L.N. 89 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Products Used in Animal Nutrition Rules, 2005

IN exercise of the powers conferred by articles 24 and 25 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Minister of Health, the Elderly and Community Care, has made the following rules:-

Title and scope.

1. (1) The title of these rules is the Products Used in Animal Nutrition Rules, 2005.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 82/471/EEC of the 30th June, 1982 on certain products which act as direct or indirect protein sources, are manufactured by certain technical processes and are put into circulation as feedingstuffs or in feedingstuffs in accordance with articles 24 and 25 of the Veterinary Services Act.

(3) These rules shall be without prejudice to other provisions concerning:

(a) additives in feedingstuffs;

(b) the fixing of maximum levels for undesirable substances and products in feedingstuffs;

(c) the fixing of maximum levels for pesticide residues on and in products intended for human or animal nutrition;

(d) the marketing of compound feedingstuffs, pathogenic micro-organisms in feedingstuffs, feedingstuffs for particular nutritional purposes, the circulation of feed materials.

Interpretation.

2. For the purpose of these rules, the following definitions shall apply:

"additives" means substances which, when incorporated in feeding-stuffs, are likely to affect their characteristics or livestock production;

"complete feeding-stuffs" means mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

"daily ration" means the average total quantity of feeding-stuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

"feeding-stuffs" means organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

"premixtures" means additive concentrates intended for the industrial manufacture of compound animal feeding-stuffs;

"supplementary feeding-stuffs" means mixtures of feeding-stuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feeding-stuffs.

Marketing of feedingstuffs.

3. (1) Feedingstuffs belonging to one of the product groups listed in the Schedule or containing such products may be marketed only if:

(a) the product in question appears in the Schedule.

(b) any conditions laid down therein are fulfilled.

(2) Competent authorities may, for experimental or scientific purposes, provide for derogations from the provisions of sub-rule (1), provided that an adequate official inspection is carried out.

(3) Products referred to in Chapter I. 1 (a) of Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector may be put into circulation only by establishments or intermediaries which meet the conditions laid down in Article 2 or Article 3 of that Directive, as appropriate.

(4) Sub-rule (3) shall apply without prejudice to Article 4 (2) of Council Directive 95/69/EC.

Applicable particulars to appear on label etc.

4. (1) Without prejudice to the labelling provisions applicable to straight and compound feedingstuffs, the products listed in the Schedule may not be marketed as feedingstuffs or incorporated in feedingstuffs unless any particulars laid down in the Schedule appear in the package or container or on a label attached thereto.

(2) For material marketed in bulk the particulars referred to in sub-rule (1) appear on an accompanying document.

Principles observed in Schedule.

5. (1) In the Schedule, the following principles are observed:

(a) A product shall not be included in the Schedule unless:

(i) it has nutritional value for animals because it provides nitrogen,or

(ii) when used sensibly it has no detrimental effect on human or animal health or on the environment and does not harm the consumer by impairing the distinctive features of animal products, or

(iii) it can be monitored in feedingstuffs.

(b) A product shall be deleted from the Schedule if one of the conditions listed in paragraph (A) is not satisfied.

(2) Criteria making it possible to define the products included in these rules, particularly the criteria of composition and purity and the physicochemical and biological properties, may be set in the light of scientific and technical knowledge.

Product conformity.

6. (1) In order to ensure that the products referred to in sections 1.1 and 1.2 of the Schedule comply with the principles set out in rule 5 (1), the dossier, prepared in accordance with the provisions of sub-rule (2) hereof, is sent officially to the Member States, to the relevant international organisation and, if it is requested that they be consulted, to the necessary scientific committees.

(2) The competent authorities and the other recipients of the dossier referred to in sub-rule (1) shall ensure, if requested on good grounds by an applicant, that information whose disclosure could adversely affect industrial or commercial property rights is kept confidential. Industrial and commercial secrecy shall not apply to:

(a) The names and composition of the product, and any information concerning the substrate and the micro-organism,

(b) The physicochemical and biological properties of the product,

(c) The interpretation of the pharmacological, toxicological and ecotoxicological data,

(d) The analytical methods for monitoring the product in the feedingstuffs.

