

DIRECTIVES

COMMISSION DIRECTIVE 2008/38/EC

of 5 March 2008

establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes

(Text with EEA relevance)

(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes ⁽¹⁾, and in particular Article 6(a) thereof,

Whereas:

- (1) Commission Directive 94/39/EC of 25 July 1994 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes ⁽²⁾ has been substantially amended several times ⁽³⁾. In the interests of clarity and rationality the said Directive should be codified.
- (2) Directive 93/74/EEC provides for the establishment of a positive list of the intended uses of animal feedingstuffs for particular nutritional purposes. That list must indicate the precise use, that is to say, the particular nutritional purpose, the essential nutritional characteristics, the labelling declarations and where appropriate the special labelling requirements.
- (3) Certain nutritional purposes cannot be included at present in the list of intended uses due to the absence of Community methods of control for the energy value in pet foods and for dietary fibre in feedingstuffs. This list must be completed as soon as these methods have been adopted.
- (4) The established list may be modified, where appropriate, following developments in scientific and technical knowledge.

(5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

(6) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Member States shall require that feedingstuffs intended for particular nutritional purposes within the meaning of Directive 93/74/EEC shall be marketed only if their intended uses are included in Part B of Annex I to this Directive and if they fulfil the other provisions laid down in that Part of Annex I.

Furthermore, the Member States shall ensure that the provisions under 'General provisions' of Part A of Annex I are complied with.

Article 2

Directive 94/39/EC, as amended by the Directives listed in Annex II, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex II, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 3

This Directive shall enter into force on 31 July 2008.

⁽¹⁾ OJ L 237, 22.9.1993, p. 23. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 207, 10.8.1994, p. 20. Directive as last amended by Directive 2008/4/EC (OJ L 6, 10.1.2008, p. 4).

⁽³⁾ See Annex II, part A.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 March 2008.

For the Commission

The President

José Manuel BARROSO

ANNEX I

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 authorised in Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁽¹⁾ as 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 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

PART B
List of intended uses

Particular nutritional purpose (1)	Essential nutritional characteristics (2)	Species or category of animals (3)	Labelling declarations (4)	Recommended length of time (5)	Other provisions (6)
Support of renal function in the case of chronic renal insufficiency ⁽¹⁾	Low level of phosphorus and restricted level of protein but of high quality	Dogs and cats	<ul style="list-style-type: none"> — Protein source(s) — Calcium — Phosphorus — Potassium — Sodium — Content of essential fatty acids (if added) 	Initially up to 6 months ⁽²⁾	<p>Indicate on the package, container or label:</p> <p>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</p> <p>Indicate in the instructions for use: 'Water should be available at all times.'</p>
Dissolution of struvite stones ⁽³⁾	<ul style="list-style-type: none"> — Urine acidifying properties, low level of magnesium, and restricted level of protein but of high quality — Urine acidifying properties and low level of magnesium 	<p>Dogs</p> <p>Cats</p>	<ul style="list-style-type: none"> — Protein source(s) — Calcium — Phosphorus — Sodium — Magnesium — Potassium — Chlorides — Sulphur — Urine acidifying substances — Calcium — Phosphorus — Sodium — Magnesium — Potassium — Chlorides — Sulphur — Total taurine — Urine acidifying substances 	5 to 12 weeks	<p>Indicate in the instructions for use: 'Water should be available at all times.'</p> <p>Indicate on the package, container or label:</p> <p>'It is recommended that a veterinarian's opinion be sought before use.'</p>

(1)	(2)	(3)	(4)	(5)	(6)
Reduction of struvite stone recurrence (?)	Urine acidifying properties and moderate level of magnesium	Dogs and cats	<ul style="list-style-type: none"> — 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 alkalinising properties	Dogs and cats	<ul style="list-style-type: none"> — Phosphorus — Calcium — Sodium — Magnesium — Potassium — Chlorides — Sulphur — Total vitamin D — Hydroxyproline — Urine alkalinising 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 alkalinising properties	Dogs and cats	<ul style="list-style-type: none"> — Total sulphur amino acids — Sodium — Potassium — Chlorides — Sulphur — Urine alkalinising 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.'

