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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 62, 6.3.2008, p. 9)

Amended by:

		Official Journal		
		No	page	date
► <b><u>M1</u></b>	Commission Directive 2008/82/EC of 30 July 2008	L 202	48	31.7.2008
► <b><u>M2</u></b>	Commission Regulation (EU) No 1070/2010 of 22 November 2010	L 306	42	23.11.2010
► <b><u>M3</u></b>	Commission Regulation (EU) No 5/2014 of 6 January 2014	L 2	3	7.1.2014
► <b><u>M4</u></b>	Commission Regulation (EU) No 1123/2014 of 22 October 2014	L 304	81	23.10.2014

**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 <sup>(1)</sup>, 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 <sup>(2)</sup> has been substantially amended several times <sup>(3)</sup>. 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,

<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).

<sup>(2)</sup> 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>(3)</sup> See Annex II, part A.

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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**

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 <sup>(1)</sup> 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 <sup>(2)</sup>, 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.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> OJ L 270, 14.12.1970, p. 1.

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10. When a feed intended for particular nutritional purposes is placed on the market in the form of a bolus, being a feed material or complementary feed intended for individual oral administration by forced feeding, the label of the feed shall, if applicable, mention the maximum period of continuously release of the bolus and the daily release rate for each additive for which a maximum content in complete feed is fixed. At the request of the competent authority the feed business operator which is placing a bolus on the market shall provide proof that the daily available additive level in the digestive tract will not exceed, if applicable, the maximum content of the additive established per kg complete feed during the whole feeding period (slow release effect). It is recommended that feed in form of bolus is administered by a veterinarian or any other competent person.

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**PART B**  
**List of intended uses**

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animals	Labelling declarations	Recommended length of time	Other provisions
(1)	(2)	(3)	(4)	(5)	(6)
▼ <b>M4</b>  Support of renal function in case of chronic renal insufficiency <sup>(1)</sup>	High quality proteins and restricted levels of phosphorus maximum 5 g/kg complete pet food with a moisture content of 12 % and crude protein maximum 220 g/kg complete pet food with a moisture content of 12 %  or	Dogs	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Potassium</li> <li>— Sodium</li> <li>— Content of essential fatty acids (if added)</li> </ul>	Initially up to 6 months <sup>(2)</sup>	<ul style="list-style-type: none"> <li>— The feed shall be placed on the market as complete feed.</li> <li>— Recommended digestibility of proteins: minimum 85 %.</li> <li>— Indicate on the labelling:  ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’</li> <li>— Indicate in the instructions for use:  ‘Water should be available at all times.’</li> </ul>
	Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Adult dogs	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Potassium</li> <li>— Sodium</li> <li>— Content of essential fatty acids (if added)</li> <li>— Lanthanum carbonate octahydrate</li> </ul>	Initially up to 6 months <sup>(2)</sup>	<ul style="list-style-type: none"> <li>— Indicate on the labelling: ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’</li> <li>— Indicate in the instructions for use:  ‘Water should be available at all times.’</li> </ul>

▼ **M4**

(1)	(2)	(3)	(4)	(5)	(6)
	<p>High quality proteins and restricted levels of phosphorus maximum 6,2 g/kg complete pet food with a moisture content of 12 % and crude protein maximum 320 g/kg complete pet food with a moisture content of 12 %</p> <p>or</p>	<p>Cats</p>	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Potassium</li> <li>— Sodium</li> <li>— Content of essential fatty acids (if added)</li> </ul>	<p>Initially up to 6 months <sup>(2)</sup></p>	<ul style="list-style-type: none"> <li>— The feed shall be placed on the market as complete feed.</li> <li>— Recommended digestibility of proteins: minimum 85 %.</li> <li>— Indicate on the labelling:  ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’</li> <li>— Indicate in the instructions for use:  ‘Water should be available at all times.’</li> </ul>
	<p>Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate</p>	<p>Adult cats</p>	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Potassium</li> <li>— Sodium</li> <li>— Content of essential fatty acids (if added)</li> <li>— Lanthanum carbonate octahydrate</li> </ul>	<p>Initially up to 6 months <sup>(2)</sup></p>	<ul style="list-style-type: none"> <li>— Indicate on the labelling: ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’</li> <li>— Indicate in the instructions for use: ‘Water should be available at all times.’</li> </ul>
<p>Dissolution of struvite stones <sup>(3)</sup></p>	<p>Urine acidifying properties, low level of magnesium, and restricted level of protein but of high quality</p>	<p>Dogs</p>	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Sodium</li> </ul>	<p>5 to 12 weeks</p>	<p>Indicate in the instructions for use:  ‘Water should be available at all times.’</p> <p>Indicate on the package, container or label:</p>