Temporary suspension etc. of applications provisions.

7. If, on the basis of detailed grounds due to new data or a new evaluation of existing data that have become evident since the adoption of the provisions in question, the competent authorities find that one of the products listed in the Schedule or its use under any conditions that have been set represents a danger to human or animal health even though it complies with the provisions of these rles, they may temporarily suspend or restrict the application of those provisions. They shall immediately inform the other Member States and the relevant international organisation thereof, giving the reasons for its decision.

Particulars to be given in official language.

8. With regard to marketing between Malta and other Member States, the particulars referred to in rule 4 shall be given in at least one of the official languages of the country of destination.

Marketing restrictions.

9. As far as the presence and labelling of the products listed in the Schedule is concerned, feedingstuffs that comply with the provisions of these rules are subject only to the marketing restrictions contained in these rules.

Animal products not subject to marketing restrictions.

10. Animal products are not subject to any marketing restriction as a result of the application of these rules.

Monitoring of compliance of feedingstuffs.

11. The competent authorities shall take all necessary measures to ensure that the compliance of feedingstuffs with the requirements of these rules is officially monitored, at least by sampling during marketing.

SCHEDULE

1	2	3	4	5	6	7
Name of product group	Name of product	Designation of nutritive principle or identity of micro-organism	Culture substrate (specifications, if any)	Composition characteristics of product	Animal species	Special provisions
1. Proteins obtained from the following groups of micro-organisms						
1.1. Bacteria						
1.1.1. Bacteria cultivated on methanol	1.1.1.1. Protein product of fermentation obtained by culture of Methylophilus Methylotrophus on methanol	Methylophilus methylotrophus NCIB strain 10.515	Methanol	-Crude protein min. 68 % - Reflectance index at least 50	- Pigs - Calves – Poultry - Fish	Declarations to be made on the label or packaging of the product: - name of the product - crude protein, - crude ash, - crude fat, - moisture content, - instructions for use, - Declaration of the words 'Avoid inhalation. - approval number Declarations to be made on the label or packaging of compound feedingstuffs: - amount of the product contained in the feedingstuff.'
1.1.2 Bacteria cultivated on natural gas	1.1.2.1 protein product of fermentation from natural gas obtained by culture of:	Methylococus capsulatus (Bath) NCIMB strain 11132 Alcaligenes acidovorans NCIMB	Natural gas: (approx. 91% methane, 5% ethane, 2% propane, 0, 5% isobutane, 0, 5% nbutane, 1% other	crude protein: min. 65%	- Pigs for fattening from 25 to 60 kg - Calves from 80 kg on - Salmon	Declarations to be made on the label or packaging of the product: - the names: "Protein product of

	Methylococus capsulatus (Bath), Alcaligenes acidovorans, Bacillus brevis et Bacillus firmus, and the cells of which have been killed	strain 12387 Bacillus brevis NCIMB strain 13288 Bacillus firmus NCIMB strain 13280	components), ammonia mineral salts			fermentation from natural gas obtained by culture of Methylococus capsulatus (Bath), Alcaligenes acidovorans, Bacillus brevis et Bacillus firmus" - crude protein - crude ash - crude fat - moisture content - instructions for use - maximum incorporation rate in - 8% pigs for fattening - 8% calves - 19% salmon (freshwater) - 33% salmon (seawater) - declaration of the words: "avoid inhalation". - approval number Declarations to be made on the label or packaging of compound feedingstuffs : - The name: "Protein product obtained by bacterial fermentation of natural gas" - amount of the product contained in the feedingstuff.
1.2. Yeasts 1.2.1. Yeasts cultivated on substrates of animal	All yeasts - obtained from the micro-organisms and substrates listed in	Saccharomyces cerevisiae, Saccharomyces carlsbergiensis,	Molasses, distillery residues, cereals and products containing starch, fruit juice,	-	All animal species	

