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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(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 and renewing such an authorisation.

(2) Calcium D-pantothenate and D-panthenol were authorised for 10 years as feed additives for all animal species by Commission Implementing Regulation (EU) No 669/2014[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, two applications were submitted for the renewal of the authorisation of calcium D-pantothenate (vitamin B_5) and D-panthenol (vitamin B_5)[for all animal species, requesting the additives to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

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(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 26 June 2024[3] and 28 January 2025[4] that, under the conditions of use currently authorised calcium D-pantothenate and D-panthenol remain safe for all animal species, the consumers and the environment. The Authority further stated that calcium D-pantothenate was considered of low toxicity by inhalation and that the exposure through inhalation is likely. In addition, it concluded that it is not irritant to the eyes and the skin, and is not a skin sensitiser. For D-panthenol, the Authority concluded that it is considered to be a skin and eye irritant, and a dermal and respiratory sensitiser. The Authority stated that the applications for renewal of the authorisation

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[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] EFSA Journal. 2024;22:e8901. https://doi.org/10.2903/j.efsa.2024.8901.

[4] EFSA Journal. 2025;23:e9252. https://doi.org/10.2903/j.efsa.2025.9252.

do not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additives. Therefore, it concluded that there is no need for assessing the efficacy of the additives in the context of the renewal of the authorisation. The Authority considered that there is no need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of calcium D-pantothenate and D-panthenol as feed additives in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005[5], evaluation reports of the Reference Laboratory are therefore not required.

(6) In view of the above, the Commission considers that calcium D-pantothenate (vitamin B_5) and D-panthenol (vitamin B_5) satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of these additives should be renewed. Currently, the name of these feed additives only refers to calcium D-pantothenate or D-panthenol. The Commission considers that it is appropriate to add the reference to the common name of the vitamin "vitamin B_5" and to grant the possibility for operators to indicate the additive on the label of feed materials and compound feed with the common name of the vitamin or with the specific chemical substance (calcium D-pantothenate or panthenol). In both cases the reference on the label should be accompanied with the identification number that is different for each additive and allows to identify the exact chemical substance that is used in the feed. Such a modification should allow farmers and, in particular pet owners, to easily identify vitamin B_5 on the label of the compound feed. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.

(7) As a consequence of the renewal of the authorisation of calcium D-pantothenate (vitamin B_5) and D-panthenol (vitamin B_5), Implementing Regulation (EU) No 669/2014 should be repealed.

(8) Since the name of the additives have been modified, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation. 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 authorisation of the substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically

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[5] 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).

well-defined substances having similar effect', is renewed subject to the conditions laid down in that Annex.

Article 2
Repeal

Regulation (EC) No 669/2014 is repealed.

Article 3
Transitional measures

1. The feed additives calcium D-pantothenate and D-panthenol as authorised by Implementing Regulation (EU) No 669/2014 check and premixtures containing those substances, which are 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 stocks concerned are exhausted.

2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are 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 stocks concerned are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are 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 stocks concerned 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