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(1)	(2)	(3)	(4)	(5)	(6)
	<ul style="list-style-type: none"> <li>— Urine acidifying properties and low level of magnesium</li> </ul>	Cats	<ul style="list-style-type: none"> <li>— Magnesium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Urine acidifying substances</li> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Sodium</li> <li>— Magnesium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Total taurine</li> <li>— Urine acidifying substances</li> </ul>		<p>'It is recommended that a veterinarian's opinion be sought before use.'</p>
Reduction of struvite stone recurrence <sup>(3)</sup>	Urine acidifying properties and moderate level of magnesium	Dogs and cats	<ul style="list-style-type: none"> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Sodium</li> <li>— Magnesium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Urine acidifying substances</li> </ul>	Up to 6 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 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	<p>Indicate on the package, container or label:</p> <p>'It is recommended that a veterinarian's opinion be sought before use.'</p>



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(1)	(2)	(3)	(4)	(5)	(6)
Reduction of oxalate stones formation	Low level of calcium, low level of vitamin D, and urine alkalisating properties	Dogs and cats	<ul style="list-style-type: none"> <li>— Phosphorus</li> <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 alkalisating substances</li> </ul>	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 alkalisating properties	Dogs and cats	<ul style="list-style-type: none"> <li>— Total sulphur amino acids</li> <li>— Sodium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Urine alkalisating substances</li> </ul>	Initially up to 1 year	Indicate on the package, container or label:  ‘It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.’
Reduction of ingredient and nutrient intolerances <sup>(4)</sup>	<ul style="list-style-type: none"> <li>— Selected protein source(s)</li> </ul> and/or  <ul style="list-style-type: none"> <li>— Selected carbohydrate source(s)</li> </ul>	Dogs and cats	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Content of essential fatty acids (if added)</li> </ul> <ul style="list-style-type: none"> <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	

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(1)	(2)	(3)	(4)	(5)	(6)
Reduction of acute intestinal absorptive disorders	Increased level of electrolytes and highly digestible ingredients	Dogs and cats	<ul style="list-style-type: none"> <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	Indicate on the package, container or label: <ul style="list-style-type: none"> <li>— ‘During periods of and recovery from acute diarrhoea.’</li> <li>— ‘It is recommended that a veterinarian’s opinion be sought before use.’</li> </ul>
Compensation for maldigestion <sup>(5)</sup>	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"> <li>— ‘It is recommended that a veterinarian’s opinion be sought before use.’</li> </ul>
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Support of heart function in the case of chronic cardiac insufficiency	Level of sodium restricted to be lower than 2,6 g/kg complete pet food with a moisture content of 12 %	Dogs and cats	<ul style="list-style-type: none"> <li>— Magnesium</li> <li>— Potassium</li> <li>— Sodium</li> </ul>	Initially up to 6 months	<ul style="list-style-type: none"> <li>— The feed shall be placed on the market as complete feed.</li> <li>— Indicate on the labelling:               <ul style="list-style-type: none"> <li>‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’</li> </ul> </li> </ul>
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Regulation of glucose supply ( <i>Diabetes mellitus</i> )	Low level of rapid glucose-releasing carbohydrates	Dogs and cats	<ul style="list-style-type: none"> <li>— Carbohydrate source(s)</li> <li>— Treatment of carbohydrates if appropriate</li> <li>— Starch</li> <li>— Total sugar</li> </ul>	Initially up to 6 months	Indicate on the package, container or label: <ul style="list-style-type: none"> <li>— ‘It is recommended that a veterinarian’s opinion be sought before use or before extending the period of use.’</li> </ul>

