

Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (Text with EEA relevance)

COMMISSION REGULATION (EU) 2020/354

of 4 March 2020

establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC<sup>(1)</sup>, and in particular Article 10(5) thereof,

Whereas:

- (1) The placing on the market and use of feed is regulated by Regulation (EC) No 767/2009. In accordance with Article 9 of that Regulation, feed intended for particular nutritional purposes may only be marketed if its intended use is included in a list of intended uses established in accordance with Article 10 of the said Regulation.
- (2) Commission Directive 2008/38/EC<sup>(2)</sup> established a list of intended uses of animal feedingstuffs for particular nutritional purposes.
- (3) Part A of Annex I to Directive 2008/38/EC established the general provisions for feed intended for particular nutritional purposes. Considering scientific and technological developments and the labelling requirements established by Regulation (EC) No 767/2009, those general provisions are to be reviewed.
- (4) Articles 11 to 17 of Regulation (EC) No 767/2009 established new principles and rules for the placing on the market of feed, including labelling. As a consequence, several entries in the list of intended uses of feed intended for particular nutritional purposes contained in Part B of Annex I to Directive 2008/38/EC became outdated, partially because of poor and overly general descriptions in the column 'Essential nutritional characteristics'. For such entries, it has been very difficult for the control authorities to verify compliance with the provisions of Regulation (EC) No 767/2009, including whether the specific composition of the feed concerned fulfils the respective particular intended nutritional purpose.

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- (5) In accordance with Article 10 of Regulation (EC) No 767/2009, the Commission received a number of applications to amend and change the conditions associated with several intended uses of feed for particular nutritional purposes, which had become outdated. Outdated entries for which no application has been submitted or for which the application was withdrawn should be removed.
- (6) As regards other intended uses of feed intended for particular nutritional purposes listed in Part B of Annex I to Directive 2008/38/EC, amendments are necessary to the provisions concerning the essential nutritional characteristics and the labelling declarations in order to adapt them to the scientific and technological developments and to improve the enforceability and clarity of the provisions.
- (7) Furthermore, the Commission received, in accordance with Article 10 of Regulation (EC) No 767/2009, applications to add the particular nutritional purposes ‘support of energy metabolism and of the muscle function in the case of rhabdomyolysis’ and ‘support in stressful situations, which will lead to the reduction of associated behaviour’ to the list of intended uses of feed intended for particular nutritional purposes.
- (8) The Commission made all applications, including the dossiers, available to the Member States.
- (9) Following the assessment of the dossiers included in those applications, the Standing Committee on Plants, Animals, Food and Feed (‘the Committee’) acknowledged that the specific composition of the feed concerned fulfils the respective particular intended nutritional purpose and that it has no adverse effects on animal health, human health, the environment or animal welfare.
- (10) Based on the above considerations, the list of intended uses of feed for particular nutritional purposes should be updated.
- (11) Since safety reasons do not require the immediate application of the new general provisions and of the updated list of intended uses of feed for particular nutritional purposes, it is appropriate to provide for transitional measures in order to avoid unnecessary disruption of commercial practices and to not create unnecessary administrative burden on the operators.
- (12) In the interests of clarity and rationality, Directive 2008/38/EC should be repealed and replaced by a Regulation, which does not contain elements that would require transpositions by the Member States into national law. The last amendments to that Directive had already been successively brought through Regulations due to the absence of need of transposition into national law of the provisions concerned. In addition, the general requirements for the placing on the market and use of feed intended for particular nutritional purposes are provided for in Regulation (EC) No 767/2009.
- (13) In order to enable Member States to make the necessary adjustments, an adequate period should be allowed before this Regulation becomes applicable.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Committee,

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HAS ADOPTED THIS REGULATION:

*Article 1*

Feed intended for particular nutritional purposes within the meaning of Regulation (EC) No 767/2009 may be marketed only if:

- the general provisions for feed intended for particular nutritional purposes laid down in Part A of the Annex to this Regulation are complied with, and
- its intended use is included in Part B of the Annex to this Regulation and the provisions of the respective entry are complied with.

*Article 2*

By way of derogation from Article 1, feed intended for particular nutritional purposes which complies with the provisions of Directive 2008/38/EC may continue to be placed on the market, provided that an application for an intended use included therein has been submitted to the Commission in accordance with Article 10 of Regulation (EC) No 767/2009 before 25 March 2021 and until the Commission decides on the respective application.

*Article 3*

Feed intended for particular nutritional purposes which has been labelled before 25 March 2022 in accordance with the rules applicable before 25 March 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 4*

Directive 2008/38/EC is repealed.

*Article 5*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 25 December 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 4 March 2020.

