EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation calcium D-pantothenate (vitamin B_5) as a feed additive for all animal species and modifying Commission Implementing Regulation (EU) No 669/2014 as regards calcium D-pantothenate

(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 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 authorisation.

(2) Calcium D-pantothenate was authorised for a period of 10 years as a feed additive by Commission Regulation (EC) No 669/2014[2] for all animal species.

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of calcium D-pantothenate (vitamin B_5) for all animal species. That application requested 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' and was accompanied by the particulars and documents required respectively under Article 14(2) .

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 June 2024[3] that, under the conditions of use currently authorised calcium D-pantothenate (vitamin B_5) remains safe for all animal species consumers and the environment. The Authority further concluded that calcium D-pantothenate (vitamin B_5) is not irritant to the eyes and the skin, and it is not a skin sensitiser. It concluded the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

(5) The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No

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1 OJ L 268, 18.10.2003, p. 29.

2 Commission Implementing Regulation (EU) No 669/2014 of 18 June 2014 concerning the authorisation of calcium D-pantothenate and D-panthenol as feed additives for all animal species, *OJ L 179, 19.6.2014, p. 62,*ELI: http://data.europa.eu/eli/reg_impl/2014/669/oj.

3 https://doi.org/10.2903/j.efsa.2024.8901.

1831/2003 for the application for renewal of the authorisation. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[4], the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application.

(6) In view of the above, the Commission considers that calcium D-pantothenate (vitamin B_5) satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) As a consequence of the renewal of the authorisation of the preparation of 25-hydroxycholecalciferol, Commission Regulation (EC) No 669/2014 should be amended to delete the Annex entry that refers to calcium D-pantothenate (vitamin B_5) .

(8) Since the name of the additive has been modified to make reference to the common name of the vitamin, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(9) 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
Authorisation

The substance 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 a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Modification of Regulation (EC) No 669/2014

The Annex entry for the additive 3a841 calcium D -pantothenate is deleted.

Article 3

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which is produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted.

[4] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

2. Compound feed and feed materials containing the substance specified in the Annex which is produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance specified in the Annex which is produced and labelled before [*24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals .

Article 4
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