or vegetable origin	columns 3 and 4 respectively - the cell of which have been killed	Kluyveromyces lactis, Kluyveromyces fragilis	whey, lactic add, hydrolyzed vegetable fibres			
1.2.2. Yeasts cultivated on substrates other than those given in 1.2.1	-	-				
1.3. Algae						
1.4. Lower fungi						
1.4.1. Products from production of antibiotics by fermentation						
	1.4.1.1. Mycelium, wet byproduct from the production of penicillin, ensiled by means of lactobacillus brevis, plantarun, sake, collenoid and streptococcus lactis to inactive the penicillin and heat treated	Nitrogenous compound Penicillium chrysogenum ATCC 48271	Different sources of carbohydrates and their hydrolysates	Nitrogen expressed as crude protein: min. 7 %	Ruminants pigs	Declaration to be made on the label or packaging of the product: - the name: "Mycelium silage from the production of penicillin" - Nitrogen expressed as crude protein - crude ash - moisture - animal species or category Declaration to be made on the label or packaging of the compound feedingstuff: - the name: "Mycelium silage from the production of penicillin"

2. Nonp-rotein nitrogenous compounds						Declarations to be made on the label or packaging of the product: - the name 'Urea', 'Biuret', ' Urcaphosphate' or' Diureidoisobutane', as the case may be, - nitrogen level; and in addition for product 2.1.3, phosphorus level, - animal species or category, - approval number Declarations to be made on the label or packaging of compound feedingstuffs: - the name 'Urea', 'Biuret', 'Ureaphosphate' or 'Diureidoisobutane' as the case may be, - amount of the product contained in the feedingstuff, - percentage of the total crude protein provided by non-protein nitrogen, - indication, in the instructions for use, of the level of total non-protein nitrogen which should not be extended in the daily ration of each animal species or category.
2.1. Urea and its derivatives	2.1.1. Urea, technically pure	$CO(NH_2)_2$	-	Urea: minimum 97%	Ruminants from the beginning of rumination	
	2.1.2. Biuret, technically pure	$(CONH_2)_2NH$	-	Biuret: minimum 97%		
	2.1.3. Ureaphosphate, technically pure	$CO(NH_2)_2 H_3PO_4$	-	Nitrogen: minimum 16, 5% Phosphorus: minimum 18 %		
	2.1.4. Diureidoisobutane, technically pure	$(CH_3)_2(CH)_2(NHCONH_2)_2$	-	Nitrogen: minimum 30% Isobutyraldehyde: minimum 35 %		

2.2. Ammonium salts	2.2.1. Ammonium lactate, produced by fermentation with Lactobacillus bulgaricus	$CH_3CHOHCOONH_4$	Whey	Nitrogen expressed as crude protein: minimum 44 %	Ruminants from the beginning of rumination	Declarations to be made on the label or packaging of the product: - the name 'Ammonium lactate from fermentation', - nitrogen expressed as crude protein, - crude ash, - moisture, - animal species or category, - approval number Declarations to be made on the label or packaging of compound feedingstuffs: - the name 'Ammonium lactate from fermentation', - amount of product contained in the feedingstuff- percentage of the total crude protein provided by non-protein nitrogen, - indication, in the instructions for use, of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species or category.
	2.2.2. Ammonium acetate in aqueuous solution	CH_3COONH_4	-	Ammonium acetate min. 55 %	Ruminants, from the start of rumination	Declarations to be made on the label or packaging of the product: - the words: Ammonium acetate,

						- nitrogen and moisture contents, - animal species or category, - approval number Declarations to be made on the label or packaging of compound feedingstuffs: - the words: Ammonium acetate - the amount of the product contained in the feedingstuff, - percentage of the total crude protein provided by non protein nitrogen, - indication in the instructions for use of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species or category.'
	2.2.3 Ammonium sulfate in aqueous solution	$(NH_4)\ 2SO_4$	-	Ammonium sulfate: minimum 35%	Ruminants from the start of rumination	Declarations to be made on the label or packaging of the product: - the words: Ammonium sulfate, - nitrogen and moisture contents, - animal species, - approval number Declarations to be made on the label or packaging of compound