*For the Commission*

*The President*

Ursula VON DER LEYEN

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## ANNEX

### PART A

#### General provisions for feed for particular nutritional purposes

1. Where there is more than one group of essential nutritional characteristics indicated in column 2 of Part B, denoted by 'and/or', for the same particular nutritional purpose, the manufacturer has the option to use either or both groups of essential characteristics, in order to achieve the particular nutritional purpose defined in column 1 of Part B. For each option the corresponding labelling declarations are given in column 4 of Part B.
2. Where an essential nutritional characteristic mentioned in column 2 of Part B is quantitatively indicated, the provisions of Article 17(2) of Regulation (EC) No 767/2009 and the permitted tolerances as established in Annex IV to that Regulation shall apply. If that Annex does not establish a tolerance for the respective labelling particular, a technical deviation of +/- 15 % shall be permitted.
3. Where a feed additive is mentioned in column 2 or column 4 of Part B, the authorisation provisions for feed additive(s) in accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council<sup>(3)</sup> are applicable and their use shall comply with the specified essential nutritional characteristic.
4. Where the declaration of a substance, also authorised as a feed additive, is required in column 4 of Part B and is accompanied by the expression 'total', the total content of the substance shall be labelled under the heading 'analytical constituents'.
5. The declarations to be given in accordance with column 4 of Part B shall be quantitative without prejudice to Directive 2004/48/EC of the European Parliament and of the Council<sup>(4)</sup>.
6. 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.
7. Where a feed intended for particular nutritional purposes is intended to meet more than one particular nutritional purpose, it shall comply with each respective entry in Part B.
8. In the case of complementary feed intended for particular nutritional purposes, guidance on the balance of the daily ration must be provided in the instructions for proper use.
9. When a feed intended for particular nutritional purposes is with an appropriate mode of use intended for individual oral administration via a bolus, this shall be established in the column 'other provisions' of the respective feed. Such feed shall exclusively contain, including a potential coating, feed materials and feed additives, unless detailed otherwise in the respective entry. It is recommended that feed intended for individual oral administration is administered by a veterinarian or any other competent person.
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 with retarding release, i.e. more than 24 hours, of the compounds, the labelling of such feed shall, if applicable, mention for each feed additive for which a maximum content in complete feed is fixed the maximum period of continuous

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release of the bolus and the daily release rate. The feed business operator which is placing a bolus on the market shall have the proof that the daily available feed 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 (retarding release effect). Such proof should be based on a peer reviewed methodology or in-house analysis.

11. In case of intended uses for which in column 2 a concentration of certain feed additives higher than 100 times the relevant fixed maximum content in complete feed is allowed for complementary feed, the concentration of those feed additives shall not be higher than 500 times the relevant fixed maximum content in complete feed, except in the case of boluses as referred to in point 10. The incorporation of such complementary feed into the animal's diet shall ensure that the uptake of the animal complies with the fixed maximum content in complete feed.

## PART B

### List of intended uses

Entry number	Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
1	2	3	4	5	6	
10	Support of renal function in case of chronic renal insufficiency	High quality proteins and phosphorus $\leq 5$ g/kg complete feed with a moisture content of 12 % <sup>d</sup> and crude protein $\leq 220$ g/kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs	— — — — —	Protein initially source (s) 6 months <sup>e</sup> Calcium Phosphorus Potassium Sodium Essential fatty acids (if added)	1. The feed shall be placed on the market as complete feed. 2. Recommended digestibility of proteins: minimum 85 %. 3. Indicate on the labelling: 'It is recommended that advice from

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					4.	a veterinarian be sought before use and before extending the period of use.’ Indicate in the instructions for proper use: ‘Water should be available at all times.’
	Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Adult dogs	— — — — — —	Protein sources Calcium Phosphorus Potassium Sodium Essential fatty acids (if added) Lanthanum carbonate octahydrate	1. 2.	Indicate on the labelling: ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’ Indicate in

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						all times.'
	High density of energy with more than 8,8 MJ/kg feed with a moisture content of 12 %. Highly digestible and highly palatable sources of starch. Restricted protein level: $\leq 106$ g crude protein/kg feed with a moisture content of 12 %. Level of sodium: 2 g/100 kg BW per day. High level of eicosapentaenoic acid and docosahexaenoic sum $\geq 0,2$ g per kg BW <sup>0,75</sup> per day	Equines	—	Protein initially and up to six months. source(s) term	1.	The feed shall be placed on the market as complementary feed. Indicate on the labelling:
			—	Calcium		— 'It is recommended that a veterinarian's opinion be sought before use or before extending the period of use.'
			—	Phosphorus		— The complementary feed should not be used in case of hypernatraemia and hyperchloraemia.
			—	Potassium		— The complementary feed should
			—	Magnesium		
			—	Sodium		
			—	Sum of eicosapentaenoic acid and docosahexaenoic acid	2.	

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							contribute to at least 10 to 20 % of the daily energy supply (approximately 0,05 to 0,1 MJ/ kg BW <sup>0,75</sup> per day).
						3.	The ration should ensure an energy supply of > 0,62 MJ/ kg BW <sup>0,75</sup> per day.
						4.	The ration should not exceed 50 mg calcium/ kg dry matter/ day.
						5.	Indicate in the

							instructions for proper use: 'Water should be available at all times.'
11	Reduction of oxalate stones formation	Low level of calcium, low level of vitamin D, and urine alkalising properties	Dogs and cats	— — — — — — — — — — —	Phosphorus Calcium Sodium Magnesium Potassium Chlorides Sulphur Vitamin D (total) Hydroxyproline Urine alkalising substances	Indicate on the labelling: 'It is recommended that a veterinarian's opinion be sought before use.'	
12	Regulation of glucose supply (Diabetes mellitus)	Total sugars (mono- and disaccharides) ≤ 62 g/kg complete feed with a moisture of 12 % <sup>d</sup>	Dogs and cats	— — — — — — — —	Carbohydrate source(s) Treatment of carbohydrates, if appropriate Starch Total sugars Fructose (if added) Essential fatty acids (if added) Source(s) of short and medium chain fatty acids	1. The feed shall be placed on the market as complete feed. 2. Indicate on the labelling: — 'Low level of mono- and disaccharides' — 'It is recommended that a veterinarian's	

