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

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Subject:	COMMISSION REGULATION (EU) No .../.. of XXX 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.

Encl.: D032598/06



Brussels, **XXX**
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[...](2014) **XXX** draft

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

of **XXX**

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

(Text with EEA relevance)

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

of **XXX**

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/EC¹, 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/EC².
- (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

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).

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 5/2014³ established the incorporation of feed additives of the functional group "Gut flora stabiliser" as referred to in Annex I to Regulation (EC) No 1831/2003⁴ into certain feed for particular nutritional purposes. However, feed additives currently registered in the group “micro-organisms” and being in the 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.

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).

Article 2

Feed included in the Annex to this Regulation that has been produced and labelled before [6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] 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 [24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication].

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,

For the Commission
José Manuel BARROSO
The President