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(1)	(2)	(3)	(4)	(5)	(6)
			<ul style="list-style-type: none"> <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>		
<p>Support of liver function in the case of chronic liver insufficiency</p>	<ul style="list-style-type: none"> <li>— High quality protein, moderate level of protein, high level of essential fatty acids and high level of highly digestible carbohydrates</li> <li>— High quality protein, moderate level of protein and high level of essential fatty acids</li> </ul>	<p>Dogs</p> <p>Cats</p>	<ul style="list-style-type: none"> <li>— Protein source(s)</li> <li>— Content of essential fatty acids</li> <li>— Highly digestible carbohydrates including their treatment if appropriate</li> <li>— Sodium</li> <li>— Total copper</li> <li>— Protein source(s)</li> <li>— Content of essential fatty acids</li> <li>— Sodium</li> <li>— Total copper</li> </ul>	<p>Initially up to 6 months</p> <p>Initially up to 6 months</p>	<p>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.'</p> <p>Indicate in the instructions for use: 'Water should be available at all times.'</p> <p>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.'</p> <p>Indicate in the instructions for use: 'Water should be available at all times.'</p>

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(1)	(2)	(3)	(4)	(5)	(6)
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"> <li>— Content of essential fatty acids</li> <li>— Content of n-3 fatty acids (if added)</li> </ul>	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.'

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Reduction of iodine levels in feed in case of hyperthyroidism	Restricted level of iodine: maximum 0,26 mg/kg complete pet food with a moisture content of 12 %	Cats	Total iodine	Initially up to 3 months	<ul style="list-style-type: none"> <li>— The feed shall be placed on the market as complete feed.</li> <li>— Indicate on the labelling:  'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul>
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Reduction of copper in the liver	Restricted level of copper: maximum 8,8 mg/kg complete pet food with a moisture content of 12 %	Dogs	Total copper	Initially up to 6 months	<ul style="list-style-type: none"> <li>— The feed shall be placed on the market as complete feed.</li> <li>— Indicate on the labelling:  'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul>
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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.
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(1)	(2)	(3)	(4)	(5)	(6)	
▼ <u>M3</u>	Nutritional restoration, convalescence <sup>(6)</sup>	High energy density, high concentrations of essential nutrients and highly digestible ingredients	Dogs and cats	<ul style="list-style-type: none"> <li>— Highly digestible ingredients, including their treatment if appropriate</li> <li>— Energy value</li> <li>— Content of n-3 and n-6 fatty acids (if added)</li> </ul>	Until restoration is achieved	In the case of feed specially presented to be given via tubing, indicate on the labelling: 'Administration under veterinary supervision.'
▼ <u>M4</u>		The complementary feed may contain <i>Enterococcus faecium</i> DSM 10663/NCIMB 10415 in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	Dogs	<i>Enterococcus faecium</i> DSM 10663/NCIMB 10415 including added amount	10 to 15 days	<ul style="list-style-type: none"> <li>— The instructions for use of the feed shall ensure that the legal maximum content of the gut flora stabiliser/micro-organism for complete feed is respected.</li> <li>— Indicate on the labelling: 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</li> </ul>
▼ <u>B</u>	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.'

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(1)	(2)	(3)	(4)	(5)	(6)
<p>Support of the metabolism of joints in the case of osteoarthritis</p>	<p>Dogs: Minimum dry matter content of total omega-3 fatty acids 3,3 % and of eicosapentaenoic acid (EPA) 0,38 %.</p> <p>Adequate level of vitamin E.</p> <p>Cats: Minimum dry matter content of total omega-3 fatty acids 1,2 % and of docosahexaenoic acid (DHA) 0,28 %.</p> <p>Increased levels of methionine and manganese.</p> <p>Adequate level of vitamin E.</p>	<p>Dogs and cats</p>	<p>Dogs: — Total omega-3 fatty acids — Total EPA — Total vitamin E</p> <p>Cats: — Total omega-3 fatty acids — Total DHA — Total methionine — Total manganese — Total vitamin E</p>	<p>Initially up to 3 months</p>	<p>It is recommended that a veterinary surgeon's opinion be sought before use or before extending the period of use.</p>

