

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 and amending Implementing Regulation (EU) No 1016/2013****(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) and Article 13(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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family and for an amendment of the terms of the current authorisation for pigs granted by Commission Implementing Regulation (EU) No 1016/2013 ⁽²⁾. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003, and by the relevant data to support the amendment request.
- (3) The application concerns the authorisation of a new use of the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for all avian species, to be classified in the additive category 'technological additives' and the modification of the terms of the current authorisation for pigs to extend the use to all trichothecene mycotoxins.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 December 2016 ⁽³⁾ that, under the proposed conditions of use, the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family does not have an adverse effect on animal health, human health or the environment. The Authority recognised that the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family has the capacity to reduce deoxynivalenol (DON) from contaminated feed. It concluded that the preparation has the capacity to reduce the 12,13-epoxide group in a number of representative trichothecenes and in other mycotoxins of the same structural type regardless of the animal species or category receiving contaminated feed. 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) In order to allow for the use of the additive with other trichothecenes, it is appropriate to amend Implementing Regulation (EU) No 1016/2013.
- (6) The assessment of the preparation of a microorganism strain DSM 11798 of the *Coriobacteriaceae* family 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 as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 1016/2013 of 23 October 2013 concerning the authorisation of a preparation of microorganism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs (OJ L 282, 24.10.2013, p. 36).

⁽³⁾ EFSA Journal 2017;15(1):4676.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in Annex I, belonging to the additive category 'technological additives' and to the functional group 'substances for the reduction of the contamination of feed by mycotoxins', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 1016/2013

The Annex to Implementing Regulation (EU) No 1016/2013 is replaced by Annex II to this Regulation.

Article 3

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, 31 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

Category of technological additives. Functional group: substances for the reduction of the contamination of feed by mycotoxins: trichothecenes

1m01	—	Microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family	<p><i>Additive composition</i></p> <p>Preparation of a microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family containing a minimum of 5×10^9 CFU/g of additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of: microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration of microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family: pour plate method using VM agar supplemented with Oxyrase.</p> <p>Identification of microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family: Pulsed Field Gel Electrophoresis (PFGE).</p>	All avian species	—	$1,7 \times 10^8$	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed. 3. The use is permitted in feed containing the following authorised coccidiostats: narasin/nicarbazin, salinomycin sodium, monensin sodium, robenidine hydrochloride, diclazuril, narasin, or nicarbazin. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including breath protections. 	21 June 2027
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: substances for the reduction of the contamination of feed by mycotoxins: trichothecenes									
1m01	—	Microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family	<p><i>Additive composition</i></p> <p>Preparation of a microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family containing a minimum of 5×10^9 CFU/g of additive.</p> <p>Solid form</p> <p><i>Characterisation of the active substance</i></p> <p>Viable cells of: microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration of microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family: pour plate method using VM agar supplemented with Oxyrase.</p> <p>Identification of microorganism strain DSM 11798 of the <i>Coriobacteriaceae</i> family: Pulsed Field Gel Electrophoresis (PFGE).</p>	Pigs	—	$1,7 \times 10^8$	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment including breath protections. 	13 November 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>