L.N. 231 of 2005

VETERINARY SERVICES ACT, 2001
(CAP. 437)

Feedingstuffs Intended for Particular Nutritional Purposes Rules, 2005

IN exercise of the powers conferred by article 26 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope.

1. (1) The title of these rules is Feedingstuffs Intended for Particular Nutritional Purposes Rules, 2005.

(2) These rules concern feedingstuffs intended for particular nutritional purposes.

(3) Feedingstuffs intended for particular nutritional purposes may be marketed only if -

(a) they fulfil the conditions referred to in rule 3,

(b) they are labelled in accordance with the provisions laid down in rule 5,

(c) their intended uses are included in the list drawn up pursuant to rule 6 and they fulfil the other provisions laid down in that list.

(4) The Veterinary Services shall ensure that the provisions under "General provisions" of Part A of the Schedule are complied with.

(5) The scope of these rules is to implement the rules found under European Union Council Directive 93/74/EEC as amended by European Union Council Directive 96/25/EC, European Union Directive 2000/16/EC, European Union Council Directive 1999/29/EC, European Union Council Regulation (EC) No 806/2003. Annex A and B to European Commission Directive 94/39/EC, establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes are hereby included as Schedule to these rules.

Definitions.

2. For the purposes of these rules, the following definitions shall apply -

(a) "the Commission" means the European Commission;

(b) "compound feedingstuffs" means mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;

(c) "feedingstuffs" means products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

(d) "feedingstuffs intended for particular nutritional purposes" means compound feedingstuffs which, by virtue of their particular composition or method of manufacture, can be clearly distinguished from both ordinary feedingstuffs and the products defined in European Union Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs, and are presented as intended to meet specific nutritional requirements;

(e) "particular nutritional purpose" means the purpose of satisfying the specific nutritional needs of certain pets or productive livestock whose process of assimilation, absorption or metabolism could be temporarily impaired or is temporarily or irreversibly impaired and are therefore able to derive benefit from ingestion of feedingstuffs appropriate to their condition;

(f) "Veterinary Services" means the competent authority within Malta as established under article 2 of the Veterinary Services Act.

Nature of composition of feedingstuffs intended for particular nutritional purposes.

3. The nature of composition of the feedingstuffs referred to in rule 1 (2) shall be such that the products are appropriate for their intended particular nutritional purpose.

Applicability of these rules.

4. These rules shall apply, subject to the specific provisions laid down therein, without prejudice to the legal provisions on -

(a) compound feedingstuffs;

(b) additives used in feedingstuffs;

(c) undesirable substances and products in animal nutrition;

(d) certain products used in animal nutrition.

Additional indications to appear on packaging, on the container or on the label of feedingstuffs.

5. (1) In addition to the labelling provisions in article 5 of European Union Council Directive 79/373/EEC on the marketing of compound feedingstuffs it is expressively required that the following additional indications appear in the space provided for the purpose on the packaging, on the container or on the label of the feedingstuffs referred to in rule 1 (2) -

(a) the qualifying expression "dietetic" together with the description of the feedingstuff;

(b) the precise use, i.e. the particular nutritional purpose;

(c) the indication of the essential nutritional characteristics of the feedingstuffs;

(d) the declarations prescribed in column 4 in the Schedule to these rules concerning the particular nutritional purpose;

(e) the recommended length of time for use of the feedingstuff.

The indications referred to in points (a) to (e) must comply with the content of the list of intended uses in the Schedule to these rules and the general provisions to be laid down in accordance with rule 6 (b).

(2) Indications other than those referred to in sub-rule (1) may be supplied in the space provided for the purpose, in so far as they are covered by rule 6 (a).

(3) without prejudice to article 5e of European Union Council Directive 79/373/EEC, the labelling of feedingstuffs as referred to in rule 1 (2) may make reference to a specific pathological condition in so far as that condition corresponds to the nutritional purpose laid down in the list of uses drawn up in accordance with rule 6 (a).

(4) the label or the directions for use of the feedingstuffs referred to in rule 1 (2) must bear the indication "It is recommended that a specialist's opinion be sought before use" ;

It may, however, be provided in the list of intended uses in the Schedule that this declaration shall be replaced for specific dietetic feedingstuffs with a recommendation to request the prior opinion of a veterinarian.

(5) the provisions of article 5c (5) of European Union Council Directive 79/373/EEC shall also apply to the feedingstuffs referred to in rule 1 (2) and intended for animals other than pets.

