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COMMISSION

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

**of **XXX****

**amending Regulation (EU) 2020/354 establishing a list of intended uses of feed intended  
for particular nutritional purposes**

# COMMISSION REGULATION (EU) .../...

of **XXX**

## amending Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes

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 list of intended uses of feed intended for particular nutritional purposes established by Commission Regulation (EU) 2020/354<sup>2</sup> may be updated in accordance with the rules and procedures laid down in Regulation (EC) No 767/2009.
- (2) The Commission received an application in accordance with Article 10 of Regulation (EC) No 767/2009 to update the list of intended uses by adding to the use for the particular nutritional purpose ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’ glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract. This request has been examined taking into account the opinion of the European Food Safety Authority (‘the Authority’) on this feed additive adopted on 29 June 2022<sup>3</sup> which showed that glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract, administered in a complementary feed in the form of a bolus in a period from 9 days before calving to immediately before calving, has the potential to prevent hypocalcaemia in dairy cows when applied as in the animal studies evaluated. In those studies, the bolus was complemented by a feed containing appropriate levels of calcium and magnesium.
- (3) The Commission received another application in accordance with Article 10 of Regulation (EC) No 767/2009 to update the list of intended uses by changing the conditions associated with the intended use of feed intended for the particular nutritional purpose ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’, namely to modify the essential nutritional characteristics linked to the Dietary Cation Anion Difference (DCAD), by introducing negative values for the cations-anions balance in the column “Essential nutritional characteristics”. In the current list of intended uses, the DCAD is set up in a positive range between higher than zero and lower than 100. The applicant proposed to include in the essential

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

<sup>2</sup> 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 (OJ L 67, 5.3.2020, p. 1). ELI: <http://data.europa.eu/eli/reg/2020/354/oj>

<sup>3</sup> EFSA Journal 2022;20(8):7434.

nutritional characteristics a negative value of DCAD. This means that the level of negative ions (anions) can be higher than the level of the positive ions (cations). The proposed change permits to reduce the pH in the urine of the animal, which triggers the excretion of calcium via urine and reduces the serum concentrations in the blood of the animal. The reduction of calcium in the serum concentrations stimulates the secretion of parathyroid hormone (PTH), which increases the release of calcium from the bone and activates vitamin D in the kidney (which, in turn, improves calcium absorption in the digestive tract). Furthermore, the negative DCAD has also the effect of increasing the feed intake by the target animals.

- (4) The Commission made the two applications, including the dossiers, available to the Member States.
- (5) The assessment of the application concerning the modification of the essential nutritional characteristics linked to the DCAD as well as the application concerning the addition to the list of intended uses of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract applied as in the animal studies evaluated shows that the specific composition of the two feeds concerned fulfil the particular intended nutritional purpose and that they do not have adverse effects on animal health, human health, the environment or animal welfare.
- (6) In view of the above, it is appropriate to update the list of intended uses of feed intended for particular nutritional purposes established by Regulation (EU) 2020/354 as regards the particular nutritional purpose ‘Reduction of the risk of milk fever and subclinical hypocalcaemia’.
- (7) Regulation (EU) 2020/354 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Entry number 60 in Part B of the Annex to Regulation (EU) 2020/354 is amended in accordance with the Annex to this Regulation.

#### *Article 2*

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*  
*The President*  
*Ursula VON DER LEYEN*