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					(if added)		opinion be sought before use and before extending the period of use.'
13	Reduction of ingredient and nutrient intolerances	Selected and limited number of protein source(s) And/or hydrolysed protein source(s) And/or selected carbohydrate source(s)	Dogs and cats	—	Protein sources: if including of intolerance if disappear appropriate (if can be used added) Initially up to 8 weeks. Carbohydrate source(s) including treatment, if appropriate (if added). Essential fatty acids (if added)	1. The feed shall be placed on the market as complete feed. 2. It is recommended to limit the number of main protein sources to 3. To indicate on the labelling: — Appropriate combination of the essential nutritional characteristics as applicable — 'It is	

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								recommended that a veterinarian's opinion be sought before use and before extending the period of use.'
14	Reduction of cystine stones formation	Urine alkalinising properties and crude protein ≤ 160 g/kg complete feed with a moisture content of 12 % <sup>d</sup> Or Proteins selected for a limited cystine and cysteine content (e.g. casein, pea protein, soy protein) and crude protein ≤ 220 g/kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs	—  —  —  —  —	Sulphur initially up to 6 month amino acids (total) Protein sources Sodium Potassium Chlorides Urine alkalinizing substances (if added)	1. The feed shall be placed on the market as complete feed. 2. Indicate in the instructions for proper use:  'Water should be available at all times' 3. Indicate on the labelling: —	'Urine alkalinising properties and low level of proteins' or 'Low	

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							level of selected proteins’, as applicable. ‘It is recommended that a veterinarian’s opinion be sought before use or before extending the period of use.’
				—		4.	For consideration of the veterinarian or nutritionist: Alkalinising properties means that the diet should be formulated to target a urinary pH $\geq$ 7.
15	Nutritional restoration, convalescence	Highly digestible ingredients with	Dogs	—	Highly digestible ingredients including	1.	Recommended apparent digestibility of Dry

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	energy density $\geq$ 3 520 kcal and crude protein $\geq$ 250 g per kg of complete feed with a moisture level 12 % <sup>d</sup>		—	their treatment, if appropriate Energy value		Matter $\geq$ 80 % or of Organic Matter $\geq$ 85 %.
	Highly digestible ingredients with energy density $\geq$ 3520 kcal and crude protein $\geq$ 270 g per kg of complete feed with a moisture level 12 % <sup>d</sup>	Cats			2.	In the case of feed specially presented to be given via tubing, indicate on the package, container or label: ‘Administration under veterinary supervision.’
					3.	The labelling may indicate the specific circumstance(s) the dietetic feed is intended for.
					4.	Indicate on the labelling:

							‘High energy density, high concentrations of essential nutrients and highly digestible ingredients’
16	Reduction of urate stones formation	Crude protein $\leq$ 130 g/kg complete feed with a moisture level of 12 % <sup>d</sup> Or Crude protein $\leq$ 220 g/kg complete feed with a moisture level of 12 % <sup>d</sup> and selected protein sources	Dogs	—	Protein to 6 sources, but lifetime use in case of irreversible disturbance of uric acid metabolism	1.  2.	The feed shall be placed on the market as complete feed. Protein quality and level of purines should be taken into account when selecting the protein source. Examples of selected protein sources of high quality with low level of purines



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						<div>include eggs, casein, soy proteins, and maize gluten. 3. Indicate in the instructions for proper use: ‘Water should be available at all times’. 4. Indicate on the labelling: — ‘It is recommended that a veterinarian’s opinion be sought before use.’ — ‘Low level of protein’ or ‘Restricted level of protein and selected protein sources’, as appropriate.</div>
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	Crude protein ≤ 317 g/kg complete feed with a moisture content of 12 % <sup>d</sup>	Cats			<div>1. The feed shall be placed on the market as complete feed.</div> <div>2. Protein quality and level of purines should be taken into account when selecting the protein source. Examples of selected protein sources of high quality with low level of purines include eggs, casein, soy proteins, and maize gluten.</div> <div>3. Indicate on the labelling:</div>
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							—	‘It is recommended that a veterinarian’s opinion be sought before use.’
							—	‘Restricted level of protein’
						4.	Indicate in the instructions for proper use: ‘Water should be available at all times’.	
17	Dissolution of struvite stones <sup>h</sup>	Urine undersaturating properties for struvite And/or Urine acidifying properties <sup>j</sup> And Magnesium ≤ 1,8 g/kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs and cats	— — — — — —	Phosphorus Calcium Sodium Magnesium Potassium Chloride Sulfur	5. 1. 2.	1. The feed shall be placed on the market as complete feed. 2. Indicate on the labelling:	— ‘It is recommended that advice from a veterinarian

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								be sought before use and before extending the period of use.’ — ‘Urine undersaturation properties for struvite and/or Urine acidifying properties.’
						3.	Indicate in the instructions for proper use: ‘Water should be available at all times.’	
						4.	Declaration of conformity supporting undersaturating and/or acidifying properties of the diet shall be made available to the	

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						3.	Indicate in the instructions for proper use: 'Water should be available at all times.'
						4.	Declaration of conformity supporting undersaturating or metastabilising and/or acidifying properties of the diet shall be made available to the relevant competent authorities upon request.
19	Compensation for maldigestion	Highly digestible diet: Apparent digestibility of — low-fibre feed (crude fibre ≤ 44	Dogs and cats	—	Highly digestible ingredients including pancreatic treatment if appropriate	Initially up to 12 weeks in the case of chronic pancreatic insufficiency	1. The feed shall be placed on the market as complete feed. 2. Indicate on