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<p>Reduction of the risk of milk fever</p>	<p>— Low level of calcium</p> <p>and/or</p> <p>— Low cations/anions ratio</p>	<p>Dairy cows</p>	<p>— Calcium — Phosphorus — Magnesium</p> <p>— Calcium — Phosphorus — Sodium — Potassium — Chlorides — Sulphur</p>	<p>1 to 4 weeks before calving</p> <p>1 to 4 weeks before calving</p>	<p>Indicate in the instructions for use: 'Stop feeding after calving'</p> <p>Indicate in the instructions for use: 'Stop feeding after calving'</p>
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(1)	(2)	(3)	(4)	(5)	(6)
Reduction of the risk of tetany (hypomagnesaemia)	High level of magnesium, easily available carbohydrates, moderate level of protein and low level of potassium	Ruminants	<ul style="list-style-type: none"> <li>— Starch</li> <li>— Total sugars</li> <li>— Magnesium</li> <li>— Sodium</li> <li>— Potassium</li> </ul>	3 to 10 weeks during periods of fast grass growth	<p>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.</p> <p>In the case of feedingstuffs for ovines indicate on the package, container or label:</p> <p>‘Especially for lactating ewes.’</p>
Reduction of the risk of acidosis	Low level of easily fermentable carbohydrates and high buffering capacity	Ruminants	<ul style="list-style-type: none"> <li>— Starch</li> <li>— Total sugars</li> </ul>	Maximum months <sup>(11)</sup> 2	<p>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.</p> <p>In the case of feedingstuffs for dairy cows indicate on the package, container or label:</p> <p>‘Especially for high yielding cows.’</p> <p>In the case of feedingstuffs for ruminants for fattening indicate on the package, container or label:</p> <p>‘Especially for intensively fed.’ <sup>(12)</sup></p>

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Long-term supply of grazing animals with trace elements and/or vitamins	<p>High level of</p> <ul style="list-style-type: none"> <li>— Trace elements</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— vitamins, provitamins and chemically well-defined substances having similar effects.</li> </ul>	Ruminants with a functional rumen	<ul style="list-style-type: none"> <li>— Names and total amounts of each added trace element, vitamin, provitamin and chemically well-defined substance having similar effects.</li> </ul>	Up to 12 months	<ul style="list-style-type: none"> <li>— Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.</li> <li>— Indicate on the labelling of the feed:</li> </ul>
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(1)	(2)	(3)	(4)	(5)	(6)
	<p>The complementary feed may contain feed additives in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>		<ul style="list-style-type: none"> <li>— Daily release rate for each trace element and/or vitamin if a bolus is used;</li> <li>— Maximum period of continuously release of the trace element or vitamin if a bolus is used.</li> </ul>		<ul style="list-style-type: none"> <li>‘— Simultaneous supplementation of additives with a maximum content from other sources to those incorporated in a bolus, if applicable, shall be avoided.</li> <li>— Before using, it is recommended to have advice from a veterinarian or nutritionist concerning:               <ul style="list-style-type: none"> <li>(1) the balance of trace elements in the daily ration;</li> <li>(2) the trace elements status of the herd</li> </ul> </li> <li>— The bolus contains x % inert iron in order to increase its density, if applicable.’</li> </ul>
<p>Compensation for insufficient iron availability after birth</p>	<p>High level of iron compounds authorised under the functional group ‘compounds of trace elements’ of the category ‘nutritional additives’ as referred to in Annex I to Regulation (EC) No 1831/2003.</p> <p>The complementary feed may contain iron in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	<p>Suckling piglets and calves</p>	<p>Total iron content</p>	<p>After birth up to 3 weeks</p>	<p>The instructions for use for the feed shall ensure that the legal maximum contents of iron for complete feed are respected.</p>