						feedingstuffs: - the words: "Ammonium sulfate", - the amount of the product contained in the feedingstuff, - percentage of the total crude protein provided by non protein nitrogen, - indication in the instructions for use of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species, - in the case of young ruminats, the incorporation rate in the daily ration may not exceed 0, 5%
2.3. By-Products from the production of amino acids by fermentation	2.3.1. Concentrated liquid By-Products from the production of Lglutamic acid by fermentation with Corynebacterium melassecola	Ammonium salts and other nitrogenous compounds	Sucrose, molasses, starch products and their hydrolysates	Nitrogen expressed as crude protein: minimum 48 % Moisture: maximum 28%	Ruminants from the beginning of rumination	Declarations to be made on the label or packaging of the product: - the name 'By-Products from the production of Lglutamic acid' in the case of product 2.3.1; 'By-Products of L-Lysine' in the case of product 2.3.2, - nitrogen, expressed as crude protein, - crude ash, - moisture,

						- animal species or category, - approval number Declarations to be made on the label or packaging of compound feedingstuffs: - the name 'By-Products from the production of Lglutamic acid' in the case of product 2.3.1; 'By-Products from the production of L-Lysine' in the case of product 2.3.2, - percentage of the total crude protein provided by non-protein nitrogen, - indication, in the instructions for use, of the level of total non-protein nitrogen which should not be exceeded in the daily ration of each animal species or category.
	2.3.2. Concentrated liquid By-Products from the production of L-Lysine monohydrochloride by fermentation with Brevibacterium lactofermentum	Ammonium salts and other nitrogenous compounds	Sucrose, molasses, starch products and their hydrolysates	Nitrogen expressed as crude protein: minimum 45 %	Ruminants from the beginning of rumination	
3. Amino acids and their salts 3.1. Methionine	3.1.1. DL-Methionine, technically pure	CH_3S (CH_2) 2CH (NH_2) COOH	-	DL-Methionine: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product:

	3.1.2. Dihydrated calcium salt of Nhydroxy methyl DL-Methionine, technically pure	[CH_3S (CH_2) 2CH (NHH_2OH) COO]2Ca.2H_2O	-	DL-Methionine: minimum 67% Formaldehyde: maximum 14% Calcium: minimum 9%	Ruminants from the beginning of rumination	- the name "DL L methionine, in the case of products 3.1.1, "Dihydrated calcium salt of Nhydroxy methylDL-Methionine" in the case of product 3.1.2, "Zincmethionine", in the case of product 3.1.3, - DL-Methionine and moisture contents, - animal species or category in the case of products 3.1.2 and 3.1.3, - approval number
	3.1.3. Methioninezinc, technically pure	[CH_3S (CH_2) 2CH (NH_2) COO]2Zn	DL-Methionine: minimum 80% Zn: maximum 18, 5%			
	3.1.4. Concentrated liquid sodium DL-Methionine technically pure	(CH_3S (CH_2) 2CH (NH_2) COO) Na	-	DL-Methionine: minimum 40, 0 % Sodium: minimum 6, 2 %	All animal species	Declarations to be made on the label or packaging of the product: - the name 'concentrated liquid sodiumDL-Methionine' - DL-Methionine content - moisture content - approval number
	3.1.5 DL-Methionine, technically pure protected with copolymer vinylpyridinelstyrene	CH_3S (CH_2) 2CH (NH_2) COOH	-	DL-Methionine: minimum 65 % copolymer vinylpyridine/ styrene: maximum 3 %	Dairy cows	Declarations to be made on the label or packaging of the product: - "Protected methionine with copolymer vinylpyridine/styrene" - DL-Methionine and moisture contents - animal species - approval number