(6) the labelling of the feedingstuffs referred to in rule 1 (2) may also highlight the presence or the low level of one or more analytical constituents which are essential for the description of the feedingstuff. In such cases, the minimum or maximum level of the analytical constituents expressed as percentage weight of the feedingstuff must be clearly indicated in the list of declared analytical constituents.

(7) the qualifying expression "dietetic" shall be reserved solely for feedingstuffs as referred to in rule 1 (2). Qualifying expressions other than "dietitic" shall be prohibited in the labelling and presentation of these feedingstuffs.

(8) Notwithstanding the provisions of article 5c (3) of European Union Council Directive 79/373/EEC, the declaration of feed materials may be made in the form of categories grouping several feed materials, even where the declaration of certain feed materials by their specific name is required to justify the nutritional characteristics of the feedingstuff.

List of intended uses of feedingstuffs intended for particular nutritional purposes.

6. Pursuant to the procedure laid down in article 9 to European Union Council Directive 93/74/EEC -

(a) a list of intended uses shall be established in accordance with the Schedule. That list shall contain -

(i) the indications referred to in rule 5(1) (b), (c), (d) and (e), and

(ii) where appropriate, the indications referred to in rule 5 (2) and rule 5 (4), second subparagraph;

(b) general provisions regarding the application of the indications referred to in paragraph (a) hereof, including applicable tolerances, may be established;

(c) the measures adopted in accordance with paragraphs (a) and (b) hereof may be modified, following developments in scientific and technical knowledge.

Marketing restrictions.

7. In Malta, feedingstuffs as referred to in rule 1 (2) are not, for reasons concerning the provisions of these rules, subject to marketing restrictions other than those provided for in these rules.

Prescribed conditions that represent a hazard.

8. (1) Where it is established that the use of a feedingstuff as referred to in rule 1 (2) or its use in the prescribed conditions presents a hazard for animal or human health or for the environment, the Veterinary Services shall immediately inform the relevant European Union Commission, giving the reasons for its decision.

(2) Appropriate measures shall be implemented as soon as possible according to decisions adopted by the European Commission.

Official inspection of feedingstuffs.

9. To allow effective official inspection of feedingstuffs as referred to in rule 1 (2), the following specific provisions shall apply -

(a) the Veterinary Services shall make all necessary arrangements for official inspection during manufacture or marketing, at least by sampling, in order to ensure compliance with the requirements of these rules; and

(b) where appropriate, the Veterinary Services shall be empowered to require the person responsible for placing the product on the market to produce data and information establishing the feedingstuff's conformity with these rules. If such data have been published in readily accessible form, a reference to the publication shall suffice.

SCHEDULE

PART A
General provisions

1. Where there is more than one group of nutritional characteristics indicated in column 2 of Part B, denoted by “and/or”, for the same nutritional purpose, the manufacturer has the option to use either or both groups of essential characteristics, in order to achieve the nutritional purpose defined in column 1. For each option the corresponding labelling declarations are given opposite in column 4.

2. Where a group of additives is mentioned in column 2 or column 4 of Part B the additive (s) used must be in Regulation (EC) No 1831/2003 of the European Parliament and of the Council corresponding to the specified essential characteristic.

3. Where the source (s) of ingredients or of analytical constituents is (are) required in column 4 of Part B, the manufacturer must make a precise declaration (e.g. specific name of the ingredient (s), animal species or part of the animal) allowing the evaluation of conformity of the feedingstuff with the corresponding essential nutritional characteristics.

4. Where the declaration of a substance, also authorised as an additive, is required in column 4 of Part B and is accompanied by the expression “total” the declared content must refer to, as appropriate, the quantity naturally present where none is added or, by derogation from in Regulation (EC) No 1831/2003 of the European Parliament and of the Council, the total quantity of the substance naturally present and the amount added as an additive.

5. The declarations required in column 4 with the reference “if added” are compulsory where the ingredient or the additive has been incorporated or increased specifically to enable the achievement of the particular nutritional purpose.

6. The declarations to be given in accordance with column 4 of Part B concerning analytical constituents and additives must be quantitative.

7. The recommended period of use indicated in column 5 of part B indicates a range within which the nutritional purpose should normally be achieved. Manufacturers can refer to more precise periods of use, within the fixed limits.

8. Where a feedingstuff is intended to meet more than one particular nutritional purpose, it must comply with the corresponding entries in Part B.

9. In the case of complementary feedingstuffs intended for particular nutritional purposes guidance on the balance of the daily ration must be provided in the instructions for use contained on the label.

