs";

(j) where appropriate, the indication of any particular significant characteristics due to the manufacturing process.

(4) The particulars to be set out in respect of premixtures containing enzymes are:

(a) the description "premixture";

(b) the indication "to be used exclusively in the manufacture of feedingstuffs";

(c) the directions for use and any safety recommendations regarding the use of premixture;

(d) the animal species or category of animals 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;

(f) the net weight and for liquids either the net volume or the net weight;

(g) the specific name of the active constituent according to their enzymatic activity and the identification number in accordance with the Schedule to these Regulations;

(h) the activity units (activity units per g or activity units per ml);

(i) the expiry date of the guarantee of the activity units in the product or the storage life from the date of manufacture;

(j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label.

(5) The particulars to be set out in respect of premixtures containing microorganisms are:

(a) the description "premixture";

(b) the indication "to be used exclusively in the manufacture of feedingstuffs";

(c) the directions for use and any safety recommendations regarding the use of the premixture;

(d) the animal species or category of animals 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;

(f) the net weight and for liquids either the net volume or the net weight;

(g) the identification of the strain and the deposit number of the strain in accordance with the Schedule to these Regulations;

(h) the number of colony- forming units (CFU/g);

(i) the expiry date of the guarantee of the CFU/g of the

product or the storage life from the date of manufacture;

(j) the name or business name and address or registered place of business of the manufacturer if he is not responsible for the particulars on the label;

(k) where appropriate, the indication of any particular significant characteristics due to the manufacturing process.

(6) The particulars to be set out in respect of compound

feedingstuffs into which enzymes have been incorporated are:

(a) the specific name of the active constituent according to

their enzymatic activity and the identification number in accordance with the Schedule to these Regulations;

(b) the activity units (activity units per kg or activity units per L) provided that such units are measurable by an official or

scientifically valid method;

(c) the expiry date of the guarantee of the activity units in the product or the storage life from the date of manufacture. (7) The particulars to be set out in respect of compound feedingstuffs into which microorganisms have been incorporated are: (a) the identification of the strain and the deposit number of the strain in accordance with the Schedule to these Regulations; (b) the number of colony-forming units (CFU/kg) provided that the number is measurable by an official or scientifically valid method; (c) the expiry date of the guarantee of the CFU/kg of the product or the storage life from the date of manufacture; (d) where appropriate, the indication of any particular significant characteristics due to the manufacturing process. (8) Particulars other than those prescribed in paragraphs (2) to (7) of these Regulations, such as the trade name, may be included on the packaging, container or on a label attached thereto, provided that they are clearly separated from the said particulars.

REG 5

5. A person shall not market an enzyme, microorganism or preparation thereof for use in animal nutrition unless it is intended to be used exclusively in the manufacture of feedingstuffs and is in a form suitable for incorporation in a feedingstuff and a person shall not administer to an animal an enzyme, microorganism or preparation thereof unless such enzyme, microorganism or preparation thereof has been incorporated in a feedingstuff in accordance with these Regulations.

REG 6

6. It shall be an offence to contravene Regulations 3, 4 or 5 of these Regulations.

REG 7

7. A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding $\pounds 1,000$.

REG 8

8. An offence under these Regulations shall be prosecuted by the Minister for Agriculture, Food and Forestry.

SCHEDULE

List of Enzymes, Microorganisms and their Preparations authorised for use in compound feedingstuffs. Enzymes