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			<div>g per kg of complete feed with a moisture level 12 %<sup>d</sup>): Crude protein ≥ 85 % Crude fat ≥ 90 % Or — fibre- enhanced feed (crude fibre &gt; 44 g per kg of complete feed with a moisture level 12 %<sup>d</sup>): Crude protein ≥ 80 % Crude fat ≥ 80 %</div>			<div>the labelling: — ‘Highly digestible feed’ — ‘It is recommended that a veterinarian’s opinion be sought before use.’</div>
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20	Reduction of intestinal absorptive disorders	Highly digestible diet: Apparent digestibility of — low-fibre feed (crude fibre $\leq 44$ g per kg of complete feed with a moisture level 12 % <sup>d</sup> ): Crude protein $\geq 85$ % Crude fat $\geq 90$ % Or — fibre-enhanced feed (crude fibre $> 44$ g per kg of complete feed with a moisture	Dogs and cats	—	Highly digestible ingredient sources including their treatment, if appropriate Sodium Potassium	Indicate on the labelling: — ‘Highly digestible feed with increased sodium and potassium’ ‘It is recommended that a veterinarian’s opinion be sought before use.’
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		level 12 % <sup>d</sup> ): Crude protein ≥ 80 % Crude fat ≥ 80 %					
		And Sodium ≥ 1,8 g per kg of complete feed with a moisture level 12 % <sup>d</sup> And Potassium ≥ 5 g per kg of complete feed with a moisture level 12 % <sup>d</sup>					
21	Reduction of acute intestinal absorptive disorders	Increased level of electrolytes: — Sodium ≥ 1,8 % — Potassium ≥ 0,6 % And Highly digestible carbohydrates: — ≥ 32 %	Dogs and cats	— — —	Sodium Potassium Carbohydrate source(s)	7 days	1. The feed shall be placed on the market as complementary feed. 2. Indicate on the labelling: — ‘During periods of and recovery from acute diarrhoea’

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						3.	<p>— 'It is recommended that a veterinarian's opinion be sought before use.'</p> <p>In case of solid feed, the recommended range of electrolytes should be calculated on the basis of a normal daily voluntary intake of water.</p>
22	Support of lipid metabolism in the case of hyperlipidaemia	Fat <sup>m</sup> ≤ 110 g/kg complete feed with a moisture content of 12 % <sup>n</sup>	Dogs and cats	—	Crude fat	Initially up to 2 months	<p>1. The feed shall be placed on the market as complete feed.</p> <p>2. Indicate on the labelling: — 'It is</p>

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							recommended that a veterinarian's opinion be sought before use or before extending the period of use.' 'Low level of fat'
23	Support of liver function in the case of chronic liver insufficiency	Moderate level of protein: Crude protein $\leq$ 279 g/kg complete feed with a moisture content of 12 % <sup>d</sup> for dogs Crude protein $\leq$ 370 g/kg complete feed with a moisture content of 12 % <sup>d</sup> for cats And Selected protein sources And Recommended dietary protein digestibility $\geq$ 85 %	Dogs and cats	— — —	Protein initially up to 6 months Copper (total) Sodium	1.  2.	The feed shall be placed on the market as complete feed. Examples of selected protein sources based on high digestibility: dairy proteins (whey, casein, milk, cottage cheese), other animal based proteins (egg,

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						3. poultry) and vegetable proteins (soy). Indicate in the instructions for proper use: 'Water should be available at all times.'
						4. Indicate on the labelling: — 'Moderate level of protein, selected and highly digestible' — 'It is recommended that a veterinarian's opinion be sought before use.'
	Low level of protein but of high quality and highly digestible carbohydrates	Equines	—  —	Protein initially and up to six months sources Highly digestible carbohydrates including their treatment,	1.	Indicate on the labelling: — 'It is recommended that a veterinarian's

				— — —	if appropriate Methionine Choline Content of n-3 fatty acids (if added)		opinion be sought before use or before extending the period of use.'
						2.	Guidance should be provided on the manner in which the feed should be fed including many small meals per day.
24	Support of heart function in the case of chronic cardiac insufficiency	Restricted level of sodium: Sodium $\leq$ 2,6 g per kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs and cats	— — —	Magnesium Potassium Sodium	1. initially up to 6 months	1. The feed shall be placed on the market as complete feed. 2. Indicate on the labelling: 'It is recommended that advice

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							from a veterinarian be sought before use and before extending the period of use.'
25	Reduction of excessive body weight	Metabolizable Energy < 3060 kcal/kg complete feed with moisture content of 12 %° Or Metabolizable Energy < 560 kcal/kg complete feed with moisture content of 85 %°	Dogs	—	Energy value	Until target body weight is achieved and after if required to maintain target bodyweight	1. The feed shall be placed on the market as complete feed. 2. To ensure that minimum requirements are met, the nutrient levels of a diet for reduction of excessive bodyweight should be increased accordingly to compensate for the restricted
		Metabolizable Energy < 3190 kcal per kg complete feed with moisture content of 12 %° Or Metabolizable Energy < 580 kcal per kg complete feed with moisture content of 85 %°	Cats				

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						3.	daily energy intake <sup>p</sup> Indicate on the labelling: — 'It is recommended that a veterinarian's opinion be sought before use.' — 'For cats, a transition period when starting the diet is advised.' — 'For an efficient weight loss or ideal weight maintenance, the recommended daily energy intake should not be exceeded.'
26	Support of skin function in the case of dermatosis	Linoleic acid $\geq 12,3$ g per kg and sum of eicosapentaenoic	Dogs and cats	— —	Indicate on the labelling: — 'It is recommended that a veterinarian's opinion be sought before use.' — 'For cats, a transition period when starting the diet is advised.' — 'For an efficient weight loss or ideal weight maintenance, the recommended daily energy intake should not be exceeded.'	Indicate on the labelling: — 'It is recommended that a veterinarian's opinion be sought before use.' — 'For cats, a transition period when starting the diet is advised.' — 'For an efficient weight loss or ideal weight maintenance, the recommended daily energy intake should not be exceeded.'	