3.2. Lysine	3.2.1. L-Lysine, technically pure	NH_2 (CH_2) 4CH (NH_2) COOH	-	L-Lysine: minimum 98%	All animal species	Declarations to be made on the label or packaging of the product: - the name "L-Lysine" in the case of product 3.2.1, "Concentrated liquid L-Lysine base" in the case of product 3.2.2, "L-Lysinemonohydrochloride " in the case of product 3.2.3, "Concentrated liquid L-Lysine monohydrochloride" in the case of product 3.2.4, "L-Lysine sulphate and its By-Products from fermentation", in the case of product 3.2.5, - L-Lysine and moisture contents - approval number
	3.2.2. Concentrated liquid L-Lysine (base)	NH_2 (CH_2) 4CH (NH_2) COOH	Saccharose, molasses, starch products and their hydrolysates	L-Lysine: minimum 60%		
	3.2.3. L-Lysinemonohydrochloride, technically pure	NH_2 (CH_2) 4CH (NH_2) COOH.HCl	-	L-Lysine: minimum 78%		
	3.2.4. Concentrated liquid L-Lysinemonohydrochloride	- NH_2 (CH_2) 4CH (NH_2) COOH.HCl	Saccharose, molasses, starch products and their hydrolysates	L-Lysine: minimum 22, 4%		
	3.2.5. L-Lysinesulphate produced by fermentation with Corynebacterium glutamicum	[NH_2 (CH_2) 4CH (NH_2) COOH]$_2$ H_2SO_4	Sugar syrup, molasses, cereals, starch products and their hydrolysates	L-Lysine: minimum 40%		
	3.2.6. L-Lysine phosphate and its By-Products produced by fermentation with Brevibacterium lactofermentum NRRL B11470	[NH_2 (CH_2) 4CH (NH_2) COOH]	Sucrose ammonia and fish solubles	L-Threonine nlinimum 98 % L-Lysine: min. 35 % Phosphorus: min. 4, 3 %	Poultry, pigs	Declarations to be made on the label or packaging of the product: - "L-Lysine and moisture content - approval number
	3.2.7 Mixtures of: (a) L-Lysinemonohydrochloride, technically pure and, (b) DL-Methionine, technically pure	NH_2 (CH_2) 4CH (NH_2) COOHHCl CH_3S (CH_2) 2CH (NH_2) COOH	-	L-Lysine + DL-Methionine minimum 50 % (including DL-Methionine minimum 15 %) Copolymer	Dairy cows	Declarations to be made on the label or packaging of the product: - the name "mixture of Ulysine monohydrochloride and DL-Methionine protected

	protected with copolymer vinylpyridine/ styrene			vinylpyridine/ styrene maximum 3 %		with copolymer vinylpyridine/styrene" - L-Lysine, DLrnethionine and moisture contents - animal species - approval number
3.3. Threonine	3.3.1. L-Threonine, technically pure	CH_3CH (OH) CH (NH_2) COOH	-	L-Threonine: minimum 98%	All animal species	Declarations to be made on the label or packaging of the product: - the name "L-Threonine" - L-Threonine and moisture contents - approval number
3.4. Tryptophan	3.4.1. L-Tryptophan, technically pure	(C_8H_5NH) CH_2CH (NH_2) COOH	-	L-Tryptophan: minimum 98 %	All animal species	Declarations to be made on the label or packaging of the product: - the name: "L-Tryptophan" - L-Tryptophan and moisture contents - approval number
3.4.2. DL-Tryptophan, technically pure,	(C, H, NH) CH, CH (NH,) COOH	-	DL-Tryptophan: minimum 98 %	All animal species		Declarations to be made on the label or packaging of the product: - the name: "L-Tryptophan" - L-Tryptophan and moisture contents - approval number
4. Analogues of amino acids						

4.1. Analogues of methionine	4.1.1 Hydroxy analogue of methionine	CH_3S (CH_2) 2CH (OH) COOH	-	Total of acids: minimum 85 % Monomer acid: minimum 65 %		All animal species Declarations to be made on the label or packaging of the product: - if appropriate, the name (column 2), - monomer acid and total acids contents in the case of product 4.1.1 and monomer acid content in the case of product 4.1.2, - moisture content, - animal species - approval number Declarations to be made on the label or packaging of compound feeding Stuffs : - if appropriate, the name (column 2), - monomer acid and total acids contents in the case of product 4.1.1 and monomer acid content in the case of product 4.1.2, - amount of the product contained in the feedingstuff.
	4.1.2 Calcium salt of hydroxy analogue of methionine	[CH_3S (CH_2) 2CH (OH) COO]2Ca	-	Monomer acid: minimum 83 % Calcium: minimum 12 %		

The contents laid down or to be declared in accordance with columns 5 and 7 refer to the product as such.

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