(1)	(2)	(3)	(4)	(5)	(6)
Reduction of ingredient and nutrient intolerances ⁽⁴⁾	<ul style="list-style-type: none"> — Selected protein source(s) and/or <ul style="list-style-type: none"> — Selected carbohydrate source(s) 	Dogs and cats	<ul style="list-style-type: none"> — 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	<ul style="list-style-type: none"> — 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: <ul style="list-style-type: none"> — 'During periods of and recovery from acute diarrhoea.' — 'It is recommended that a veterinarian's opinion be sought before use.'
Compensation for maldigestion ⁽²⁾	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 the case of chronic pancreatic insufficiency	Indicate on the package, container or label: <ul style="list-style-type: none"> — 'It is recommended that a veterinarian's opinion be sought before use.'
Support of heart function in the case of chronic cardiac insufficiency	Low level of sodium and increased K/Na ratio	Dogs and cats	<ul style="list-style-type: none"> — Sodium — Potassium — Magnesium 	Initially up to 6 months	Indicate on the package, container or label: <ul style="list-style-type: none"> — 'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'
Regulation of glucose supply (<i>Diabetes mellitus</i>)	Low level of rapid glucose-releasing carbohydrates	Dogs and cats	<ul style="list-style-type: none"> — 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: <ul style="list-style-type: none"> — '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 the case of chronic liver insufficiency	<ul style="list-style-type: none"> — High quality protein, moderate level of protein, high level of essential fatty acids and high level of highly digestible carbohydrates — High quality protein, moderate level of protein and high level of essential fatty acids 	Dogs Cats	<ul style="list-style-type: none"> — Protein source(s) — Content of essential fatty acids — Highly digestible carbohydrates including their treatment if appropriate — Sodium — Total copper — Protein source(s) — Content of essential fatty acids — Sodium — Total copper 	Initially up to 6 months 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.’ 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 the case of hyperlipidaemia	Low level of fat and high level of essential fatty acids	Dogs and cats	<ul style="list-style-type: none"> — 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.

(1)	(2)	(3)	(4)	(5)	(6)
Nutritional restoration, convalescence ⁽⁶⁾	High energy density, high concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	<ul style="list-style-type: none"> — 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	<p>In the case of feedstuffs specially presented to be given via tubing, indicate on the package, container or label:</p> <p>‘Administration under veterinary supervision.’</p>
Support of skin function in the 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	<p>Indicate on the package, container or label:</p> <p>‘It is recommended that a veterinarian’s opinion be sought before use.’</p>
Reduction of the risk of milk fever	<ul style="list-style-type: none"> — Low level of calcium <p>and/or</p> <ul style="list-style-type: none"> — Low cations/anions ratio <p>or</p> <ul style="list-style-type: none"> — High level of zeolite (synthetic sodium aluminium silicate) 	Dairy cows	<ul style="list-style-type: none"> — Calcium — Phosphorus — Magnesium <ul style="list-style-type: none"> — Calcium — Phosphorus — Sodium — Potassium — Chlorides — Sulphur 	<p>1 to 4 weeks before calving</p> <p>1 to 4 weeks before calving</p>	<p>Indicate in the instructions for use:</p> <p>‘Stop feeding after calving’</p> <p>Indicate in the instructions for use:</p> <p>‘Stop feeding after calving’</p>
			Content of synthetic sodium aluminium silicate	The 2 weeks before calving	<p>Indicate in the instructions for use:</p> <ul style="list-style-type: none"> — ‘The amount of feed shall be restricted to ensure that a daily intake of 500 g sodium aluminium-silicate per animal is not exceeded.’ — ‘Stop feeding after calving’

(1)	(2)	(3)	(4)	(5)	(6)
	or — High level of calcium in the form of highly available calcium salts		Total calcium content, sources and respective quantity of calcium	Star 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 glucogenic energy sources	Dairy cows and ewes	— Ingredients providing glucogenic energy sources — Propan-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 the case of feedingstuffs for ovines indicate on the package, container or label: 'Especially for lactating ewes.'
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 the case of feedingstuffs for dairy cows indicate on the 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⁾

(1)	(2)	(3)	(4)	(5)	(6)
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 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 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.
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.'