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	and excessive loss of hair	acid and docosahexaenoic acid $\geq 2,9$ g per kg of complete feed with a moisture content of 12 % <sup>d</sup>			acid and docosahexaenoic acid	recommended that a veterinarian's opinion be sought before use.' 'High level of linoleic acid (LA) and of sum of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)'
		Linoleic acid $\geq 18,5$ g per kg and sum of eicosapentaenoic acid and docosahexaenoic acid $\geq 0,39$ g per kg of complete feed with a moisture content of 12 % <sup>d</sup>	Dogs			—
		Linoleic acid $\geq 18,5$ g per kg and sum of eicosapentaenoic acid and docosahexaenoic acid $\geq 0,09$ g per kg of complete feed with a moisture content of 12 % <sup>d</sup>	Cats			
27	Support of the metabolism of joints in the case of osteoarthritis	Total omega-3 fatty acids $\geq 29$ g per kg and eicosapentaenoic acid $\geq 3,3$ g per kg complete feed with a moisture content of 12 % <sup>d</sup> And	Dogs	— — —	Omega-3 fatty acids (total) Eicosapentaenoic acid (total) Vitamin E (total)	Indicate on the labelling: — 'It is recommended that advice from a veterinarian be sought before



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		Adequate levels of vitamin E				use and before extending the period of use.'
		Total omega-3 fatty acids $\geq 10,6$ g per kg complete feed with a moisture content of 12 % <sup>d</sup> and docosahexaenoic acid $\geq 2,5$ g per kg complete feed with a moisture content of 12 % <sup>d</sup> And Increased levels of methionine and manganese Adequate levels of vitamin E.	Cats	—	Omega-3 fatty acids (total) Docosahexaenoic acid (total) Methionine (total) Manganese (total) Vitamin E (total)	
28	Reduction of copper in the liver	Restricted level of copper: copper $\leq 8,8$ mg per kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs	Copper (total)	Initially up to 6 months	1. The feed shall be placed on the market as complete feed. 2. Indicate on the labelling: — 'It is

							that recommended that advice from a veterinarian be sought before use and before extending the period of use.'
29	Reduction of iodine levels in feed in case of hyperthyroidism	Restricted level of iodine: iodine ≤ 0,26 mg per kg complete feed with a moisture content of 12 % <sup>d</sup>	Cats	Iodine (total)	Initially up to 3 months	1. The feed shall be placed on the market as complete feed.  2. Indicate on the labelling: — 'It is recommended that advice from a veterinarian be sought before use and before extending the period of use.'	

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30	Support in stressful situations, which will lead to the reduction of associated behaviour	1-3 g trypsin-hydrolysed bovine casein per kg complete feed with a moisture content of 12 % <sup>d</sup>	Dogs	Trypsin-hydrolysed bovine casein	Initially up to 2 months	1.  2.	The feed shall be placed on the market as complete feed. Indicate on the labelling: — ‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’
50	Support the preparation for oestrus and reproduction	—	High level of selenium and a minimum content of vitamin E per kg complete feed with a moisture	Mammals Names and total amounts of each added trace element and vitamin	—  —	Cows: 2 weeks before the end of gestation until the next gestation is confirmed. Sows: 7 days before	Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in

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	content of 12 % for pigs of 50 mg, rabbits of 35 mg, for dogs, cats, mink of 88 mg; a minimum content of vitamin E per animal and day for ovines of 100 mg, cattle of 300 mg, horses of 1 100 mg			until 3 days after parturition and 7 days before until 3 days <sup>2</sup> . mating. Other female mammals: from the last part of gestation until the next gestation is confirmed. Males: during periods of reproductive activity.	an inert, non- bioavailable form, in order to increase its density. The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected. Indicate on the labelling of the feed guidance on the situations in which the use of the feed is appropriate.
Or —	High level(s) of vitamins A and/ or vitamin				

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		D and/ or a minimum content of beta- carotene of 300 mg per animal and day.			
	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.				
	—	High level(s) of vitamin A and/ or vitamin D	Birds	Names and total amounts of each added trace element and vitamin	—
	Or —	High level(s) of selenium and/ or zinc and/ or a			For females: during oestrus — For males: during periods of reproductive activity

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		minimum content of vitamin E of 40 mg/kg complete feed with a moisture content of 12 %.				
		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.				
51	Support the regeneration of hooves, trotters and skin	High level of zinc. The complementary feed may contain zinc in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	Horses, ruminants and pigs	— — —	Zinc Up to 8 (total) Methionine (total) Biotin (if added)	1. The instructions for proper use for the feed shall ensure that the legal maximum contents of zinc

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						2.	for complete feed are respected. Application in the form of bolus is allowed for ruminants. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.
52	Support for nutritional imbalances in dietary transition	Minimum supply via the dietetic feed of: —	Ruminants Pigs Rabbits Poultry Selenium: 0,1 mg/kg complete feed with a moisture content of	Name and total amount of the nutritional additives, if appropriate	2 to 15 days	1.	Application in the form of bolus is allowed for ruminants and pigs. A bolus may contain