▼ M3

(1)	(2)	(3)	(4)	(5)	(6)
<p>Support the regeneration of hooves, trotters and skin</p>	<p>High level of zinc.</p> <p>The complementary feed may contain zinc in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	<p>Horses, ruminants and pigs</p>	<p>Total amount of</p> <ul style="list-style-type: none"> <li>— zinc</li> <li>— methionine</li> </ul>	<p>Up to 8 weeks</p>	<p>The instructions of use for the feed shall ensure that the legal maximum contents of zinc for complete feed are respected.</p>
<p>Support the preparation for oestrus and reproduction</p>	<ul style="list-style-type: none"> <li>— High level of selenium and a minimum content of vitamin E per kg complete feed with a moisture content of 12 % for pigs of 53 mg, rabbits of 35 mg, for dogs, cats, mink of 88 mg;</li> <li>a minimum content of vitamin E per animal and day for ovines of 100 mg, cattle of 300 mg, horses of 1 100 mg</li> <li>or</li> <li>— High level(s) of vitamins A and/or vitamin D and/or a minimum content of beta- carotene of 300 mg per animal and day.</li> </ul> <p>The complementary feed may contain selenium, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	<p>Mammals</p>	<p>Names and total amounts of each added trace element and vitamin.</p>	<ul style="list-style-type: none"> <li>— Cows: 2 weeks before the end of gestation until the next gestation is confirmed.</li> <li>— Sows: 7 days before until 3 days after parturition and 7 days before until 3 days mating.</li> <li>— Other female mammals: from the last part of gestation until the next gestation is confirmed.</li> <li>— Males: during periods of reproductive activity.</li> </ul>	<ul style="list-style-type: none"> <li>— The instructions of use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.</li> <li>— Indicate on the labelling of the feed: ‘Guidance on the situations in which the use of the feed is appropriate.’</li> </ul>

▼ **M3**

(1)	(2)	(3)	(4)	(5)	(6)
	<ul style="list-style-type: none"> <li>— High level(s) of vitamin A and/or vitamin D</li> <li>or</li> <li>— High level(s) of selenium and/or zinc and/or a minimum content of vitamin E of 44 mg/kg complete feed with a moisture content of 12 %.</li> </ul> <p>The complementary feed may contain selenium, zinc, vitamin A and D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Birds	Names and total amounts of each added trace element and vitamin.	<ul style="list-style-type: none"> <li>— For females: during oestrus</li> <li>— For males: during periods of reproductive activity</li> </ul>	

▼ **M4**

Stabilisation of water and electrolyte balance to support the physiological digestion	<ul style="list-style-type: none"> <li>— Predominantly electrolytes: sodium, potassium and chlorides</li> <li>— Buffering capacity<sup>(1)</sup>: minimum 60 mmol per litre potion ready prepared for feeding</li> <li>— Easily digestible carbohydrates</li> </ul>	Calves, pigs, lambs, kids and foals	<ul style="list-style-type: none"> <li>— Sodium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Carbohydrate source(s)</li> <li>— Bicarbonates and/or citrates (if added)</li> </ul>	1 to 7 days	<ul style="list-style-type: none"> <li>— Recommended range of electrolytes per litre potion ready prepared for feeding: <ul style="list-style-type: none"> <li>Sodium: 1,7 g – 3,5 g</li> <li>Potassium: 0,4 g – 2,0 g</li> <li>Chlorides: 1 g – 2,8 g</li> </ul> </li> <li>— Indicate on the labelling: <ul style="list-style-type: none"> <li>(1) 'In case of risk of, during periods of, or recovery from digestive disturbance (diarrhoea).'</li> </ul> </li> </ul>
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▼ **M4**

(1)	(2)	(3)	(4)	(5)	(6)
					<p>(2) 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'</p> <p>— Indicate in the instructions for use:</p> <p>(1) The recommended intake of the ready stirred potion and of milk, if appropriate.</p> <p>(2) In case of bicarbonates and/or citrates are above 40 mmol per litre potion ready prepared for feeding: 'Simultaneous feeding of milk should be avoided in animals with abomasum'</p>

