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 \pm 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⁽¹⁾ 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⁽²⁾.
- 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

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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 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 inhouse 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.

- (1) 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).
- (2) Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45).

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Changes and effects yet to be applied to the whole legislation item and associated provisions

Signature words omitted by virtue of S.I. 2019/654, reg. 148 (as inserted) by S.I. 2020/1504 reg. 12(23)