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## **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)

(OJ L 062, 6.3.2008, p.9)

## Amended by:

									Official Journal	
								No	page	date
<u>►M1</u>	Commission		2008/8	2/EC	Text	with	EEA	L 202	48	31.7.2008
	relevance of 3	30 July 2008								
► <u>M2</u>	Commission	Regulation	(EU)	No	1070	/2010 0	f <u>22</u>	L 306	42	23.11.2010
	November 20	<u>10</u>								

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# 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 timelimits 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.

#### ANNEX I

## PART A

#### **General provisions**

- 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 (<u>5</u>), 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

characteristics	Species or category of animals	U	Recommended length of time	Other provisions
(2)	(3)	(4)	(5)	(6)

of renal in case of	phosphorus and	Dogs and cats	— Protein source(s)	Initially up to 6 months (2)	Indicate on the package, container or label:	
	restricted level of protein but of high		— Calcium		'It is recommended that a veterinarian's opinio	
-	quality		— Phosphorus		before use or before extending the period of u	
			— Potassium		Indicate in the instructions for use:	
			— Sodium		'Water should be available at all times.'	
			— Content of essential fatty acids (if added)			
	or					
	Reduced phosphorus absorption by means	Adult cats	— Protein source(s)	Initially up to 6 months $(2)$	Indicate on the package, container or label:	
	of incorporation of Lanthanum carbonate		— Calcium		'It is recommended that a veterinarian's opinio	
	octahydrate			— Phosphorus		before use or before extending the period of
			— Potassium		Indicate in the instructions for use:	
			— Sodium		'Water should be available at all times.'	
			— Lanthanum carbonate octahydrate			
			— Content of essential fatty acids (if added)			

ion of	— Urine acidifying	Dogs	— Protein source(s)	5 to 12 weeks	Indicate in the instructions for use:
stones $(3)$	properties, low level of	Dogs	— Calcium	5 10 12 weeks	'Water should be available at all times.'
	magnesium, and restricted level	evel Phosphorus		Indicate on the package, container or label:	
	of protein but of high quality		— Sodium		'It is recommended that a veterinarian's opinio
			— Magnesium		before use.'
			— Potassium		
			— Chlorides		
			— Sulphur		
			— Urine acidifying substances		
	— Urine acidifying	Cats	— Calcium		
	properties and low level of magnesium	evel of	— Phosphorus		
			— Sodium		
			— Magnesium		
			— Potassium		
			— Chlorides		
			— Sulphur		
			— Total taurine		
			— Urine acidifying substances		
	Urine acidifying properties and	Dogs and cats	— Calcium	Up to 6 months	Indicate on the package, container or label:
$\frac{1}{(3)}$	moderate level of magnesium	cats	— Phosphorus		'It is recommended that a veterinarian's opinio
	-		— Sodium		before use.'
			— Magnesium		
			— Potassium		
			— Chlorides		
			— Sulphur		

			— Urine acidifying substances		
on of urate ormation	Low level of purines, low level of protein but of high quality		Protein source(s)	but lifetime use	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinio before use.'
stones on	Low level of calcium, low level of vitamin D, and urine alkalising properties	cats	<ul> <li>Calcium</li> <li>Sodium</li> <li>Magnesium</li> <li>Potassium</li> <li>Chlorides</li> <li>Sulphur</li> <li>Total vitamin D</li> <li>Hydroxyproline</li> <li>Urine alkalising substances</li> </ul>		Indicate on the package, container or label: 'It is recommended that a veterinarian's opinio before use.'
	Low level of protein, moderate level of sulphur amino acids and urine alkalising properties		<ul> <li>— Total sulphur amino acids</li> <li>— Sodium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Urine alkalising substances</li> </ul>	Initially up to 1 year	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinic before use or before extending the period of us
on of ent and nces (4)	<ul> <li>Selected protein source(s)</li> <li>and/or</li> <li>Selected carbohydrate source(s)</li> </ul>	Dogs and cats	<ul> <li>Protein source(s)</li> <li>Content of essential fatty acids (if added)</li> <li>Carbohydrate source(s)</li> <li>Content of essential fatty acids (if added)</li> </ul>	3 to 8 weeks: if signs of intolerance disappear this feed can be used indefinitely	

