L.N. 258 of 2006

VETERINARY SERVICES ACT
(CAP. 437)

Use and Marketing of Enzymes, Micro-organisms and their Preparations in Animal Nutrition Rules, 2006

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability.

1. (1) The title of these rules shall be Use and Marketing of Enzymes, Micro-organisms and their Preparations in Animal Nutrition Rules, 2006.

(2) The scope of these regulations is to transpose the provisions found in European Union Directive 93/113/EC of the 14th December, 1993 concerning the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition, as amended by Directive 97/40/EC of the 25th June, 1997.

(3) These rules shall apply to the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition and shall apply without prejudice to Directive 70/524/EEC and particularly to the provisions concerning the authorization of enzymes, micro-organisms and their preparations for use as additives.

(4) By way of derogation from Article 3 of Directive 70/524/EEC, Malta shall temporarily allow the use and marketing of enzymes, micro-organisms and their preparations in animal nutrition within their territory, provided that, on the basis of the information available, the products do not present a danger to human or animal health, and that they are included in the list established by virtue of Article 3.

Definitions.

2. In these regulations:

"Commission" shall mean the European Commission;

"Community" shall mean the European Community.

Prohibition of all forms of use other than incorporation into feedingstuffs

3. (1) All forms of use for animal nutrition other than the incorporation of such products into feedingstuffs shall be prohibited.

(2) On the basis of the information provided by the persons responsible for putting the products into circulation Malta shall forward to the Commission:

(a) a list of enzymes and micro-organisms and their preparations according to the model given in Schedule I,

(b) an identification note drawn up for each product according to the model given in Schedule II by the person responsible for putting the product into circulation.

Commission to communicate list to Malta.

4. (1) As and when the requested information reaches it, the Commission shall communicate to Malta the lists of enzymes, microorganisms or their preparations sent to it in accordance with rule 3.

(2) Where enzymes, micro-organisms or preparations manufactured by Member States are included in several national lists, it may be agreed between the Malta and the Member States concerned that a single dossier should be submitted by one of them. In such case, the Member State appointed to submit such dossier shall inform the Commission accordingly.

Where certain conditions cannot be satisfied.

5. Where Malta finds it impossible to satisfy any of the conditions referred to in regulation 3, for an enzyme, micro-organisms or preparation used in their territory, it shall take all the necessary measures to ensure that the enzyme, micro-organism or preparation obtained from them is no longer used or marketed in their territories.

Conditions for marketing.

6. (1) Enzymes, micro-organisms and their preparations, as well as premixtures and compound feedingstuffs in which they have been incorporated, may be marketed only if the particulars listed below, which must be clearly visible, legible and indelible and for which the producer, packer, importer, vendor or distributor established within the Community shall be held responsible, are shown on the packaging, the container or on a label attached thereto:-

A. *for enzymes and their preparations:*

(a) the specific name of the active constituent or constituents according to their enzymatic activity or activities and the identification number or numbers according to the International Union of Biochemistry;

(b) the activity units (activity units (1) per gor 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 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";

B. *for micro-organisms and their preparations:*

(a) the identifications of the strain or strains according to a recognized international code of nomenclature and the deposit number of the strain or strains;

(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 or the storage life from the date of manufacture.

(1) Units of activity expressed as μ mole of product released per minute per gram of enzymatic preparation.

(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, indication of any particular significant characteristics due to the manufacturing process;

C. *for premixtures containing enzymes*:

(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 premixtures;

(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 or constituents according to their enzymatic activity or activities and the identification number(s) according to the International Union of Biochemistry;

(h) the activity units (activity units per gor activity units per ml);

(i) the expiry date of the guarantee 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;

D. *for premixtures containing micro-organisms:*

(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 premixtures;

(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 volume or net weight;

(g) the identification of the strain or strains according to a recognized international code of nomenclature and the deposit number or numbers of the strain(s);

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

(i) the expiry date of the guarantee 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, indication of any particular significant characteristics due to the manufacturing process;

E. *for compound feeds into which enzymes have been incorporated:*

(a) the specific name of the active constituent or constituents according to their enzymatic activity or activities and the identification number according to the International Union of Biochemistry;

(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 or the storage life from the date of manufacture.

