L.N. 49 of 2009

VETERINARY SERVICES ACT
(CAP. 437)

List of Intended Uses of Animal Feedingstuffs for Particular Nutritional Purposes Rules, 2009

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

Title, scope and commencement.

1. (1) The title of these rules is the List of Intended Uses of Animal Feedingstuffs for Particular Nutritional Purposes Rules, 2009.

(2) The scope of these rules is to transpose Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes, as amended by Directive 2008/82/EC as regards feedingstuffs intended for the support of the renal function in case of chronic renal insufficiency, and codifying Directive 94/39/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes, as last amended by Directive 2008/4/EC as regards feedingstuffs intended for the reduction of the risk of milk fever, and subsequently repealing Directive 94/39/EC.

Definitions.

2. (1) Unless otherwise established in these rules, the definitions provided in the Veterinary Services Act shall apply.

(2) For the purpose of these rules and unless the context otherwise requires:

"authorised provider" means a person authorised by the Authority to manufacture animal products for particular nutritional purposes by making use of sources of ingredients or other similar constituents of the product or by making use of additives to such product in terms of the Schedule to these rules or who provides final consumers with nutritive products produced by animals;

"competent authority" means the Veterinary Services

within Malta as provided under article 2 of the Veterinary Services Act;

"general benefits" means all those benefits that the consumer acquires from those particular nutritive products produced by animals;

"milk fever" means a hypocalcaemic paresis (disorder of nerve and muscle function) at parturition, caused by sudden and large demand of calcium from blood due to the onset of lactation;

"final consumer" means the person who acquires nutritive products produced by animals for her own use.

Applicability.

3. (1) These rules shall apply for the reduction and prevention of the risk of milk fever so as to safeguard animal health, human health and the environment as well as for the measures provided in these rules regarding the food producing chain and animal health:

Provided that the competent authority shall consider the marginal risk as one which cannot be completely excluded:

Provided further that the competent authority shall ensure that the individual risk is balanced with the general benefits of the administration and considers such balance as necessary.

(2) The competent authority shall take all the appropriate and necessary measures to reduce the risk presented to the consumer together with any additional risk to the environment in accordance with the provisions established in the Schedule to these rules.

(3) These measures shall include the direct confiscation of the product, the suspension of activities carried out by the authorised provider when such activities are presenting a risk to the final consumer and to the environment, and the application of fines.

(4) The competent Authority shall also ensure that there is conformity with the dispositions mentioned under "General Dispositions" of Part A of the Schedule to these regulations.

Marketing of feedingstuffs intended for particular nutritional purposes.

4. Feedingstuffs intended for particular nutritional purposes within the meaning of European Union Council Directive

93/74/EEC shall be marketed in Malta only if their intended uses are included in the Schedule to these rules and if they fulfill the other provisions laid down in the Schedule.

5. The List of Intended Uses of Animal Feedingstuffs for Particular Nutritional Purposes rules, 2005 are hereby being revoked. Revokes L.N. 70 of 2005.

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 or additives used must be authorised in Regulation (EC) No 1831/2003 of the European Parliament and of the Council as corresponding to the specified essential characteristic.

3. Where the source or sources of ingredients or of analytical constituents 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 Council Directive 70/524/EEC (2), the total quantity of the substance naturally present and the amount added as an additive.

5. The declarations required in column 4 of Part B 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

[Regulation 3(2)]

List of Intended Uses

Particular Nutritional Purpose	Essential Nutritional Characteristics	Species or Category of Animals	Labelling Declarations	Recommended Length of Time	Other Provisions
Support of renal function in the case of chronic renal insufficiency[1]	Low level of phosphorus ad restricted level of protein but of high quality	Dogs and cats	- Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Contents of essential fatty acids (if added)	Initially up to 6 months[2]	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'.
	or				
	Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Adult cats	- Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Lanthanum carbonate octahydrate - Contents of essential fatty acids (if added)	Initially up to 6 months[2]	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'.
Dissolution of struvite stones[3]	- 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 time'. 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		

Reduction of struvite stone recurrence[3]	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 prines, 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 alkalizing properties	Dogs and cats	- Phosphorus - Calcium - Sodium - Magnesium - Potassium - Chlorides - Sulphur - Total vitamin D - Hydroxyproline - Urine alkalizing 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 alkalizing properties	Dogs and cats	- Total sulphur amino acids - Sodium - Potassium - Chlorides - Sulphur - Urine alkalizing 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 intolerences[4]	- 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	
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 diarrhea.' - 'It is recommended that a veterinarian's opinion be sought before use'.
Compensation for maldigestion[5]	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 (*Diabetis mellitus*)	Low level of rapid glucose-releasing carbohydrates	Dogs and cats	- Carbohydrate source(s) - Treatment of carbohydrate 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'.