▼ **B**

Reduction of the risk of urinary calculi	Low level of phosphorus, magnesium, and urine acidifying properties	Ruminants	<ul style="list-style-type: none"> <li>— Calcium</li> <li>— Phosphorus</li> <li>— Sodium</li> <li>— Magnesium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Sulphur</li> <li>— Urine acidifying substances</li> </ul>	Up to 6 weeks	<p>Indicate on the package, container or label: 'Especially for intensively fed young animals.'</p> <p>Indicate in the instructions for use: 'Water should be available at all times.'</p>
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▼ **B**

(1)	(2)	(3)	(4)	(5)	(6)
Reduction of stress reactions	<ul style="list-style-type: none"> <li>— High level magnesium</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>— Highly digestible ingredients</li> </ul>	Pigs	<ul style="list-style-type: none"> <li>— Magnesium</li> <li>— Highly digestible ingredients including their treatment if appropriate</li> <li>— Content of n-3 fatty acids (if added)</li> </ul>	1 to 7 days	Guidance shall be provided on the situation in which the use of this feed is appropriate.

▼ **M3**

Stabilisation of physiological digestion	Low buffering capacity, and highly digestible ingredients	Piglets	<ul style="list-style-type: none"> <li>— Highly digestible ingredients including their treatment if appropriate</li> <li>— Buffering capacity</li> <li>— Source(s) of astringent substances (if added)</li> <li>— Source(s) of mucilaginous substances (if added)</li> </ul>	2 to 4 weeks	Indicate on the labelling:  'In case of risk of, during periods of, or recovery from, digestive disturbance.'
	Highly digestible ingredients	Pigs	<ul style="list-style-type: none"> <li>— Highly digestible ingredients including their treatment if appropriate</li> <li>— Source(s) of astringent substances (if added)</li> <li>— Source(s) of mucilaginous substances (if added)</li> </ul>		

▼ **M3**

(1)	(2)	(3)	(4)	(5)	(6)
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▼ **M4**

	<p>Feed additives of the functional group 'Gut flora stabiliser' of the category 'zootechnical additives' as referred to in Annex I to Regulation (EC) No 1831/2003 or, pending the re-authorisation procedure as referred to in Article 10 of Regulation (EC) No 1831/2003, feed additives of the group 'micro-organisms'.</p> <p>The complementary feed may contain feed additives of the functional group of 'gut flora stabilisers/micro-organisms' in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	<p>Animal species for which the gut flora stabiliser/micro-organism is authorised</p>	<p>Name and added amount of the gut flora stabiliser/micro-organism</p>	<p>Up to 4 weeks</p>	<p>— Indicate on the labelling of the feed:</p> <p>(1) 'In case of risk of, during periods of, or recovery from digestive disturbance'.</p> <p>(2) If applicable: 'The feed contains a gut flora stabiliser/micro-organism in a concentration above 100 times the authorised maximum content in complete feed'.</p> <p>— The instructions for use of the feed shall ensure that the legal maximum content of the gut flora stabiliser/micro-organism for complete feed is respected.</p>
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▼ **B**

<p>Reduction of the risk of constipation</p>	<p>Ingredients stimulating intestinal passage</p>	<p>Sows</p>	<p>Ingredients stimulating intestinal passage</p>	<p>10 to 14 days before and 10 to 14 days after farrowing</p>	
<p>Reduction of the risk of fatty liver syndrome</p>	<p>Low energy and high proportion of metabolisable energy from lipids with high level of polyunsaturated fatty acids</p>	<p>Laying hens</p>	<p>— Energy value (calculated according to EC method)</p> <p>— Percentage of metabolisable energy from lipids</p> <p>— Content of poly-unsaturated fatty acids</p>	<p>Up to 12 weeks</p>	

▼B

(1)	(2)	(3)	(4)	(5)	(6)
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"> <li>— Percentage of saturated fatty acids in relation to total fatty acids</li> <li>— Total vitamin A</li> <li>— Total vitamin D</li> <li>— Total vitamin E</li> <li>— Total vitamin K</li> </ul>	During the first 2 weeks after hatching	
Compensation for chronic insufficiency of small intestine function	Highly precaecally digestible carbohydrates proteins and fats	Equines <sup>(14)</sup>	— 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>
Compensation for chronic digestive disorders of large intestine	Highly digestible fibre	Equines	<ul style="list-style-type: none"> <li>— Fibre source(s)</li> <li>— Content of n-3 fatty acids (if added)</li> </ul>	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>

