EUROPEAN
COMMISSION

Brussels, XXX
SANTE/9232772/2022 CIS
(POOL/G5/2022/9232772/9232772-EN
CIS.docx)
[…](2023) XXX draft

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

**of XXX**

**concerning the authorisation of a preparation of *glycosylated 1,25-dihydroxycholecalciferol* from *Solanum glaucophyllum* extract as a feed additive for dairy cows**

(Text with EEA relevance)

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**concerning the authorisation of a preparation of *glycosylated 1,25-dihydroxycholecalciferol* from *Solanum glaucophyllum* extract as a feed additive for dairy cows**

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract as a feed additive for dairy cows and other dairy ruminants, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. The preparation is intended to be used only in a complementary feed consisting of an encapsulated, controlled-release bolus to reduce the risk of milk fever and subclinical hypocalcaemia.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 June 2022[2] that the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract, as applied in the animal studies evaluated, is safe for dairy cows when administered in a bolus containing 500µg of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract once during the pre-parturient period (from 9 days before calving to immediately before calving). In the animal studies evaluated, the bolus was complemented by a feed containing appropriate levels of calcium and magnesium. Owing to a lack of data, the Authority was neither in the position to conclude on the safety of the subsequent administration

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
[2] EFSA Journal 2022;20(8):7434.

of a second bolus as recommended by the applicant, if the cow has not calved within 9 days after bolus administration, nor on the safety for use in dairy ruminants other than cows (*Bos taurus*). It further concluded that the preparation is safe for consumers and the environment and that it is not irritating to skin and eyes and it is not a sensitiser. It considered that exposure via inhalation is unlikely when used in a bolus. The Authority concluded that the administration of the additive in a bolus containing 500µg of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract 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. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) Subsequently, the applicant withdrew the application for authorisation of the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract for all dairy ruminants except for dairy cows.

(6) The Commission considers that the active substance of the feed additive is the glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract. The feed additive consists of a preparation containing the active substance that is stabilised with maltodextrin or other suitable carriers. The preparation is subsequently to be incorporated in a bolus that is regarded as a complementary feed.

(7) The assessment of the preparation of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised for the sole use in a complementary feed in the form of a bolus.

(8) In addition, for safety reasons, the Commission considers that the maximum release level of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract released from the bolus in the body of the animals should be indicated as maximum content of complete feed. Taking into account that glycosylated 1,25-hydroxycholecalciferol is a precursor of 25-hydroxycholecalciferol and that the Authority stated in its opinion of 5 July 2023[3] concerning 25-hydroxycholecalciferol produced with *Saccharomyces cerevisiae* CBS 146008 that no conclusion on the potential of that substance to be a skin sensitiser or on its effects on the respiratory system could be reached due to absence of data, the Commission considers that appropriate breathing and skin protective measures should be taken to prevent adverse effects on the health of the users of the additive, when handling the substance in view of the incorporation in a bolus. Furthermore, the Commission considers that as 25-hydroxycholecalciferol depresses the activity of 1α-hydroxylase in the kidney, the simultaneous use of glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract with that additive should not be allowed.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

[3] EFSA Journal 2023;21(8):8168.

HAS ADOPTED THIS REGULATION:

*Article 1*
*Authorisation*

The preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*
*Entry into force*

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*