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intended uses of animal feedingstuffs for particular nutritional purposes (Text with EEA relevance) (Codified version) (repealed)

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(Codified version) (repealed)

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.

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⁽⁴⁾ 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⁽⁵⁾, 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

List of intended uses

Particular nutritional purpose	Essential nutritional characteristic	Species or category of sanimals	Labelling declarations	Recommende length of time	dOther provisions
(1)	(2)	(3)	(4)	(5)	(6)
Support of renal function in the case of chronic renal insufficiency ^a	Low level of phosphorus and restricted level of protein but of high quality	Dogs and cats	sourc — Calci	phorus sium im ent tial	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 ^e	and restri- level of prote but of high qualit	fying arties, esium, eted in	 source Calci Phosp Sodiu Magr Potas Chloo Sulph Urine acidir subst 	um phorus im tesium sium tides tur fying ances	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 acidit prope	fying	— Phos — Sodiu	phorus	

	and low level of magn	esium		Potas Chlor Sulph Total taurir Urine acidit subst	tides tur te	
Reduction of struvite stone recurrence ^e	Urine acidifying properties and moderate level of magnesium	Dogs and cats		Phosp Sodiu Magr Potas Chlor Sulph Urine acidit	esium sium ides ur	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		Calci Sodiu Magr Potas Chlor Sulph Total vitam D Hydr Urine alkali	esium sium rides nur iin oxyproline	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	Dogs and cats			ım sium	Indicate on the package, container or label: It is recommended that a

	alkalising properties		— t a	Sulphur Urine alkalising substances	veteri opinic be sou before or bef extend the pe of use	nght e use ore ding riod
Reduction of ingredient and nutrient intolerances ^d	prote sourc			Protein to 8 weeks: source(\$) igns of Conteint tolerance of disappear essent this feed fatty can be used acids indefinitely (if added)		
	and/or — Selec carbo sourc	hydrate	- C c f f	Carbohydrate source(s) Content of essential fatty acids (if added)		
Reduction of acute intestinal absorptive disorders	Increased level of electrolytes and highly digestible ingredients	Dogs and cats	i i t t t i i i i i i t t i i i t t i i t t i i i i i i t t t i	Highlyl to 2 weeks digestible ngredients ncluding heir reatment f appropriate Sodium Potassium Source(s) of nucilaginous substances (if added)	Indicate the pack containe label: 	age,

Compensation for maldigestion ^e	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: 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	— Potas	u h nitially up to socumonths nesium	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 (<i>Diabetes</i> <i>mellitus</i>)	Low level of rapid glucose- releasing carbohydrates	Dogs and cats	- Treat of carbo if	ose d) ent tial d) ce(s)	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		Dogs		chain fatty acids (if added) Proteininitially up to	Indicate on
liver function in the case of chronic liver insufficiency	 High quali prote mode level of prote high level of essen fatty acids and high level of high level of 	y in, rate in, tial tial y tible hydrates		source(s)nonths Content of essential fatty acids Highly digestible carbohydrates including their treatment if appropriate Sodium Total copper	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 quali prote mode level of prote and high level of essen fatty acids	ty in, rate in tial		Proteininitially up to source(s)nonths Content of essential fatty acids Sodium Total copper	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	Low level of fat and	Dogs and cats	<u> </u>	Contentially up to of 2 months	Indicate on the package,

metabolism in the case of hyperlipidaemi	high level of essential fatty acids		essen fatty acids Conte of n-3 fatty acids (if addec	≎nt	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 ^r	High energy density, high concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	diges ingre- inclue their treatm if	nent priate 39	In the case of feedingstuffs specially presented to be given via tubing, indicate on the package, container or label: Administration under veterinary supervision.

			acids (if addec		
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	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 calciu and/or	Dairy cows	— Phos	uhto 4 weeks bofase csilving	Indicate in the instructions for use: Stop feeding after calving
	- Low cation anion ratio		 Phosp Sodiu Potas Chlor 	PhosphofuseinstructionSodiumalvingfor use:PotassiumStopChloridesfeedingSulphurafter	Stop feeding
	or — High level of zeolit (synt sodiu alum silica	e hetic m inium	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 500 g sodium aluminium-

							silicate per animal is not exceeded.' 'Stop feeding after calving'
	or — High level of calcin in the form of highl availa calcin salts	y able	Total calc content, sources an respective quantity of calcium	nd e	Star at first signs of parturition to two days subsequent to parturition	Indicate the pack containe label: 	age,
Reduction of the risk of ketosis ^{gh}	Ingredients providing glucogenic energy sources	Dairy cows and ewes		provi gluco energ sourc	dictors weeks differ calving ⁱ geast 6 weeks ybefore and eshe first 3 weeks after lambing ⁱ		

			 (if addec as a gluco precu Glyce (if addec as a gluco precu	se rsor) erol I se	
Reduction of the risk of tetany (hypomagnesa	High level of magnesium, easily envia)able carbohydrates, moderate level of protein and low level of potassium	Ruminants	Total sugar Magr	h3 to 10 weeks during speriods of daistingrass ingrowth sium	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		hMaximum 2 months ^k s	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

