



2024/2899

21.11.2024

**COMMISSION REGULATION (EU) 2024/2899**

**of 20 November 2024**

**amending Regulation (EU) 2020/354 establishing a list of intended uses of feed intended 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/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 orally 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 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.

<sup>(1)</sup> OJ L 229, 1.9.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/767/oj>.

<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.

- (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, 20 November 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

ANNEX

| Entry number | Particular nutritional purpose                                    | Essential nutritional characteristics (GP1)                                                                                                                                                                                                                                                                                                      | Species or category of animal | Labelling declarations (GP2)                                                                    | Recommended length of time                                            | Other provisions                                                                                                                                                                                                                                                                               |
|--------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "60          | Reduction of the risk of milk fever and subclinical hypocalcaemia | Low cations/anions ratio<br>For the total ration:<br>— Minimum acidification via feed for particular nutritional purpose: 100 mEq/kg dry matter<br>— Objective: Range from negative DCAD <sup>17</sup> values to < 100 (mEq/kg dry matter) DCAD values<br>Or                                                                                     | Dairy cows                    | — Calcium<br>— Phosphorus<br>— Magnesium<br>— Sodium<br>— Potassium<br>— Chlorides<br>— Sulphur | From 3 weeks before calving until calving                             | Indicate in the instructions for proper use: 'Stop feeding after calving'                                                                                                                                                                                                                      |
|              |                                                                   | Zeolite (sodium aluminium silicate): 250 – 500 g / day<br>Or                                                                                                                                                                                                                                                                                     |                               | Sodium aluminium silicate                                                                       | From 3 weeks before calving until calving                             | Indicate in the instructions for proper use:<br>— 'The amount of feed shall be restricted to ensure that a daily intake of 500 g sodium aluminium-silicate per animal is not exceeded.'<br>— The duration of use shall be restricted to a maximum of 2 weeks<br>— 'Stop feeding after calving' |
|              |                                                                   | Supply of rumen protected feed materials rich in phytic acid (> 6 %) and having a calcium content < 0,2 %, to achieve a minimum of 28 g and a maximum of 32 g available calcium per cow per day.<br>Or                                                                                                                                           |                               | Calcium                                                                                         | From 4 weeks before calving until calving                             | Indicate in the instructions for proper use: 'Stop feeding after calving'                                                                                                                                                                                                                      |
|              |                                                                   | High level of calcium in the form of highly available sources of calcium: calcium chloride and/or calcium sulfate and/or dicalcium phosphate and/or calcium carbonate and/or calcium propionate and/or calcium formate. and/or 'any other calcium source having a similar effect' Calcium provided by one or a combination of these sources with |                               | — Calcium<br>— Calcium sources                                                                  | From first signs of parturition to two days Subsequent to parturition | — Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.<br>— Indicate in the instructions for proper use the number of applications and the time before and after calving.                    |

(<sup>17</sup>) DCAD (Dietary Cation Anion Difference; expressed in mEq/kg dry matter) = (Na+K) – (Cl +S).

| Entry number | Particular nutritional purpose | Essential nutritional characteristics (GP1)                                                                                                                                      | Species or category of animal | Labelling declarations (GP2)                                                                                                                                                              | Recommended length of time                                                                                                                                                                                                       | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|              |                                | a minimum of 50 g per cow per day<br>Or                                                                                                                                          |                               |                                                                                                                                                                                           |                                                                                                                                                                                                                                  | — Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.                                                                                                                                                                                                                                                                                                                                                       |
|              |                                | Supply of calcium in the form of calcium pidolate in a minimum of 5,5 g per cow per day<br>Or                                                                                    |                               | — Calcium<br>— Calcium pidolate                                                                                                                                                           | From first signs of parturition to two days subsequent to parturition                                                                                                                                                            | — Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.<br>— Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.                                                                                                                                                                                           |
|              |                                | Waxy-leaf nightshade meal allowing a daily release of 38-46 µg 1,25 dihydroxycholecalciferol-glycoside per day<br>Or                                                             |                               | — Waxy-leaf nightshade meal<br>— Content of 1,25 dihydroxycholecalciferol-glycoside<br>— Crude fibre<br>— Magnesium<br>— Crude fat<br>— Starch<br>— Vitamin D3 (total) as cholecalciferol | From two days before calving or first signs of parturition to 10 days subsequent to parturition                                                                                                                                  | — Application in the form of bolus is allowed. A bolus may contain up to 20 % iron in an inert, non-bioavailable form, in order to increase its density.<br>— Indicate on the labelling: 'It is recommended that a nutritional expert's opinion be sought before use'.                                                                                                                                                                                           |
|              |                                | Glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract allowing a daily release of 15-80 µg of glycosylated 1,25-dihydroxycholecalciferol per day. | Dairy cows                    | — Glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract<br>— Vitamin D <sub>3</sub> (total) as Cholecalciferol                                             | One oral administration of the bolus containing glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract during the pre-parturient period (from 9 days before calving to immediately before calving) | 1. Glycosylated 1,25-dihydroxycholecalciferol from <i>Solanum glaucophyllum</i> extract shall be orally administered once in the form of a bolus with daily administration of:<br>— a minimum of calcium of 60 g per cow during one week before calving and 84 g per cow until the end of the third week of lactation;<br>— a minimum of magnesium of 18 g per cow during one week before calving and 26 g per cow until the end of the third week of lactation. |

| Entry number | Particular nutritional purpose | Essential nutritional characteristics (GP1) | Species or category of animal | Labelling declarations (GP2) | Recommended length of time | Other provisions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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|              |                                |                                             |                               |                              |                            | <p>2. Indicate on the labelling of the feed: 'The application of the bolus shall be done only once during the pre-parturient period from 9 days before calving to immediately before calving. Calcium and magnesium shall be administered daily at the following levels:</p> <ul style="list-style-type: none"><li>— a minimum of calcium of 60 g per cow during one week before calving and 84 g per cow until the end of the third week of lactation;</li><li>— a minimum of magnesium of 18 g per cow during one week before calving and 26 g per cow until the end of the third week of lactation'</li></ul> <p>It is recommended that advice from a veterinarian or a nutritionist be sought before use."</p> |