al absorptive rs		Dogs a cats	nd	<ul> <li>Highly digestible ingredients including their treatment if appropriate</li> <li>Sodium</li> <li>Potassium</li> <li>Source(s) of mucilaginous substances (if added)</li> </ul>	1 to 2 weeks	<ul> <li>Indicate on the package, container or label:</li> <li>— 'During periods of and recovery from acute dia</li> <li>— 'It is recommended that a veterinarian's opinion use.'</li> </ul>
	Highly digestible ingredients and low level of fat					Indicate on the package, container or label: 'It is recommended that a veterinarian's opinio before use.'
	Low level of sodium and increased K/Na ratio		ind	— Sodium — Potassium — Magnesium	Initially up to 6 months	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinic before use or before extending the period of us
supply	Low level of rapid glucose-releasing carbohydrates	Dogs a cats	ind	<ul> <li>Carbohydrate source(s)</li> <li>Treatment of carbohydrates if appropriate</li> <li>Starch</li> <li>Total sugar</li> <li>Fructose (if added)</li> <li>Content of essential fatty acids (if added)</li> <li>Source(s) of short and medium chain fatty acids (if added)</li> </ul>	Initially up to 6 months	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinic before use or before extending the period of us
of liver n in the case ronic liver iency	<ul> <li>High quality protein, moderate level of protein, high level of essential fatty acids and high level of highly digestible carbohydrates</li> </ul>	Dogs		<ul> <li>Protein source(s)</li> <li>Content of essential fatty acids</li> <li>Highly digestible carbohydrates including their treatment if appropriate</li> </ul>	Initially up to 6 months	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinic before use or before extending the period of us Indicate in the instructions for use: 'Water should be available at all times.'

			— Sodium		
	I		— Total copper		
	protein,	Cats	— Protein source(s)	Initially up to 6 months	Indicate on the package, container or label:
	moderate level of protein and high level of		— Content of essential fatty acids		'It is recommended that a veterinarian's opinio before use or before extending the period of us
	essential fatty acids		— Sodium		Indicate in the instructions for use:
			— Total copper		'Water should be available at all times.'
lism in the	Low level of fat and high level of essential fatty acids		nd — Content of essential fatty acids	I Initially up to 2 months	Indicate on the package, container or label:
of pidaemia	fatty actus		— Content of n-3 fatty acids (if added)		'It is recommended that a veterinarian's opinion before use or before extending the period of us
on of 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 before use or before extending the period of us
on of ve body		Dogs an cats	nd Energy value	Until target body weight is achieved	In the instructions for use an appropriate daily recommended.
ion, scence <u>(6)</u>	High energy density, high concentrations of essential nutrients and highly digestible ingredients	cats	ingredients, including		In the case of feedingstuffs specially presented to be given indicate on the package, container or label: 'Administration under veterinary supervision.
			— Content of n-3 and n-6 fatty acids (if added)		
	-	Dogs an cats	nd Content of essential fatty acids	Up to 2 months	Indicate on the package, container or label:
natosis and ve loss of	-				'It is recommended that a veterinarian's opinio before use.'

of	the	Dogs:	Dogs	and	Dogs:	Initially up to 3	It is recommended that a veterinary surgeon's opinion
lism	of		cats			months	use or before extending the period of use.
the case	e of	i i i i i i i i i i i i i i i i i i i			— Total omega-3 fatty	7	
hritis		matter content of			acids		
		total omega-3					
		fatty acids 3,3 %			— Total EPA		
		and of					
		eicosapentaenoic			— Total vitamin E		
		acid (EPA)					
		0,38 %.			Catal		
					Cats:		
		Adequate level					

of vitamin E.	— Total omega-3 fatty acids
Cats: Minimum dry matter content of total omega-3 fatty acids 1,2 % and of docosahexaenoic	<ul> <li>— Total DHA</li> <li>— Total methionine</li> <li>— Total manganese</li> </ul>
acid (DHA) 0,28 %. Increased levels of methionine and manganese. Adequate level of vitamin E.	— Total vitamin E