Trade nameActive constituent(s) (Source, organism and strain number)Activity unit(s)/g (Liquids/ml)Person responsible for putting the product into circulation (name and address)Allzyme ABEC 3.2.1.1, a-Amylase (Bacillus subtilis CBS 495.94)9,250 P2 4,625 L3Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme AFEC 3.2.1.1, a-Amylase (Aspergillus oryzaeCBS 518.94)6,750 P 3,375 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme BGEC 3.2.1.6, Endo-1,3(4)-ß-glucanase (Trichoderma viride CBS 517.94)650 P 325 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 Ireland 2Powder 3Liquid Trade nameActive constituent(s) (Source, organism and strain number)Activity unit(s)/g (liquids/ml)Person responsible for putting the product into circulation (name and address)Allzyme CEC 3.2.1.4, Cellulase (Trichoderma viride CBS 516.94)190 P 95 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme LEC 3.1.1.3, Triacylglycerol lipase (Aspergillus oryzae CBS 523.94)900 P 450 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme PBEC 3.4.24.28, Bacillolysin (Bacillus subtilis CBS 494.94)50 P 25 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme PFEC 3.4.23.18, Aspergillopepsin I (Aspergillus niger CBS 519.94)24,500 P 12,250 LAlltech Ireland Unit 28 Cookstown Industrial Estate

Tallaght, Dublin 24 IrelandAllzyme PhytaseEC 3.1.3.8,3-Phytase (Aspergillus niger CBS 521.94)100 P 50 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAllzyme PTEC 3.2.1.37, Xylan 1,4—ß-xylosidase (Aspergillus niger CBS 520.94)600 P 300 LAlltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandStafizym C 80EC 3.2.1.4, Endo-1,4-ß-glucanase EC 3.2.1.21, β-glucosidase EC 3.2.1.91, Cellulose 1,4-B-cellobiosidase (Trichoderma reesei CNCM MA 6 10-W)400 P 80 LDCL Yeast Ltd Salatine House 19 Cedar Road Sutton Surrey SM2 5JG UKStafizym X 70EC 3.2.1.8 Endo 1,4-B-xylanase EC 3.2.1.37, Xylan 1,4-B-xylosidase (Trichoderma reesei CNCM MA 6 10-W)7,000 P 7.000 LDCL Yeast Ltd Salatine House 19 Cedar Road Sutton Surrey SM2 5JG UKAvizyme 1 100EC 3.2.1.6, Endo-1,4-ß-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-1,4-B-xylanase (Trichoderma longibrachiatum ATCC 2105 and Trichoderma viride var koningii IMI 135) EC 3.4.24.28, Bacillolysin (Bacillus subtilis DSM 9554 and Bacillus subtilis ATCC 2107)100

300

800Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKAvizyme 1200EC 3.2.1.6, Endo-l,4-β-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-l,4-β-xylanase (Trichoderma longibrachiatum ATCC 2105 and Trichoderma viride var koningii IMI 135) EC 3.4.24.28, Bacillolysin (Bacillus subtilis DSM 9554 and Bacillus subtilis ATCC 2107)100

2,500

800Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKAvizyme TXEC 3.2.1.6, Endo-1,4-β-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma viride var koningii IMI 135) EC 3.2.24.28, Bacillolysin (Bacillus subtilis ATCC 2107) EC 3.2.1.1, a-Amylase (Bacillus subtilis var. amyloliquefaciens DSM 9553) EC 3.2.1.15, Polygalacturonase (Aspergillus niger var acculeatus CBS 589.94)150

1,500

800

500

50Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKAvizyme 1300EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma longibrachiatum ATCC 2105 and Trichoderma viride var koningii IMI 135) EC 3.4.24.28, Bacillolysin (Bacillus subtilis DSM 9554 and Bacillus subtilis ATCC 2107)2,500

800Finnfeeds International Ltd
Market House
Marlborough
Wiltshire SN8 1AA
UKPorzyme 8100EC 3.2.1.6, Endo-1.4-β-glucanase (Trichoderma longibrachiatum ATCC 2106)
EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma longibrachiatum ATCC 2105 and Trichoderma longibrachiatum ATCC 2106 and Trichoderma viride var koningii IMI 135)
EC 3.2.1.1, a-Amylase (Bacillus subtilis DSM 9554)250

400

1,000Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKPorzyme 9300EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma longibrachiatum ATCC 2105 and Trichoderma viride var koningii IMI 135)4,000Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKPorzyme SF 100EC 3.2.1.6, Endo-1,4-β-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma longibrachiatum ATCC 2106 and Trichoderma viride var koningii IMI 135) EC 3.2.1.15, Polygalacturonase (Aspergillus niger var aculeatus CBS 589.94)400 400

50Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKPorzyme SPEC 3.2.1.6, Endo-1,4-β-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma longibrachiatum ATCC 2106 and Trichoderma viride var koningii IMI 135) EC 3.2.1.1, a- Amylase (Bacillus subtilis var amyloliquefaciens DSM 9553)250

400

1,000Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 IAA UKPorzyme TP 100EC 3.2.1.6, Endo-1,4-β-glucanase (Trichoderma longibrachiatum ATCC 2106) EC 3.2.1.8, Endo-1.4-β-xylanase (Trichoderma longibrachiatum ATCC 2106 and Trichoderma viride var koningii IMI 135) EC 3.2.1.1, a-Amylase (Bacillus subtilis var amyloliquefaciens DSM 9553) EC 3.2.1.15, Polygalacturonase (Aspergillus niger var aculeatus CBS 589.94)150

4,000

1,000

25Finnfeeds International Ltd Market House Marlborough Wiltshire SN8 1AA UKKemzyme LiquidEC 3.2.1.1, a-Amylase (Bacillus amyloliquefaciens DSM 9553) EC 3.2.1.4, Cellulase (Trichoderma reesei CBS 592.94) EC 3.2.1.6, Endo-1,3(4)-B-glucanase (Aspergillus aculeatus CBS 589.94)400

120,000

10,000Kemin UK Ltd Becor House Green Lane Lincon LN6 9DL UKKemzyme W DryEC 3.2.1.1, a-Amylase (Bacillus amyloliquefaciens DSM 9553) EC 3.4.24.28, Bacillolysin (Bacillus subtilis DSM 9554) EC 3.2.1.4, Cellulase (Trichoderma reesei CBS 592.94) EC 3.2.1.6, Endo-1,3(4)-β-glucanase (Aspergillus aculeatus CBS 589.94) EC 3.2.1.8, Endo-l,4-B-xylanase (Trichoderma viride ATCC 13631 EC 3.1.1.3, Triacylglycerol lipase (Rhizopus japonicus 41-A-0547)400

450

4,000

2,350

20,000

100Kemin UK Ltd Becor House Green Lane Lincon LN6 9DL UKKemzyme W LiquidEC 3.2.1.1, a-Amylase (Bacillus amyloliquefaciens DSM 9553) EC 3.2.1.4, Cellulase (Trichoderma reesei CBS 592.94) EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma reesei CBS 571.93) EC 3.2.1.6, Endo-1,3(4)-β-glucanase (Aspergillus aculeatus CBS 589.94400 120,000 210,00 10,000Kemin UK Ltd Becor House Green Lane Lincon LN6 9DL UKBio-Feed BetaEC 3.2.1.8, Endo 1,4-B-xylanase600 CT4Novo Nordisk A/S(CT, MG, L, SL)(Humicola insolens DSM 1800)450 MG5Novo Alle300 LDK-2880 BagsvaerdDenmarkEC 3.2.1.1, a-Amylase(Bacillus amyloliquefaciens DSM 9553)Innozyme BetaEC 3.2.1.8, Endo 1,4-B-xylanase600 G6Trouw Nutrition(G&L)(Humicola insolens DSM 1800)300 LWinchamNorthwichEC 3.2.1.1, a-Amylase50 GCheshire CW9 6DF(Bacillus amyloliquefaciens DSM 9553)25 LUKBio-Feed PlusEC 3.2.1.8, Endo 1,4-β-xylanase800 CT & MGNovo Nordisk A/S(CT, MG, L, SL)(Humicola insolens DSM 1800)550 LNovo Alle1,600 SLDK-2880 BagsvaerdDenmarkEC 3.2.1.4, Endo-1,4-B-glucanase75 CT & MG(Humicola insolens DSM 1800)50 L150 SLInnozyme AlphaEC 3.2.1.8, Endo-1.4-B-xylanase800 GTrouw Nutrition(G & L)(Humicola insolens DSM 1800)550 LWinchamNorthwichEC 3.2.1.4, Endol,4-B-glucanase75 G 50 LCheshire CW9 6DF(Humicola insolens DSM 1800)UKCerezyme EZEC 3.2.1.8, Endo 1,4-ß-xylanase (Trichoderma longibrachiatum CBS 614.94) EC 3.2.1.6, Endo-1,3(4)-ß-glucanase (Bacillus subtilis CBS 613.94)75 P 125 L 300 P 500 LNutec (Ireland) Ltd Greenhills Centre Greenhills Road Tallaght, Dublin 24

