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COMMISSION

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

of **XXX**

concerning the renewal of the authorisation of a preparation of the bacterial strain DSM 11798 of the *Eggerthellaceae* family as a feed additive for pigs, poultry and ornamental birds and repealing Implementing Regulations (EU) No 1016/2013 and 2017/930

(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 nutrition¹, 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) A preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family was authorised for a period of 10 years as a feed additive for pigs by Commission Implementing Regulation (EU) No 1016/2013² and for all avian species by Commission Implementing Regulation (EU) 2017/930³.
- (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 the bacterial strain DSM 11798 of the *Eggerthellaceae* family (previously taxonomically identified as belonging to the *Coriobacteriaceae* family) as a feed additive for pigs and all avian species, requesting the additive to be classified in the additive category ‘technological additives’ and in the functional group ‘substances for the reduction of the contamination of feed by mycotoxins’. 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 20 March 2025⁴ that the preparation of the bacterial strain DSM 11798 of the *Eggerthellaceae* family remains safe for piglets, pigs for fattening and all avian

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 1016/2013 of 23 October 2013 concerning the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs (OJ L 282, 24.10.2013, pp. 36, ELI: http://data.europa.eu/eli/reg_impl/2013/1016/oj).

³ Commission Implementing Regulation (EU) 2017/930 of 31 May 2017 concerning the authorisation of a preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for all avian species (OJ L 141, 1.6.2017, pp. 6, ELI: http://data.europa.eu/eli/reg_impl/2017/930/oj).

⁴ Journal, 23(4), e9360. <https://doi.org/10.2903/j.efsa.2025.9360>.

species, consumers and the environment under the approved terms of the authorisation. It also concluded that the preparation of the bacterial strain DSM 11798 of the *Eggerthellaceae* family is not irritant to skin or eyes but it should be considered a potential skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. The Authority stated that 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, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

- (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 the bacterial strain DSM 11798 of the *Eggerthellaceae* family as a feed additive in the context of the previous authorisations are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005⁵ an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of the bacterial strain DSM 11798 of the *Eggerthellaceae* family 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 the bacterial strain DSM 11798 of the *Eggerthellaceae* family as a feed additive, Implementing Regulations (EU) No 1016/2013 and (EU) 2017/930 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of the bacterial strain DSM 11798 of the *Eggerthellaceae* family, 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 'substances for the reduction of the contamination of feed by mycotoxins', is renewed subject to the conditions laid down in that Annex.

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 additives (OJ L 059 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

Article 2

Repeal

Implementing Regulations (EU) No 1016/2013 and (EU) 2017/930 are repealed.

Article 3

Transitional measures

1. The preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family, as authorised by Implementing Regulations (EU) No 1016/2013 and (EU) 2017/930 and premixtures containing those additives, which are intended for pigs and all avian species and which are produced and labelled before [*6 months from 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 intended for pigs and all avian species which are produced and labelled before [*12 months from 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 intended for pigs and all avian species and which are produced and labelled before [*24 months from 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