on of the nilk fever	<ul> <li>Low level of calcium</li> </ul>	Dairy cows		1 to 4 weeks before calving	Indicate in the instructions for use:
		1	— Phosphorus		'Stop feeding after calving'
		′	— Magnesium		
	and/or				
	— Low cations/anions			1 to 4 weeks before calving	Indicate in the instructions for use:
	ratio	/	— Phosphorus		'Stop feeding after calving'
		1	— Sodium		
		1	— Potassium		
			— Chlorides		
		′	— Sulphur		
	or				
	<ul> <li>High level of zeolite</li> </ul>			The 2 weeks before calving	Indicate in the instructions for use:
	(synthetic sodium aluminium silicate)				— 'The amount of feed shall be restricted to e intake of 500 g sodium aluminium-silicate p exceeded.'
		/			— 'Stop feeding after calving'
	or	1			
	<ul> <li>High level of calcium in the form of highly</li> </ul>		Total calcium content, sources and respective quantity of calcium		
	available calcium salts			two days subsequent to	time before and after calving.
	<u>1</u>	/	1/	<u>/</u> /	1

				parturition	— The text 'It is recommended that a nutritional e sought before use'
on of the cetosis <u>(7) (8)</u>	Ingredients providing glucogenic energy sources	Dairy cows and ewes	energy sources	3 to 6 weeks after calving (9) Last 6 weeks before and the first 3 weeks after lambing (10)	
on of the of tetany agnesaemia)	magnesium, easily	Ruminants	<ul> <li>— Starch</li> <li>— Total sugars</li> <li>— Magnesium</li> <li>— Sodium</li> <li>— Potassium</li> </ul>		In the instructions for use guidance shall be provided of the daily ration, with regard to the inclusion of fibre and energy sources. In the case of feedingstuffs for ovines indicate on the pa or label: 'Especially for lactating ewes.'
on of the 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 of the daily ration, with regard to the inclusion of fibre and fermentable carbohydrate sources. In the case of feedingstuffs for dairy cows indicate on th container or label: 'Especially for high yielding cows.' In the case of feedingstuffs for ruminants for fattening i package, container or label: 'Especially for intensively fed.' (12)
	Predominantly electrolytes and easily absorbable carbohydrates	Calves Piglets Lambs Kids Foals	<ul> <li>Carbohydrate source(s)</li> <li>Sodium</li> <li>Potassium</li> <li>Chlorides</li> </ul>	1 to 7 days (1 to 3 days if fed exclusively)	Indicate on the package, container or label:
	Low level of phosphorus, magnesium, and urine acidifying properties	Ruminants	— Calcium — Phosphorus — Sodium — Magnesium	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.'

			— Potassium		
			— Chlorides		
			— Sulphur		
			— Urine acidifying substances		
on of stress	magnesium	Pigs	— Magnesium		Guidance shall be provided on the situation in which the situation is appropriate.
	and/or	′	′	1 '	
	<ul> <li>Highly digestible ingredients</li> </ul>		— Highly digestible ingredients including their treatment if appropriate		
			— Content of n-3 fatty acids (if added)		
ation of ogical n	— Low buffering capacity, and highly digestible ingredients	Piglets	— Highly digestible ingredients including their treatment if appropriate		Indicate on the package, container or label: 'In case of risk of, during periods of, or recove digestive disturbance.'
			— Buffering capacity		
			— Source(s) of astringent substances (if added)		
			— Source(s) of mucilaginous substances (if added)		
	<ul> <li>Highly digestible ingredients</li> </ul>	Pigs	— Highly digestible ingredients including their treatment if appropriate		
			— Source(s) of astringent substances (if added)		
			Source(s) of mucilaginous substances (if added)		
-	Ingredients stimulating intestinal passage	Sows	intestinal passage	10 to 14 days before and 10 to 14 days after farrowing	
fatty liver ne	metabolisable energy from lipids with high	hens	(calculated according to EC method)		
			— Percentage of		