IrelandCerezyme SZEC 3.2.1.8, Endo 1,4-ß-xylanase (Trichoderma longibrachiatum CBS 614.94) EC 3.2.1.6, Endo-1,3(4)- β -glucanase (Bacillus subtilis CBS 613.94)300 P 500 L 75 P 125 LNutec (Ireland) Ltd Greenhills Centre Greenhills Road Tallaght, Dublin 24 IrelandOptizyme Super-PEC 3.2.1.6, Endo-1,3(4)-ß-glucanase (Penicillium funiculosum IMI 134756)21,500 P 55,000 LOptivite Ltd Main Street Laneham Retford Nottinghamshire DN22 0NA UKWheatzymeEC 3.2.1.8, Endo-l,4-ß-xylanase (Trichoderma longibrachiatum IMI 143)17,600 P 35,000 LOptivite Ltd Main Street Laneham Retford Nottinghamshire DN22 0NA UKBioglucanase 10BEC 3.2.1.6, Endo-1,3(4)-B-glucanase (Bacillus subtilis CBS 613.94)2,500 to 10,000Quest International Ireland Ltd Killnagleary Carrigaline Co. Cork IreandBiopentosanase XEC 3.2.1.8, Endo-1,4-B-xylanase (Trichoderma longibrachiatum CBS 614.94)750 to 3,000Quest International Ireland Ltd Killnagleary Carrigaline Co. Cork IreandBioxylanase 10LEC 3.2.1.8, Endo-1,4-ß-xylanase (Trichoderma longibrachiatum CBS 614.94)2,500 to 10,000Quest International Ireland Ltd Killnagleary Carrigaline Co. Cork IreandBioxylanase 2EC 3.2.1.8, Endo-1,4-ß-xylanase (Aspergillus awamori CBS 612.94)750 to 3,000Quest International Ireland Ltd Killnagleary Carrigaline Co. Cork IreandRoxazyme GEC 3.2.1.4, Cellulase EC 3.2.1.6, Endo-1,3(4)-ß-glucanase EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma viride CTV 002 NIBH FERM BP-4447)8,000 18,000 26,000Roche Products Ltd Vitamins & Fine Chemicals Division

Heanor Gate Heanor Derbyshire DE75 7SG UKRoxazyme G2EC 3.2.1.4, Cellulase EC 3.2.1.6, Endo-1,3(4)-ß-glucanase EC 3.2.1.8, Endo-1,4-β-xylanase (Trichoderma viride CTV 002 NIBH FERM BP-4447) or (Trichoderma longibrachiatum M2-C38 M93 ATCC 74252)8,000 18,000 26,000Roche Products Ltd Vitamins & Fine Chemicals Division Heanor Gate Heanor Derbyshire DE75 7SG UK 4 Coated Thermotolerant Granule 5 Micro Granule 6 Granule Microorganisms Trade nameActive constituent(s)No. of colony forming units/g (x 109)Person responsible for putting the product into circulation (name and address)All-LacLactobacillus acidophilus CBS 525.9420Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandAll-StrepStreptococcus faecium CBS 524.9420Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandYea-Sacc1026Saccharomyces cerevisiae CBS 493.940.1Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandYea-Sacc8417Saccharomyces cerevisiae CBS 492.940.1Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandBiosaf Sc 47Saccharomyces cerevisiae NCYC Sc 4710DCL Yeast Ltd Salatine House 19 Cedar Road Sutton Surrey SM2 5JG UKGardionLactobacillus casei subsp. casei NCIMB 30096 Enterococcus faecium NCIMB 30098 Alliin concentrate, lyophilised2