PART B
List of Intended Uses of Animal Feedingstuffs for Particular Nutritional Purposes

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animals	Labelling declarations	Recommended length of time for use	Other provisions
1	2	3	4	5	6
Support of Renal Function in case of chronic and renal insufficiency	- Low level of phosphorus and restricted level of protein but of high quality	Dogs and Cats	- Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Content of essential fatty acids	Initially up to 6 months (2)	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before extending the period of use" Indicate in the instructions for use: "Water should be available at all times."
Dissolution of struvite stones (4)	- Urine acidifying properties, low level of magnesium, and restricted level of protein but of high quality	Dogs	- Protein source(s) - Calcium - Phosphorus - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Urine acidifying substances	5 to 12 weeks	Indicate in the instructions for use: "Water should be available at all times." Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use."
	- Urine acidifying properties and low level of magnesium	Cats	- Calcium - Phosphorus - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Total taurine - Urine acidifying substances		

1	2	3	4	5	6
Reduction of struvite stone recurrence [4]	Urine acidifying properties and moderate level of magnesium	Dogs and cats	- Calcium - Phosphorus - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Urine acidifying substances	Up to 6 months	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use."
Reduction of urate stones formation	Low level of purines, low level of protein but of high quality	Dogs and cats	Protein source(s)	Up to 6 months but lifetime use in cases of irreversible disturbance of uric acid metabolism	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use."
Reduction of oxalate stones formation	Low level of calcium, low level of vitamin D, and urine alkalising properties	Dogs and cats	- Phosphorus - Calcium - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Total vitamin D - Hydroxyproline - Urine alkalising substances	Up to 6 months	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use."
Reduction of cystine stones formation	Low level of protein, moderate level of sulphur amino acids, and urine alkalising properties	Dogs and cats	- Total sulphur amino acids - Sodium - Potassium - Chlorides - Sulphur - Urine alkalising substances	Initially up to 1 year	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use."
Reduction of ingredient and nutrient intolerances [5]	- Selected protein source(s) and/or - Selected carbohydrate source(s)	Dogs and cats	- Protein source(s) - Content of essential fatty acids (if added) - Carbohydrate source(s) - Content of essential fatty acids (if added)	3 to 8 weeks: if signs of intolerance disappear this feed can be used indefinitely	

1	2	3	4	5	6
Reduction of acute intestinal absorptive disorders	Increased level of electrolytes and highly digestible ingredients	Dogs and cats	- Highly digestible ingredients including their treatment if appropriate - Sodium - Potassium - Source(s) of mucilaginous substances (if added)	1 to 2 weeks	Indicate on the package, container or label: - "During periods of and recovery from acute diarrhoea." - "It is recommended that a veterinarian's opinion be sought before use."
Compensation for maldigestion [(6)]	Highly digestible ingredients and low level of fat	Dogs and cats	Highly digestible ingredients including their treatment if appropriate	3 to 12 weeks, but lifetime in case of chronic pancreatic insufficiency	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use."
Support of heart function in case of chronic cardiac insufficiency	Low level of sodium and increased K/Na ratio	Dogs and cats	- Sodium - Potassium - Magnesium	Initially up to 6 months	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use."
Regulation of glucose supply (Diabetes mellitus)	Low level of rapid glucosereleasing carbohydrates	Dogs and cats	-Carbohydrate source(s) - Treatment of carbohydrates if appropriate - Starch - Total sugar - Fructose (if added) - Content of essential fatty acids (if added) - Source(s) of short and medium chain fatty acids (if added)	Initially up to 6 months	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use."

1	2	3	4	5	6
Support of liver function in case of chronic liver insufficiency	- High quality protein, moderate level of protein, high level of essential fatty acids and high level of highly digestible carbohydrates	Dogs	- Protein source(s) - Content of essential fatty acids - Highly digestible carbohydrates including their treatment if appropriate - Sodium - Total copper	Initially up to 6 months	Indicate on the package, container or label: “It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.” Indicate in the instruction for use: “Water should be available at all times”
	- High quality protein, moderate level of protein, moderate level of fat and high level of essential fatty acids	Cats	- Protein source(s) - Content of essential fatty acids - Sodium - Total copper	Initially up to 6 months	Indicate on the package, container or label: “It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.” Indicate in the instruction for use: “Water should be available at all times”
Regulation of lipid metabolism in case of hyperlipidaemia	Low level of fat and high level of essential fatty acids	Dogs and cats	- Content of essential fatty acids - Content of n-3 fatty acids (if added)	Initially up to 2 months	Indicate on the package, container or label: “It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.”
Reduction of copper in the liver	Low level of copper	Dogs	Total copper	Initially up to 6 months	Indicate on the package, container or label: “It is recommended that a opinion be sought before use or before extending the period of use.”
Reduction of excessive body weight	- Low energy density	Dogs and cats	- Energy value (calculated according to EC method)	Until target body weight is achieved	In the instructions for use an appropriate daily intake must be recommended