(1)	(2)	(3)	(4)	(5)	(6)
	— Highly digestible ingredients	Pigs	<ul style="list-style-type: none"> — 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 metabolisable energy from lipids with high level of polyunsaturated fatty acids	Laying hens	<ul style="list-style-type: none"> — Energy value (calculated according to EC method) — Percentage of metabolisable energy from lipids — Content of poly-unsaturated 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	<ul style="list-style-type: none"> — 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 preceacally digestible carbohydrates proteins and fats	Equines ⁽¹³⁾	<ul style="list-style-type: none"> — Source(s) of highly digestible carbohydrates, proteins and fats, including their treatment if appropriate 	Initially up to six months	<p>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.</p> <p>Indicate on the package, container or label:</p> <p>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</p>

(1)	(2)	(3)	(4)	(5)	(6)
Compensation for chronic digestive disorders of large intestine	Highly digestible fibre	Equines	<ul style="list-style-type: none"> — Fibre source(s) — Content of n-3 fatty acids (if added) 	Initially up to six months	<p>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.</p> <p>Indicate on the package, container or label:</p> <p>'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'</p>
Reduction of stress reactions	Highly digestible ingredients	Equines	<ul style="list-style-type: none"> — 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 the cases of heavy sweating	Predominantly electrolytes and easily absorbable carbohydrates	Equines	<ul style="list-style-type: none"> — Calcium — Sodium — Magnesium — Potassium — Chlorides — Glucose 	One to three days	<p>Guidance shall be provided on the situations in which the use of the feed is appropriate.</p> <p>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.</p> <p>Indicate on the instructions for use: 'Water should be available at all times.'</p>
Nutritional restoration, convalescence	High concentration of essential nutrients and highly digestible ingredients	Equines	<ul style="list-style-type: none"> — Highly digestible ingredients, including their treatment if appropriate — Content of n-3 and n-6 fatty acids (if added) 	Until restoration is achieved	<p>Guidance shall be provided on the situations in which the use of the feed is appropriate.</p> <p>In the case of feedingstuffs specially presented to be given via tubing, indicate on the package, container or label:</p> <p>'Administration under veterinary supervision.'</p>

(1)	(2)	(3)	(4)	(5)	(6)
Support of liver function in the 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 in the 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.'

(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 the case of feedingstuffs for cats, 'feline lower urinary tract disease' or 'feline urological syndrome — FUS' may complete the particular nutritional purpose.

(4) In the 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 pancreatic insufficiency'.

(6) In the 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 'acetonæmia'.

(8) The manufacturers may also recommend the use for 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.

ANNEX II

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 2)

Commission Directive 94/39/EC	(OJ L 207, 10.8.1994, p. 20)
Commission Directive 95/9/EC	(OJ L 91, 22.4.1995, p. 35)
Commission Directive 2002/1/EC	(OJ L 5, 9.1.2002, p. 8)
Commission Directive 2008/4/EC	(OJ L 6, 10.1.2008, p. 4)

PART B

List of time-limits for transposition into national law

(referred to in Article 2)

Directive	Time-limit for transposition
94/39/EC	30 June 1995
95/9/EC	30 June 1995
2002/1/EC	20 November 2002
2008/4/EC	30 July 2008

ANNEX III

Correlation table

Directive 94/39/EC	This Directive
Article 1	Article 1
Article 2	—
—	Article 2
Article 3	Article 3
—	Article 4
Annex	Annex I
—	Annex II
—	Annex III