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	And/or —	12 %  Zinc: 15 mg/ kg complete feed with a moisture content of 12 %  And/or —			up to 20 % iron in an inert, non- bioavailable form, in order to increase its density. The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.
		Copper: 2 mg/ kg complete feed with a moisture content of 12 % for sheep and 5 mg/ kg complete feed with a moisture content of 12 % for other species  And/or —			3. Indicate on the labelling of the feed guidance on the situations in which the
		Vitamin A: 2000 IU/			



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		kg complete feed with a moisture content of 12 %			use of the feed is appropriate.
	And/or —	Vitamin D: 400 IU/ kg complete feed with a moisture content of 12 %			
	And/or —	Vitamin E: 35 mg/ kg complete feed with a moisture content of 12 % for poultry, 10 mg/ kg complete feed with a moisture content of 12			

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		<p>% for ruminants, 40 mg/ kg complete feed with a moisture content of 12 % for rabbits and 20 mg/ kg complete feed for pigs with a moisture content of 12 %</p> <p>The complementary feed may contain selenium, zinc, copper, vitamin A and vitamin D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>			
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		with a moisture content of 12 % for other species		
	And/or —	Iodine: 0,2 mg/ kg complete feed with a moisture content of 12 %		
	And/or —	Manganese: 20 mg/ kg complete feed with a moisture content of 12 %		
	And/or —	Vitamin A: 1500 IU/ kg complete feed with a moisture content of 12 %		

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	And/or —	Vitamin D: 400 IU/ kg complete feed with a moisture content of 12 %		
	And/or —	Vitamin E: 100 mg/ kg complete feed with a moisture content of 12 % for calves and 50 mg/ kg complete feed with a moisture content of 12 % for lambs, kids and piglets.		
	The complementary feed may			

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		contain selenium, zinc, copper, iodine, manganese, vitamin A and vitamin D in a concentration higher than 100 times the relevant fixed maximum content in complete feed.						
54	Support the regeneration of the skin and appendages	—	Minimum supply of zinc compounds via dietetic feed corresponding to 20 mg/kg complete feed with a moisture content of 12 %	Mammals and poultry	Name and total amount of the nutritional additives, if appropriate	—	Up to 8 weeks	1. The instructions for proper use for the feed shall ensure that the respective legal maximum contents for complete feed are respected.
		And —	High level of copper and/or iodine and/or selenium			—	Complementary feed for ruminants containing biotin: Up to 6 months	2. Indicate on the labelling of the feed guidance on the situations in which
		and/or						

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			<p>vitamin B6 and/or vitamin E and/or vitamin A and/or methionine and/or cystine and/or or minimum supply of 0,4 mg biotin/kg complete feed with a moisture content of 12 % for ruminants. The complementary feed may contain zinc, copper, iodine, selenium and vitamin A in a concentration higher than 100 times the relevant fixed maximum content in complete feed.</p>				the use of the feed is appropriate.
55	Stabilisation of water and electrolyte balance to support the physiological digestion	—	<p>Predominantly electrolytes, sodium, potassium and chlorides Buffering capacity" in case of liquid feed:</p>	— — — —	<p>Sodium 7 days Potassium Chlorides Carbohydrate source(s) Bicarbonates and/or citrates (if added)</p>	1.	Recommended range of electrolytes per litre potion ready prepared for feeding: Sodium: 1.7

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		minimum			g
		60			—
		mmol			3.5
		per			g
		litre			Potassium:
		portion			0.4
		ready			g
		prepared			—
		for			2
		feeding			g
	—	Easily			Chlorides:
		digestible			1
		carbohydrates			g
					—
					2.8
				2.	g
					In
					case
					of
					solid
					feed,
					the
					recommended
					range
					of
					electrolytes
					should
					be
					calculated
					on
					the
					basis
					of
					a
					normal
					daily
					voluntary
					intake
					of
					water.
				3.	Indicate
					on
					the
					labelling:
					—
					‘In
					case
					of
					risk
					of,
					during
					periods
					of,
					or



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									recovery from digestive disturbance (diarrhoea).’
							—		‘It is recommended that advice from a veterinarian be sought before use and before extending the period of use.’
							4.	Indicate in the instructions for proper use:	
							—		The recommended intake of the ready stirred potion and of milk, if appropriate.
							—		In case of bicarbonates and/or citrates are above

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							40 mmol per litre potion ready prepared for feeding of ruminants: ‘Simultaneous feeding of milk should be avoided in animals with abomasum’
56	Reduction of the risk of tetany (hypomagnesaemia)	High level of magnesium, available carbohydrates, moderate level of protein and low level of potassium	Ruminants	— — — — —	Start to 10 weeks (total) during periods of fast grass growth	1.	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.

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						2.	In the instructions for proper use guidance shall be provided on the balance of the daily ration, with regard to the inclusion of fibre and easily available energy sources.
						3.	In the case of feed for ovines indicate on the labelling: 'Especially for lactating ewes.'
57	Reduction of the risk of acidosis	Low level of easily fermentable carbohydrates and high buffering capacity	Ruminants	— —	Startup to 2 months <sup>a</sup> (total)	1.	Application in the form of bolus is allowed.

3.

