

COMMISSION REGULATION (EU) No 1123/2014**of 22 October 2014****amending Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes****(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 ⁽¹⁾, and in particular Article 10(5) thereof,

Whereas:

- (1) The Commission received in accordance with Article 10 of Regulation (EC) No 767/2009 an application to add the particular nutritional purpose 'stabilisation of water and electrolyte balance to support the physiological digestion' and to add to the particular nutritional purpose 'support of renal function in case of chronic renal insufficiency' adult dogs as target species to the list of intended uses of feed intended for particular nutritional purposes in Part B of Annex I to Commission Directive 2008/38/EC ⁽²⁾.
- (2) Furthermore, the Commission received in accordance with Article 10 of Regulation (EC) No 767/2009 applications to change the conditions associated with the particular nutritional purposes 'support of heart function in the case of chronic cardiac insufficiency' and 'support of renal function in case of chronic renal insufficiency' as regards 'cats and dogs' and 'reduction of copper in the liver'.
- (3) The Commission made all applications, including the dossiers, available to the Member States.
- (4) After assessing the dossiers included in those applications, the Standing Committee on the Food Chain and Animal Health (the Committee) acknowledged that the specific composition of the feeds concerned fulfils the respective particular intended nutritional purposes and that it has no adverse effects on animal health, human health, the environment or animal welfare. The applications are therefore valid.
- (5) As a result of the assessment of the Committee, the particular nutritional purposes 'stabilisation of water and electrolyte balance to support the physiological digestion' and 'support of renal function in case of chronic renal insufficiency' for adult dogs should be added to the list of intended uses and the conditions associated with the particular nutritional purposes 'support of heart function in the case of chronic cardiac insufficiency' and 'support of renal function in case of chronic renal insufficiency' as regards 'cats and dogs' and 'reduction of copper in the liver' should be changed. As a consequence of the new entry 'stabilisation of water and electrolyte balance to support the physiological digestion', the particular nutritional purpose 'stabilisation of water and electrolyte balance' is no longer necessary and should be deleted.
- (6) In order to ensure compliance with the maximum contents for certain nutrients established as 'essential nutritional characteristics' of some particular nutritional purposes, the requirement to place the respective dietetic feed as complete feed on the market should be foreseen. This provision would also ensure the safe use of the feed concerned.
- (7) Annex I to Directive 2008/38/EC as amended by Commission Regulation (EU) No 5/2014 ⁽³⁾ established the incorporation of feed additives of the functional group 'Gut flora stabiliser' as referred to in Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council ⁽⁴⁾ into certain feed for particular nutritional purposes. However, feed additives currently registered in the group 'micro-organisms' and being in the

⁽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⁾ Commission Regulation (EU) No 5/2014 of 6 January 2014 amending Directive 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes (OJ L 2, 7.1.2014, p. 3).

⁽⁴⁾ 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).

re-authorisation procedure as referred to in Article 10 of Regulation (EC) No 1831/2003 could be similarly incorporated into those feeds for particular nutritional purposes. Consequently, the existing feed additives of the group 'micro-organisms' should, pending their re-authorisation, be also covered by Annex I to Directive 2008/38/EC.

- (8) Directive 2008/38/EC should therefore be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications for the feed currently legally placed on the market, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Committee and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Directive 2008/38/EC is amended in accordance with the Annex to this Regulation.

Article 2

Feed included in the Annex to this Regulation that has been produced and labelled before 12 May 2015 and which is in compliance with Directive 2008/38/EC before entry into force of this Regulation may continue to be placed on the market and used until the existing stocks are exhausted. In case this feed is intended for pets, the date mentioned in the last sentence is 12 November 2016.

Article 3

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

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

Done at Brussels, 22 October 2014.

For the Commission

The President

José Manuel BARROSO

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

(a) The row of the particular nutritional purpose 'support of heart function in the case of chronic cardiac insufficiency' is replaced by the following:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
'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	— Magnesium — Potassium — Sodium	Initially up to 6 months	— 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:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
'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	Dogs	— Protein source(s) — Calcium — Phosphorus — Potassium — Sodium — Content of essential fatty acids (if added)	Initially up to 6 months (**)	— 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."
	Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Adult dogs	— Protein source(s) — Calcium — Phosphorus — Potassium — Sodium	Initially up to 6 months (**)	— 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."

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
			<ul style="list-style-type: none"> — Content of essential fatty acids (if added) — Lanthanum carbonate octahydrate 		
	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	Cats	<ul style="list-style-type: none"> — Protein source(s) — Calcium — Phosphorus — Potassium — Sodium — Content of essential fatty acids (if added) 	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.”
	Reduced phosphorus absorption by means of incorporation of Lanthanum carbonate octahydrate	Adult cats	<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"> — 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.”

(*) 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.’

(c) The row of the particular nutritional purpose ‘reduction of copper in the liver’ is replaced by the following:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
‘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:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
'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"> — 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."

(e) The row for the particular nutritional purpose 'stabilisation of water and electrolyte balance' is replaced by the following:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
'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'

(*) 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; $[SID] = [mmol Na^+/l] + [mmol K^+/l] + [mmol Ca^{++}/l] + [mmol Mg^{++}/l] - [mmol Cl^-/l] - [mmol Other Strong Anions/l]$.

(f) The row of the particular nutritional purpose 'nutritional restoration, convalescence', species or category of animals 'Dogs' is replaced by the following:

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
	'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

Particular nutritional purpose	Essential nutritional characteristics	Species or category of animal	Labelling declarations	Recommended length of time	Other provisions
	<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>	Animal species for which the gut flora stabiliser/micro-organism is authorised	Name and added amount of the gut flora stabiliser/micro-organism	Up to 4 weeks	<ul style="list-style-type: none"> — Indicate on the labelling of the feed: <ol style="list-style-type: none"> (1) 'In case of risk of, during periods of, or recovery from digestive disturbance.' (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.' — 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.'