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Subject:	COMMISSION REGULATION (EU) .../... of XXX establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC

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Delegations will find attached document D063616/02.

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Encl.: D063616/02



Brussels, **XXX**  
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[...](2019) **XXX** draft

**COMMISSION REGULATION (EU) .../...**

**of **XXX****

**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) .../...

of **XXX**

**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.
- (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

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<sup>1</sup> OJ L 229, 1.9.2009, p. 1.

<sup>2</sup> 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).

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,

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 [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*], and until the Commission decides on the respective application.

#### *Article 3*

Feed intended for particular nutritional purposes which has been labelled before [*24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*9 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*].

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

Done at Brussels,

*For the Commission  
The President*

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