	polyunsaturated fatty acids		metabolisable energy from lipids		
			— Content of poly- unsaturated fatty acids		
orption	saturated fatty acids and high level of fat		saturated fatty acids in		
			— Total vitamin A		
			— Total vitamin D		
			— Total vitamin E		
			— Total vitamin K		
iency of	Highly precaecally digestible carbohydrates proteins and fats	Equines (13)		six months	Guidance should be provided on the situations in which feed is appropriate and the manner in which it should be many small meals per day. Indicate on the package, container or label:
					'It is recommended that a veterinarian's opinio before use or before extending the period of us
nsation for digestive rs of large e	Highly digestible fibre	Equines		six months	Guidance should be provided on the situations in which feed is appropriate and the manner in which the feed sh Indicate on the package, container or label: 'It is recommended that a veterinarian's opinic before use or before extending the period of us
on of stress is	Highly digestible ingredients	Equines		Two to four weeks	Guidance shall be provided on the precise situations in the feed is appropriate.
yte loss in es of heavy	electrolytes and	Equines	— Calcium — Sodium — Magnesium — Potassium	days	Guidance shall be provided on the situations in which the is appropriate. When the feed corresponds to a significant part of the d guidance should be provided to prevent the risk of abru- nature of the feed. Indicate on the instructions for use:
			— Chlorides — Glucose		'Water should be available at all times.'
	I	<u> </u>	- Glucose	[]	

High concentration of essential nutrients and highly digestible ingredients	Equines	ingredients, including	restoration is	Guidance shall be provided on the situations in which t is appropriate. In the case of feedingstuffs specially presented to be gi indicate on the package, container or label: 'Administration under veterinary supervision.
but of high quality	Equines	<ul> <li>Protein and fibre sources</li> <li>Highly digestible carbohydrates including their treatment if appropriate</li> <li>Methionine</li> <li>Choline</li> <li>Content of n-3 fatty acids (if added)</li> </ul>	Initially up to six months	Guidance should be provided on the manner in which t fed including many small meals per day. Indicate on the package, container or label: 'It is recommended that a veterinarian's opinio before use or before extending the period of u
but of high quality	Equines	<ul> <li>Protein source(s)</li> <li>Calcium</li> <li>Phosphorus</li> <li>Potassium</li> <li>Magnesium</li> <li>Sodium</li> </ul>	Initially up to six months	Indicate on the package, container or label: 'It is recommended that a veterinarian's opinio before use or before extending the period of u Indicate in the instructions for use: 'Water should be available at all times.'
	essential nutrients and highly digestible ingredients Low level of protein but of high quality and highly digestible carbohydrates Low level of protein but of high quality and low level of	and highly digestible ingredientsImage: Image: Ima	essential nutrients and highly digestible ingredients	essential nutrients and highly digestible ingredients Low level of protein but of high quality and highly digestible carbohydrates Low level of protein but of high quality and highly digestible carbohydrates Low level of protein but of high quality and highly digestible carbohydrates — Highly digestible carbohydrates including their treatment if appropriate — Methionine — Content of n-3 fatty acids (if added) Low level of protein but of high quality and low level of phosphorus — Hoghnessium — Magnesium — Magnesium

ppropriate the manufacturer may also recommend use for temporary renal insufficiency.

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

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

he case of feedingstuffs for a particular intolerance reference to the specific intolerance can replace 'ingredient and nutrient'.

e manufacturer may complete the particular nutritional purpose with the reference: 'exocrine pancreatic insufficiency'.

he case of feedingstuffs for cats, the manufacturer may complete the particular nutritional purpose with a reference to 'Feline hepatic lipidosis'.

e term 'ketosis' may be replaced by 'acetonaemia'.

e manufacturers may also recommend the use for ketosis recuperation.

he case of feedingstuffs for dairy cows.

the case of feedingstuffs for ewes.

the case of feedingstuffs for dairy cows: 'maximum two months from the start of lactation'.

licate the category of ruminants concerned.

the case of feedingstuffs specially prepared to meet the specific conditions of very old animals (easily ingestible ingredients) a reference to 'old animals' cation of the species or category of animals.

ANNEX II

PART A

## Repealed Directive with list of its successive amendments

Commission Directive	(OJ L 207,
94/39/EC	10.8.1994, p. 20)
Commission Directive	(OJ L 91,
95/9/EC	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)

## (referred to in Article 2)

PART B

## List of time-limits for transposition into national law

#### (referred to in Article 2)

Directive	Time-limit transposition	for
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

<sup>(1)</sup> 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).

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

<sup>(</sup>  $\underline{2}$  ) 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).

<sup>(&</sup>lt;u>3</u>) See Annex II, part A.