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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Levilactobacillus brevis* DSM 23231 as a feed additive for all animal species and amending Implementing Regulation (EU) No 399/2014

(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 authorisation.

(2) The preparation of *Levilactobacillus brevis* DSM 23231 (previously identified as *Lactobacillus brevis* DSM 23231) was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 399/2014[2].

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Levilactobacillus brevis* DSM 23231 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 15 November 2023[3] that the preparation of *Levilactobacillus brevis* DSM 23231 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive should be considered a respiratory sensitiser and that on the basis of the studies submitted regarding user safety it was shown not to be a skin or eye irritant. The Authority was not in the position to conclude on the skin sensitisation potential of the additive. It also indicated

[1] OJ L 268, 18.10.2003, p. 29, ELI: https://eur-lex.europa.eu/eli/reg/2003/1831/oj.

[2] Commission Implementing Regulation (EU) No 399/2014 of 22 April 2014 concerning the authorisation of the preparations of *Lactobacillus brevis* DSM 23231, *Lactobacillus brevis* DSMZ 16680, *Lactobacillus plantarum* CECT 4528 and *Lactobacillus fermentum* NCIMB 30169 as feed additives for all animal species (OJ L 119, 23.4.2014, p. 40, ELI: http://data.europa.eu/eli/reg_impl/2014/399/oj).

[3] EFSA Journal 2023;21:e8461.

that there is no need for assessing the efficacy of the additive as the application for renewal of its authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation which would have an impact on the efficacy of the additive.

(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 the preparation of *Levilactobacillus brevis* DSM 23231 as a feed additive 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[4], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Levilactobacillus brevis* DSM 23231 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. 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 the preparation of *Levilactobacillus brevis* DSM 23231 as a feed additive, Implementing Regulation (EU) No 399/2014 should be amended.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Levilactobacillus brevis* DSM 23231, 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.

(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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 399/2014

In the Annex to Implementing Regulation (EU) No 399/2014, entry 1k20744 on '*Lactobacillus brevis* DSM 23231' is deleted.

[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 additives (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

Article 3

Transitional measures

The preparation specified in the Annex and feed containing it, 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 existing stocks are exhausted.

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