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)

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(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 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[(2)] 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uses of feed intended for particular nutritional purposes contained in Part B of Annex I to Directive 2008/38/EC became outdated, partially because of poor and overly general descriptions in the column ‘Essential nutritional characteristics’.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.

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*

(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 rhabdomyolosis' 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[(3)] 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[(4)].

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 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

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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 ≤ 5 g/kg complete feed with a moisture content of 12 %[d] and crude protein ≤ 220 g/kg complete feed with a moisture content of 12 %[d]	Dogs	— Protein source(s) — Calcium — Phosphorus — Potassium — Sodium — Essential fatty acids (if added)	Initially up to 6 months[e]	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 a veterinarian be sought