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 digestive 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 instructions for use: 'Water should be available at all times.'
	- High quality protein, moderate level of protein 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 instructions for use: 'Water should be available at all times.'
Regulation of lipid metabolism in case of hyperlipidaema	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 veterinarian's 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	Until target body weight is achieved	In the instructions for use an appropriate daily intake must be recommended

Nutritional restoration, convalescence[6]	High energy density, high concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	- Highly digestible ingredients, including their treatment if appropriate - Energy value - 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'
Support of skin function in case of dermatosis and excessive loss of hair	High level of essential fatty acids	Dogs and cats	Content of essential fatty acids	Up to 2 months	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinion be sought before use'.
Reduction of the risk of milk fever	- Low level of calcium and/or	Dairy cows	- Calcium - Phosphorus - Magnesium	1 to 4 weeks before calving	Indicate in the instructions for use: 'Stop feeding after calving'
	- Low cations/anions ratio or		- Calcium - Phosphorus - Sodium - Potassium - Chlorides - Sulphur	1 to 4 weeks before calving	Indicate in the instructions for use: 'Stop feeding after calving'
	- High level of zeolite (synthetic sodium aluminium silicate) or		Content of synthetic sodium aluminium silicate	The 2 weeks before calving	Indicate in the instructions for use: - 'The amount of feed shall be restricted to ensure that a daily intake of 500g sodium aluminium-silcate per animal is not exceeded.' - 'Stop feeding after calving'
	- High level of calcium in the form of highly available calcium salts		Total calcium content, sources and respective quantity of calcium	Start at first signs of parturition to two days subsequent to parturition	Indicate on the package, container or label: - The instruction of use, i.e. the number of applications and the time before and after calving. - The text 'It is recommended that a nutritional expert's opinion be sought before use'.

Reduction of the risk of ketosis[7] [8]	Ingredients providing gluco-genic 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 package, container or label: 'Especially for lactating ewes'.
Reduction of the risk of acidosis	Low level of easily fermentable carbohydrates and highly 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 package, container or label: 'Especially for high yielding cows'. In the case of feedingstuffs for ruminants for fattening indicate on the package, container or label: 'Especially for intensively fed'.[12]

Stabilization of water and electrolyte balance	Predominately 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 the case of risk of, during periods of, or recovery from digestive disturbance (diarrhea)'. - 'It it recommended that a veterinarian's opinion be sought before use'.
Reduction of the risk of urinary calculi	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 of 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.
Stabilization of physiological digestion	- Low buffering capacity, and highly digestible ingredients - Highly digestible ingredients	Piglets Pigs	- Highly digestible ingredients including their treatment if appropriate - Buffering capacity - Source(s) of astringent substances (if added) - Source(s) of mucilaginous substances (if added) - Highly digestible ingredients including their treatment if appropriate - Source(s) of astringent substances (if added) - Source(s) of mucilaginous substances	2 to 4 weeks	Indicate on the package, container or label: 'In case of risk of, during periods of, or recovery from, digestive disturbance.'

			(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 metabolisable energy from lipids with high level of poly-unsaturated fatty acids.	Laying hens	- Energy value (calculated according to EEC method) - Percentage of metabolisable energy form lipids - Content of the polyunsaturated fatty acids	Up to 12 weeks	
Compensation for mal-absorption	Low level of saturated fatty acids and high level of fatty 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, protein and fats.	Equines[13]	- 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'.

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 situation in which the use of the feed is appropriate.
Compensation of electrolyte loss in cases of heavy sweating	Predominantly electrolyte and easily absorbable carbohydrates	Equines	- Calcium - Sodium - Magnesium - Potassium - Chlorides - Glucose	One to three day	Guidance shall be provided on the situations in which the use of the food 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 - Contents 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 packages, container or label: 'Administration under veterinary supervision'

Nutritional restoration, convalescence	High concentration of essential nutrients and highly digestible ingredients	Equines	- Highly digestible ingredients including their treatment if appropriate - Contents 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 packages, container or label: 'Administration under veterinary supervision'
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 up 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	Low level of protein but of	Equines	- Protein source(s) - Calcium	Initially up to six months	Indicate on the package, container or label:

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