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From:	European Commission
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	D032598/06
Subject:	ANNEX to the COMMISSION REGULATION (EU) No .../.. amending Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (Text with EEA relevance)

Delegations will find attached document D032598/06 ANNEX 1.

Encl.: D032598/06 ANNEX 1



Brussels, **XXX**
SANCO/12606/2013 Rev. 2 ANNEX
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ANNEX.doc) D032598/06
[...] (2014) **XXX** draft

ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) No .../..

**amending Directive 2008/38/EC establishing a list of intended uses of animal
feedingstuffs for particular nutritional purposes**

ANNEX

Part B of Annex I to Directive 2008/38/EC is amended as follows:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
(a) The row of the particular nutritional purpose 'support of heart function in the case of chronic cardiac insufficiency' is replaced by the following:					
'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"> - Magnesium - Potassium - Sodium 	Initially up to 6 months	<ul style="list-style-type: none"> - 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."
(b) The row of the particular nutritional purpose 'support of renal function in case of chronic renal insufficiency' is replaced by the following:					
'Support of renal function in case of chronic renal insufficiency*	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 Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Dogs Adult dogs	<ul style="list-style-type: none"> - Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Content of essential fatty acids (if added) - Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Content of essential fatty acids (if added) 	Initially up to 6 months** Initially up to 6 months**	<ul style="list-style-type: none"> - The feed shall be placed on the market as complete feed. - Recommended digestibility of proteins: minimum 85%. - 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 the instructions for use: "Water should be available at all times." - 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 the instructions for use: "Water should be available at all times."

				<ul style="list-style-type: none"> - Lanthanum carbonate octahydrate 	<ul style="list-style-type: none"> - Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Content of essential fatty acids (if added) 	<ul style="list-style-type: none"> - Protein source(s) - Calcium - Phosphorus - Potassium - Sodium - Content of essential fatty acids (if added) - Lanthanum carbonate octahydrate 	Initially up to 6 months**	<ul style="list-style-type: none"> - The feed shall be placed on the market as complete feed. - Recommended digestibility of proteins: minimum 85%. - 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 the instructions for use: "Water should be available at all times." 	
	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% or Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Cats	Adult cats				Initially up to 6 months**	<ul style="list-style-type: none"> - 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 the instructions for use: "Water should be available at all times." 	
(c) The row of the particular nutritional purpose 'reduction of copper in the liver' is replaced by the following:									
'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"> - 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." 	
(d) The row of the particular nutritional purpose 'reduction of iodine levels in feed in case of hyperthyroidism' is replaced by the following:									
'Reduction of iodine levels in feed in case of	Restricted level of iodine: maximum 0,26 mg/kg complete pet food with a moisture	Cats		Total iodine			Initially up to 3 months	<ul style="list-style-type: none"> - The feed shall be placed on the market as complete feed. - Indicate on the labelling: 	

hyperthyroidism	content of 12%					"It is recommended that advice from a veterinarian be sought before use and before extending the period of use."
(e) The row for the particular nutritional purpose 'stabilisation of water and electrolyte balance' is replaced by the following:						
'Stabilisation of water and electrolyte balance to support the physiological digestion	<ul style="list-style-type: none"> - Predominantly electrolytes: sodium, potassium and chlorides - Buffering capacity***: minimum 60 mmol per litre potion ready prepared for feeding - Easily digestible carbohydrates 	Calves, pigs, lambs, kids and foals	<ul style="list-style-type: none"> - Sodium - Potassium - Chlorides - Carbohydrate source(s) - Bicarbonates and/or citrates (if added) 	1 to 7 days	<ul style="list-style-type: none"> - Recommended range of electrolytes per litre potion ready prepared for feeding: Sodium: 1,7 g – 3,5 g Potassium: 0,4 g – 2,0 g Chlorides: 1 g – 2,8 g - Indicate on the labelling: (1) "In case of risk of, during periods of, or recovery from digestive disturbance (diarrhoea)." (2) "It is recommended that advice from a veterinarian be sought before use and before extending the period of use." - Indicate in the instructions for use: (1) The recommended intake of the ready stirred potion and of milk, if appropriate. (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." 	
(f) The row of the particular nutritional purpose 'nutritional restoration, convalescence', species or category of animals 'Dogs' is replaced by the following:						
	'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"> - 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. - Indicate on the labelling: "It is recommended that advice from a veterinarian be sought before use and before extending the period of use." 	
(g) The row of the particular nutritional purpose 'stabilisation of physiological digestion', species or category of animals 'Animal species for which the gut flora stabiliser is authorised' is replaced by the following:						
	'Feed additives of the functional	Animal	Name and added amount	Up to 4 weeks	- Indicate on the labelling of the feed:	

	<p>group "Gut flora stabiliser" of the category "zotechnical 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>species for which the gut flora stabiliser/micro-organism is authorised</p>	<p>of the gut flora stabiliser/micro-organism</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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If appropriate the manufacturer may also recommend use for temporary renal insufficiency.

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

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].