						4.	of feed for dairy cows indicate on the labelling: 'Especially for high yielding cows.' In the case of feed for ruminants for fattening indicate on the labelling: 'Especially for intensively fed'.
58	Reduction of the risk of urinary calculi	Low level of phosphorus, magnesium, and urine acidifying properties	Ruminants	— — — — — — —	Calcium to 6 Phosphorus Sodium Magnesium Potassium Chlorides Sulphur Urine acidifying substances	1.	Indicate on the labelling: 'Especially for intensively fed young animals.'
						2.	Indicate in the instructions for proper use: 'Water should be available

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					is used	
				—		
60	Reduction of the risk of milk fever and subclinical hypocalcaemia	Low cations/anions ratio For the total ration:	Dairy cows	— — — — — —	Calcium 3 Phosphorus Magnesium Sodium Potassium Chlorides Sulphur	Indicate in the instructions for proper use: ‘Stop feeding after calving’

incorporated in a bolus, if applicable, shall be avoided. Before using, it is recommended to have advice from a veterinarian or nutritionist concerning:

(a) the balance of trace elements in the daily ration

(b) the trace element status of the herd

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	—	100 mEq/ kg dry matter Objective: 0 < DCAD <sup>s</sup> (mEq/ kg dry matter) < 100			
	Or				
	Zeolite (sodium aluminium silicate): 250 – 500 g/day		Sodium aluminium silicate	From 3 weeks before calving until calving	Indicate in the instructions for proper 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.’ — The duration of use shall be restricted



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					to a maximum of 2 weeks. 'Stop feeding after calving'
	Or Supply of rumen protected feed materials rich in phytic acid (> 6 %) and having a calcium content < 0,2 %, to achieve a minimum of 28 g and a maximum of 32 g available calcium per cow per day. Or		—	Calcium from 4 weeks before calving until calving	Indicate in the instructions for proper use: 'Stop feeding after calving'
	High level of calcium in the form of highly available sources of calcium: calcium chloride and/or calcium sulfate and/or dicalcium phosphate and/or calcium carbonate and/or		— —	Calcium from first signs of source of parturition to two days subsequent to parturition	1. Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an

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	calcium propionate and/or calcium formate. and/or 'any other calcium source having a similar effect' Calcium provided by one or a combination of these sources with a minimum of 50 g per cow per day Or				2. Indicate in the instructions for proper use the number of applications and the time before and after calving. 3. Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.
	Calcium pidolate in a minimum of 5,5 g per cow per day Or	— —	Calcium pidolate	from first calving to two days subsequent to parturition	1. Application in the form of bolus is allowed.

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						2.	A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density. Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.
	Waxy-leaf nightshade meal allowing a daily release of 38 – 46 µg 1,25 dihydroxycholecalciferol-glycoside per day		— — — — — —	Waxy-leaf nightshade meal Consent of parturition 1,25 dihydroxycholecalciferol-glycoside Crude fibre Magnesium Crude fat Starch	From two days before nightshade meal or first 10 days of parturition	1.	Application in the form of bolus is allowed. A bolus may contain up to 20

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				—	Vitamin D3 (total) as cholecalciferol	2.	% iron in an inert, non-bioavailable form, in order to increase its density. Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.
61	Reduction of the risk of ketosis <sup>t</sup>	—	Min Dairy supply of and goats propane-1,2-diol or propylene glycol: 250 g/day for dairy cows 50 g/day for ewes or goats	—	Propylene glycol three weeks before added six weeks after calving for the dairy cows form Between six weeks before and three weeks after parturition if for ewes added goats	1.	Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable
		Or					

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	—	Minimum supply of propionates (calcium or sodium salts): 110 g/day for dairy cows 22 g/day for ewes or goats		2.	form, in order to increase its density. Indicate on the labelling: ‘During the supply of calcium or sodium propionates at the end of gestation, an evaluation of the mineral equilibrium in association with the risk of hypocalcaemie after parturition is necessary.’
	Or	Minimum combined supply of propane-1,2-diol and propionates (sodium or calcium salts), as long as:			
	—	The combination of propane-1,2-diol and propionates for dairy cows is such that propionates 0,44 x			

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		—	propane-1,2 diol > 110 g/day The combination of propane-1,2-diol and propionates for ewes or goats is such that propionates 0,44 x propane-1,2 diol > 22 g/day			
62	Reduction of stress reactions	—  And/or —	High Pigs level magnesium  Highly digestible ingredients	—    —	Magnesium 7 days 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.
63	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	

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64	Compensation for insufficient iron availability after birth	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. The complementary feed may contain iron in a concentration higher than 100 times the relevant fixed maximum content in complete feed.	Suckling piglets and calves	Iron (total)	After birth up to 3 weeks	The instructions for proper use shall ensure that the legal maximum contents of iron for complete feed are respected.
65	Compensation for malabsorption	Low level of saturated fatty acids and high level of fat soluble vitamins	Poultry excluding geese and pigeons	—  —  —	Percentage of the first 2 weeks after hatching in relation to total fatty acids Vitamin A (total) Vitamin D (total)	

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				—	Vitamin E (total)	
				—	Vitamin K (total)	
66	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	—	Energy to 12 weeks (calculated according to EC method)	
				—	Percentage of metabolisable energy from lipids	
				—	Content of poly-unsaturated fatty acids	
67	Support the preparation for and recovery from sport effort	High level of selenium and a minimum content of 50 mg vitamin E per kg complete feed with moisture content of 12 %. The complementary feed may contain compounds of selenium in a concentration higher than 100 times the relevant fixed maximum content in	Equidae	—	Vitamin E (total)	Up to 8 weeks before sport effort – Up to 4 weeks after sport effort
				—	Selenium (total)	The instructions for proper use for the feed shall ensure that the legal maximum contents of selenium for complete feed are respected.