▼ **B**

(1)	(2)	(3)	(4)	(5)	(6)
Reduction of stress reactions	Highly digestible ingredients	Equines	<ul style="list-style-type: none"> <li>— Magnesium</li> <li>— Highly digestible ingredients including their treatment if appropriate</li> <li>— Content of n-3 fatty acids (if added)</li> </ul>	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"> <li>— Calcium</li> <li>— Sodium</li> <li>— Magnesium</li> <li>— Potassium</li> <li>— Chlorides</li> <li>— Glucose</li> </ul>	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:</p> <p>‘Water should be available at all times.’</p>
Support the preparation for and recovery from sport effort	<p>High level of selenium and a minimum content of 50 mg vitamin E per kg complete feed with moisture content of 12 %.</p> <p>The complementary feed may contain compounds of selenium in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>	Equidae	<p>Total amount of</p> <ul style="list-style-type: none"> <li>— vitamin E</li> <li>— selenium.</li> </ul>	Up to 8 weeks before sport effort – Up to 4 weeks after sport effort	The instructions for use for the feed shall ensure that the legal maximum contents of selenium for complete feed are respected.

▼ **M3**



▼B

(1)	(2)	(3)	(4)	(5)	(6)
Nutritional restoration, convalescence	High concentration of essential nutrients and highly digestible ingredients	Equines	<ul style="list-style-type: none"> <li>— Highly digestible ingredients, including their treatment if appropriate</li> <li>— Content of n-3 and n-6 fatty acids (if added)</li> </ul>	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>
Support of liver function in the case of chronic liver insufficiency	Low level of protein but of high quality and highly digestible carbohydrates	Equines	<ul style="list-style-type: none"> <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	<p>Guidance should be provided on the manner in which the feed 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>

▼ **B**

(1)	(2)	(3)	(4)	(5)	(6)
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	<ul style="list-style-type: none"> <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	<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:</p> <p>‘Water should be available at all times.’</p>

► **M4** <sup>(1)</sup> If appropriate the manufacturer may also recommend use for temporary renal insufficiency.

<sup>(2)</sup> If the feed is recommended for temporary renal insufficiency the recommended period for use shall be two to four weeks. ◀

<sup>(3)</sup> In the case of feedingstuffs for cats, ‘feline lower urinary tract disease’ or ‘feline urological syndrome — FUS’ may complete the particular nutritional purpose.

<sup>(4)</sup> In the case of feedingstuffs for a particular intolerance reference to the specific intolerance can replace ‘ingredient and nutrient’.

<sup>(5)</sup> The manufacturer may complete the particular nutritional purpose with the reference: ‘exocrine pancreatic insufficiency’.

► **M3** <sup>(6)</sup> The manufacturer may complete the particular nutritional purpose with a reference to ‘Feline hepatic lipidosis’. ◀

<sup>(7)</sup> The term ‘ketosis’ may be replaced by ‘acetonaemia’.

<sup>(8)</sup> The manufacturers may also recommend the use for ketosis recuperation.

<sup>(9)</sup> In the case of feedingstuffs for dairy cows.

<sup>(10)</sup> In the case of feedingstuffs for ewes.

<sup>(11)</sup> In the case of feedingstuffs for dairy cows: ‘maximum two months from the start of lactation’.

<sup>(12)</sup> Indicate the category of ruminants concerned.

► **M4** <sup>(13)</sup> Calculated by the Strong Ion Difference method (SID-Value): SID is the difference between the sums of concentrations of the strong cations and strong anions;  $[SID] = [mmol Na^+/l] + [mmol K^+/l] + [mmol Ca^{++}/l] + [mmol Mg^{++}/l] - [mmol Cl^-/l] - [mmol Other Strong Anions/l]$ . ◀

<sup>(14)</sup> 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

**▼B***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