Stabilisation of water and electrolyte balance	Predominantly electrolytes and easily absorbable carbohydrates	Calves Piglets Lambs Kids Foals	sourc Sodiu	ollytdrättdays e((b)to 3 udays if fed sexurlusively) ides	carbohyd sources. In the cas feedingst for dairy cows ind on the package, container label: Espect for hig yieldin cows. In the cas feedingst for rumir for fatten indicate of the packa container label: Espect for initensi fed. ¹ Indicate of the packa container label: Espect for	se of cuffs icate f or ially gh ng se of cuffs nants ing on age, f or ially ively on age, f or 'In case of risk of, during periods of, or recovery
						periods of, or

				before use.'
Reduction of the risk of urinary calculi	Low level of phosphorus, magnesium, and urine acidifying properties	Ruminants	Calciuthp to 6 Phosphorethes Sodium Magnesium Potassium Chlorides Sulphur Urine acidifying substances	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	and/or — High diges	esium ly	 1 to 7 days Magnesium Highly digestible ingredients including their treatment if appropriate Content of n-3 fatty acids (if added)	Guidance shall be provided on the situation in which the use of this feed is appropriate.
Stabilisation of physiological digestion	— Low buffe capac and highl diges ingre	ity, y	 Highly to 4 weeks digestible ingredients including their treatment if appropriate Buffering capacity Source(s) of	Indicate on the package, container or label: In case of risk of, during periods of, or recovery from, digestive disturbance.

				astrin subst (if addec Sourc of mucil subst (if addec	ances l) ce(s) aginous ances	
	— High diges ingre	Pigs y tible dients		includ their treatmif appro Source of astrin subst (if addece Source of	tible dients ding nent priate ce(s) gent ances 1) ce(s) aginous ances	
Reduction of the risk of constipation	Ingredients stimulating intestinal passage	Sows	Ingredie stimulati intestina passage	ng	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 polyunsaturate fatty acids	Laying hens		value (calcu accor to EC metho Perce of	od) ntage polisable y ent	

			unsat fatty acids	urated	
Compensation for malabsorption	of saturated	Poultry excluding geese and pigeons	of satura fatty acids in relati to total fatty acids Total vitam A Total vitam E Total vitam K	in in in	
Compensation for chronic insufficiency of small intestine function	Highly precaecally digestible carbohydrates proteins and fats	Equines ^m	of highl diges carbo prote and fats, includ their treatr if	tible hydrates, ins ding	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 Initially up to source(is) months Content of n-3 fatty acids (if added)	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		Magnesiumto four Highlyweeks digestible ingredients including their treatment if appropriate Content of n-3 fatty acids (if added)	Guidance shall be provided on the precise situations in which the use of the feed is appropriate.
Compensation of electrolyte	Predominantly electrolytes	Equines	<u> </u>	Calciume to three Sodiumays	Guidance shall be

loss in the cases of heavy sweating	and easily absorbable carbohydrates		Magnesium Potassium Chlorides Glucose	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	HighlyUntil digest ilekt oration is ingred achts ;ved including their treatment if appropriate Content of n-3 and n-6 fatty acids (if added)	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.

Support of liver function in the case of	Low level of protein but of high quality	Equines	_	Protein initially up to and six months fibre	Guidance should be provided on
chronic liver insufficiency	and highly digestible carbohydrates		_	sources Highly digestible carbohydrates	the manner in which the feed should be
				including their treatment if appropriate Methionine Choline Content of n-3 fatty acids (if added)	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		Proteilmitially up to source(is) months Calcium Phosphorus Potassium Magnesium Sodium	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.

b If the feedingstuff is recommended for temporary renal insufficiency the recommended period for use shall be two to four weeks.

- **c** In the case of feedingstuffs for cats, 'feline lower urinary tract disease' or 'feline urological syndrome FUS' may complete the particular nutritional purpose.
- **d** In the case of feedingstuffs for a particular intolerance reference to the specific intolerance can replace 'ingredient and nutrient'.
- e The manufacturer may complete the particular nutritional purpose with the reference: 'exocrine pancreatic insufficiency'.
- **f** In the case of feedingstuffs for cats, the manufacturer may complete the particular nutritional purpose with a reference to 'Feline hepatic lipidosis'.
- **g** The term 'ketosis' may be replaced by 'acetonaemia'.
- **h** The manufacturers may also recommend the use for ketosis recuperation.
- $i \qquad \mbox{In the case of feedingstuffs for dairy cows.}$
- j In the case of feedingstuffs for ewes.
- \mathbf{k} In the case of feedingstuffs for dairy cows: 'maximum two months from the start of lactation'.
- I Indicate the category of ruminants concerned.
- **m** 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

- (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.
- (4) OJ L 268, 18.10.2003, p. 29.
- (5) OJ L 270, 14.12.1970, p. 1.