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		complete feed.					
68	Compensation of electrolyte loss in the cases of heavy sweating	Must contain sodium chloride and should contain potassium chloride. Low levels of Magnesium, Calcium and Phosphorus The inclusion of other electrolyte salts is optional.	Equines	— — — — —	Sodium Chlorides Potassium Calcium Magnesium Phosphorus	One to three days after heavy sweating.	1. Guidance shall be provided on the situations in which the use of the feed is appropriate.  2. The instructions for proper use must give administration guidelines based on the duration and intensity of exercise performed relevant to the formulation and presentation of the feed.  3. Indicate on the labelling: — ‘Water should be

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							available at all times.’ — In the case of the administration of electrolytes not mixed with water (e.g. in feed or in syringe format): ‘Water must be available for at least 20 minutes or preferably for 1 hour post administration
						4.	Furthermore guidance must be given to monitor subsequent drinking, if insufficient water intake is

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						5.	observed veterinary advice should be sought. Guidance may optionally be given regarding the quantity of water (in litres) to be provided alongside in feed or syringed electrolytes.
69	Support of energy metabolism and of the muscle function in the case of rhabdomyolosis	Starch and sugar not more than 20 % of available energy. Crude fat more than 20 % of available energy Minimum of 350 IU Vitamin E/kg complete feed with a moisture content of 12 %	Equines	— — — —	Starch Sugar Crude fat Vitamin E (total)	Initially for minimum of 3 months 1. 2.	Guidance shall be provided on the situations in which the use of this feed is appropriate. The instructions for proper use shall contain guidance on

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							the balance of the daily ration and the appropriate daily intake. Indicate on the labelling: 'It is recommended that a veterinarian's opinion be sought before use.'
70	Compensation for chronic digestive disorders of large intestine	—	Star Equines content to provide < 1 g/kg BW/meal (< 0,5 g/kg BW/meal, if diarrhoea present) Cereal grains processed via a hydrothermal treatment,	—	Star Crude fat	Long term use until resolution of the issue	1. Guidance shall be provided — on the precise situations in which the use of the feed is appropriate, in particular whether the product is for use in

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		—	such as extrusion, micronisation, expansion or flaking, to improve small intestinal starch digestion Additional supply of water soluble vitamins and adequate minerals/ electrolytes levels — Additional supply of oil if no diarrhoea			2.	animals with concurrent diarrhoea or not. on meal size and forage intake. The instructions for proper use shall refer, depending on the oil content, to the potential gradual use and suggest a monitoring for diarrhoea. Indicate on the labelling the processing used for the cereal grains.
71	Compensation for chronic insufficiency of small intestine function	— —	Highly digestible fibres High quality protein	—	Highly digestible feed materials including their	1.	Guidance shall be provided on

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		—	sources and lysine > 4,3 % of crude protein	—	processing, if appropriate. Total sugar and starch Protein sources	—	the precise situations in which the use of the feed is appropriate meal size and forage intake.
		—	Total sugar and starch to provide a maximum of 0,5 g/kg BW/ meal	—		2.	The instructions for proper use shall refer, depending on the oil content, to the potential gradual use and suggest a monitoring for diarrhoea.
72	Stabilisation of the physiological digestion	Feed additives of the functional group 'Gut flora stabiliser' as referred to in Annex I to	Animal species for which the gut flora stabiliser or micro-organism is authorised	Name and added amount of the gut flora stabiliser or micro-organism	Up to 4 weeks	1.	Indicate on the labelling: 'In case of risk of, during



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<b>l</b>	'exocrine pancreatic insufficiency' may be added.
<b>m</b>	The minimum recommendations according to the FEDIAF Nutritional Guidelines ( <a href="http://www.fediaf.org/self-regulation/nutrition.html">http://www.fediaf.org/self-regulation/nutrition.html</a> ) for all essential fatty acids shall be met in the daily ration.
<b>n</b>	based on a diet with a dry matter energy density of 3500 kcal Metabolisable Energy/kg calculated using the equation described in the FEDIAF Nutritional Guidelines ( <a href="http://www.fediaf.org/self-regulation/nutrition.html">http://www.fediaf.org/self-regulation/nutrition.html</a> ). The values shall be adapted if the energy density deviates from the 3500 kcal Metabolisable Energy/kg.
<b>o</b>	Metabolisable Energy/kg calculated using the equation described in the FEDIAF (2019) Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs.
<b>p</b>	FEDIAF (2019) Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs.
<b>q</b>	In the case of feed for dairy cows: 'maximum two months from the start of lactation'.
<b>r</b>	Indicate the category of ruminants concerned.
<b>s</b>	$DCAD \text{ (mEq/kg dry matter)} = (Na + K) - (Cl + S)$ .
<b>t</b>	The term 'ketosis' may be replaced by 'acetonaemia' and the person responsible for the labelling may also recommend the use for ketosis recuperation.
<b>u</b>	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; $[SID] = [mmol Na^+/l] + [mmol K^+/l] + [mmol Ca^{++}/l] + [mmol Mg^{++}/l] - [mmol Cl/l] - [mmol Other Strong Anions/l]$ .



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**Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2020/354. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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- (1) [OJ L 229, 1.9.2009, p. 1.](#)
- (2) Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes ([OJ L 62, 6.3.2008, p. 9.](#)).
- (3) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([OJ L 268, 18.10.2003, p. 29.](#)).
- (4) Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ([OJ L 157, 30.4.2004, p. 45.](#)).

**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- Art. 2 words substituted by S.I. 2019/654, reg. 147 (as inserted) by [S.I. 2020/1504](#) reg. 12(23)

**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Signature words omitted by virtue of S.I. 2019/654, reg. 148 (as inserted) by [S.I. 2020/1504](#) reg. 12(23)