1	2	3	4	5	6
Nutritional restoration, convalescence	- High energy density, highly concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	- Highly digestible ingredients, including their treatment if appropriate - Energy value (calculated according to EC method) - Content of n-3 and n-6 fatty acids (if added)	Until restoration is achieved	In the case of feedingstuffs specially presented to be given via tubing, indicate on the package, container or label "Administration under veterinary supervision"
In case of feedingstuffs for cats, the manufacturer may complete the particular nutritional purpose with a reference to "Feline hepatic lipidosis".'					
Reduction of the risk of milk fever	- Low level of calcium and/or - Low cations/anions ratio	Dairy cows	- Calcium - Phosphorus - Magnesium - Calcium - Phosphorus - Sodium - Potassium - Chlorides - Sulphur	1 to 4 weeks before calving	Indicate in the instructions for use: “Stop feeding after calving.”
Reduction of the risk of ketosis (7) (8)	Ingredients providing glucogenic energy sources	Dairy cows and ewes	- Ingredients providing glucogenic energy sources - Propane-1,2-diol (if added as a glucose precursor) - Glycerol (if added as a glucose precursor)	3 to 6 weeks after calving (9) Last 6 weeks before and the first 3 weeks after lambing (10)	
Reduction of the risk of tetany (hypomagnesaemia)	High level of magnesium, easily available carbohydrates, moderate level of protein and low level of potassium	Ruminants	- Starch - Total sugars - Magnesium - Sodium - Potassium	3 to 10 weeks during periods of fast grass growth	In the instructions for use guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily available energy sources. In case of feedingstuffs for ovines indicate on the package, container or label: “Especially for lactating ewes.”

1	2	3	4	5	6
Reduction of the risk of acidosis	Low level of easily fermentable carbohydrates and high buffering capacity	Ruminants	- Starch - Total sugars	Maximum 2 months (11)	In the instructions for use guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily fermentable carbohydrate sources. In case of feedingstuffs for dairy cows indicate on the package, container or label: “Especially for high yielding cows.” In case of feedingstuffs for ruminants for fattening indicate on the package, container or label: “Especially for intensively fed...” (12)
Stabilisation of water and electrolyte balance	Predominantly electrolytes and easily absorbable carbohydrates	Calves Piglets Lambs Kids Foals	- Carbohydrate source(s) - Sodium - Potassium - Chlorides	1 to 7 days (1 to 3 days if fed exclusively)	Indicate on the package, container or label: “In case of risk of, during periods of, or recovery from digestive disturbance (diarrhoea). - It is recommended that a veterinarian's opinion be sought before use.”
Reduction of the risk of urinary calcull	Low level of phosphorus, magnesium, and urine acidifying properties	Ruminants	- Calcium - Phosphorus - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Urine acidifying substances	Up to 6 weeks	Indicate on the package, container or label: “Especially for intensively fed young animals.” Indicate in the instructions for use: “Water should be available at all times.”
Reduction of stress reactions	- High level magnesium and/or - Highly digestible ingredients	Pigs	- Magnesium - Highly digestible ingredients including their treatment if appropriate - Content of n-3 fatty acids (if added)	1 to 7 days	Guidance shall be provided on the situation in which the use of this feed is appropriate.