6 900mg/gInterprise Ltd Unit 12, Baglan Industrial Park Port Talbot SA12 7DJ UKProtexin CompounderLactobacillus plantarum ATCC 14917 Lactobacillus delbrueckii subsp. bulgaricus ATCC 11842 Lactobacillus acidophilus ATCC 4356 Lactobacillus rhamnosus ATCC 4769 Bifidobacterium bifidum ATCC 29521 Streptococcus salivarius subsp.thermophilus ATCC 19258 Enterococcus faecium ATCC 19434 Aspergillus oryzae ATCC 42531 Candida pintolepesii ATCC 229870.0126 0.0206 0.0206 0.0206 0.0200 0.0410 0.0590 0.00532 0.00532Probiotics International Ltd Matts Lane Stoke-sub-Hamdon Somerset TA14 6QE UKProtexin MixerLactobacillus plantarum ATCC 14917 Lactobacillus delbrueckii subsp. bulgaricus ATCC 11842 Lactobacillus acidophilus ATCC 4356 Lactobacillus rhamnosus ATCC 4769 Bifidobacterium bifidum ATCC 29521 Streptococcus salivarius subsp. thermophilus ATCC 19258 Enterococcus faecium ATCC 19434 Aspergillus oryzae ATCC 42531 Candida pintolepesii ATCC 229870.00441 0.00721 0.00721 0.00721 0.00700 0.01440 0.02070 0.00186 0.00186Probiotics International Ltd Matts Lane Stoke-sub-Hamdon Somerset TA14 6OE UKCernivet LBC GEnterococcus faecium Cernelle 68 NCIB 1041535Rhône Mérieux 21 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandLevucell SB 20 Levugen SB 20 Levorol SB 20 Levupro SB 20 Proficell SB 20 Lallemand SB 20Saccharomyces cerevisiae CNCM I-107920Santel/Groupe Agritek Avenue des Cyprès BP 10 53950 LOUVERNE FranceLevucell SC 20 Levugen SC 20 Levorol SC 20 Levupro SC 20 Proficell SC 20 Lallemand SC 20Saccharmonyces cerevisiae CNCM I-107720Santel/Groupe Agritek Avenue de Cyprès BP 10 53950 LOUVERNE France

Enzymes and microorganisms

Trade nameActive constituents (Source organism and strain number)Activity unit(s)/g or CFU/g (x 109)Person responsible for putting the product into circulation (name and address)Lacto-SaccEC 3.2.1.1, a-Amylase (Bacillus subtilis CBS 495.94) EC 3.2.1.4, Cellulase (Trichoderma viride CBS 516.94) EC 3.4.23.18, Aspergillopepsin I (Aspergillus niger CBS 519.94)8.80 0.44 26.40Alltech Ireland Unit 28 Cookstown Industrial Estate Tallaght, Dublin 24 IrelandLactobacillus acidophilus CBS 525.94 Streptococcus faecium CBS 524.94 Saccharomyces cerevisiae CBS 493.940.110 0.077 0.0396Provita B Sacc IIEC 3.2.1.1, a-Amylase (Bacillus subtilis ATCC 31783) Ec 3.2.1.1, a-Amylase (Aspergillus oryzae NRRL 6992)

Bacillus subtilis ATCC 3178312,000 17,000 0.5Provita Eurotech Ltd 21 Bankmore Road Omagh Co. Tyrone BT79 0EU Northern Ireland

GIVEN under my Official Seal, this 5th day of September, 1995. IVAN YATES, Minister for Agriculture, Food and Forestry.

EXPLANATORY NOTE.

These Regulations which give effect to Council Directive 93/113/EC introduce controls on the marketing and use of enzymes, microorganisms and their preparations in animal nutrition. Only those products containing enzymes and microorganisms which are set out in the Schedule to these Regulations may be marketed and used in animal feedingstuffs. In addition, the labelling particulars applicable to such products, and to premixtures and compound feedingstuffs containing such products, are set out in the Regulations.