F. *For compound feeds into which micro-organisms have been incorporated:*

(a) the identification of the strain or strains according to a recognized international code of nomenclature and the deposit number or numbers of the strain or strains;

(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 or the storage life from the date of manufacture;

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

(2) Particulars other than those prescribed in sub-rule (1), under A, B, C and D such as the trade name, may be included on the packaging, containers or on a label attached thereto, provided that they are clearly separated from the said particulars.

SCHEDULE I

Rule 3(2)(a)

Trade name	Active constituents	Activity units per g or number of Colony-forming units per g	Person responsible for putting into circulation

SCHEDULE II

MODEL OF IDENTIFICATION NOTE REFERRED TO REGULATION 3(a) (ii)

(to be filled in by the person responsible for putting the product into circulation)

1. **Identity of the product**

Trade name.

Qualitative and quantitative composition:

- active substance (If the active substance is a mixture of clearly definable active components, indicate the main components),

- other components,

- impurities,

- undesirable substances.

Name or business name and address or registered place of business of the manufacturer.

Place of manufacture

Name or business name and address or registered place of business of the person responsible for placing the product on the market, if he is not the manufacturer.

2. **Specifications concerning the active substance**

2.1. For micro-organisms:-

– name and taxonomic description according to an international code of nomenclature (Such as "Bergeyís Manual of Systematic Bacteriology", "The Yeasts, a taxonomic study" by Lodder and Kreger van Rij, "Ainsworth and Bisbyís Dictionary of the Fungi" by Hawksworth, Sutton and Ainsworth or "The Genus Asperigillus" by Raper and Fennel),

– name and place of culture collection where the strain is registered and deposited and the number of registration and deposit,

– state whether genetic manipulation has taken place,

– the number of colony-forming units (CFU/g).

2.2. For enzymes:

- name according to main enzymatic activities and Community number (Enzyme Nomenclature Recommendations (1984) of the Nomenclature Committee of the International Union of Biochemistry, Academic Press 1984),

- state the biological origin. In the case of microbial origin, the information required in the first two indents of point 2.1, must be given,

- state whether the organism of origin has been genetically manipulated,

- relevant activities with regard to appropriate types of chemically pure substrates (expressed in activity units per g Activity units expressed as μmole of product released per minute per gram of enzymatic preparation).

NB: If the active substance is a mixture of active components, all the components must be described separately with an indication of their proportion in the mixture.

3. **Properties of the product**

Main effect:

- information concerning effectiveness,

- justification for the presence of each component if the substance is a mixture of active components. Other effects.

Other effects.

4. **Product safety**

Available information on safety.

5. **Conditions for the use of product**

Uses provided for in animal nutrition (species or categories of animal, type of feedingstuffs, period of use, etc).

Proposed dosage in premixes and feedingstuffs (appropriate units of biological activity such as CFU per gram of product for micro-organisms or activity units per gram for enzyme preparations).

Other known uses of the active substance or the preparation (in foodstuffs, human or veterinary medicine, industry etc).

Recommendations concerning product safety in relation to targeted species, the consumer and the environment.

If necessary, measures for the prevention of risks and means of protection during manufacture and use.

6. **Technological information**

Stability of the product:

- with regard to atmospheric agents,

- during the preparation of premixes and feedingstuffs,

- during the storage of premixes and feedingstuffs,

– description of the process of manufacture and methods used concerning the control of the quality of the product during its manufacture.

7. **Control**

Method(s) of analysis for determining the active component(s) in:

- the product itself,

- premixes,

- feedingstuffs.

8. **Attestation of the person responsible certifying the accuracy of the information given.**

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*
Prezz40ċ – *Price 40c*