1	2	3	4	5	6
Stabilisation of physiological digestion	- Low buffering capacity, and highly digestible ingredients	Piglets	- Highly digestible ingredients including their treatment if appropriate - Buffering capacity - Source(s) of astringent substances (if added) - Source(s) of mucilaginous substances (if added)	2 to 4 weeks	Indicate on the package, container or label: “In case of risk of, during periods of, or recovery from, digestive disturbance.”
	- Highly digestible ingredients	Pigs	- Highly digestible ingredients including their treatment if appropriate - Source(s) of astringent substances (if added) - Source(s) of mucilaginous substances (if added)		
Reduction of the risk of constipation	Ingredients stimulating intestinal passage	Sows	Ingredients stimulating intestinal passage	10 to 14 days before and 10 to 14 days after farrowing	
Reduction of the risk of fatty liver syndrome	Low energy and high proportion of metabolizable energy from lipids with high level of polyunsaturated fatty acids	Laying hens	- Energy value (calculated according to EEC method) - Percentage of metabolisable energy from lipids - Content of polyunsaturated fatty acids	Up to 12 weeks	
Compensation for malabsorption	Low level of saturated fatty acids and high level of fat soluble vitamins	Poultry excluding geese and pigeons	- Percentage of saturated fatty acids in relation to total fatty acids - Total vitamin A - Total vitamin D - Total vitamin E - Total vitamin K	During the first 2 weeks after hatching	
Compensation for chronic insufficiency of small intestine function	- Highly precaecally digestible carbohydrates, proteins and fats	Equines [(2)]	- Source(s) of highly digestible carbohydrates, proteins and fats, including their treatment if appropriate	Initially up to six months	Guidance should be provided on the situations in which the use of the feed is appropriate and the manner in which it should be fed including many small meals per day Indicate on the package, container or label : "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use"

1	2	3	4	5	6
Compensation for chronic digestive disorders of large intestine	- Highly digestible fibre	Equines	- Fibre source(s) - Content of n-3 fatty acids (if added)	Initially up to six months	Guidance should be provided on the situations in which the use of the feed is appropriate and the manner in which the feed should be fed Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use"
Reduction of stress reactions	- Highly digestible ingredients	Equines	- Magnesium - Highly digestible ingredients including their treatment if appropriate - Content of n-3 fatty acids (if added)	Two to four weeks	Guidance shall be provided on the precise situations in which the use of the feed is appropriate
Compensation of electrolyte loss in cases of heavy sweating	Predominantly electrolytes and easily absorbable carbohydrates	Equines	- Calcium - Sodium - Magnesium - Potassium - Chlorides - Glucose	One to three days	Guidance shall be provided on the situations in which the use of the feed is appropriate When the feed corresponds to a significant part of the daily ration, guidance should be provided to prevent the risk of abrupt changes in the nature of the feed Indicate on the instructions for use: "Water should be available at all times"
Nutritional restoration, convalescence	- High concentration of essential nutrients and highly digestible ingredients	Equines	- Highly digestible ingredients, including their treatment if appropriate - Content of n-3 and n-6 fatty acids (if added)	Until restoration is achieved	Guidance shall be provided on the situations in which the use of the feed is appropriate In the case of feedingstuffs specially presented to be given via tubing, indicate on the package, container or label: "Administration under veterinary supervision"

1	2	3	4	5	6
Support of liver function in case of chronic liver insufficiency	Low level of protein but of high quality and highly digestible carbohydrates	Equines	- Protein and fibre sources - Highly digestible carbohydrates including their treatment if appropriate - Methionine - Choline - Content of n-3 fatty acids (if added)	Initially tip to six months	Guidance should be provided on the manner in which the feed should be fed including many small meals per day Indicate on the package, container or label : "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use"
Support of renal function in case of chronic renal insufficiency	Low level of protein but of high quality and low level of phosphorus	Equines	- Protein source(s) - Calcium - Phosphorus - Potassium - Magnesium - Sodium	Initially up to six months	Indicate on the package, container or label: "It is recommended that a veterinarian's opinion be sought before use or before extending the period of use." Indicate in the instructions for use: "Water should be available at all times."
In case of feedingstuffs specially prepared to meet the specific conditions of very old animals (easily ingestible ingredients) a reference to "old animals" shall complete the indication of the species or category of animals.”					

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(2) If appropriate the manufacturer may also recommend use of temporary renal insufficiency.
(3) If the feedingstuff is recommended for temporary renal insufficiency the recommended period for use shall be two to four weeks.
(4) In case of feedingstuffs for cats, “feline lower urinary tract disease” or “feline urological syndrome - F.U.S.” may complete the particular nutritional purpose.
(5) In case of feedingstuffs for a particular intolerance reference to the specific intolerance can replace “ingredient and nutrient”.
(6) The manufacturer may complete the particular nutritional purpose with the reference: “exocrine pancreatic insufficiency”.
(7) The term “ketosis” may be replaced by “acetonaemia”.
(8) The manufacturers may also recommend the use for ketosis recuperation.
(9) In the case of feedingtuffs for dairy cows.
(10) In the case of feedingstuffs for ewes.
(11) In case of feedingstuffs for dairy cows: “maximum two months from the start of lactation”.
(12) Indicate the category of ruminants concerned.