

REGULATIONS

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

(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) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of a micro-organism strain DSM 11798 of the *Coriobacteriaceae* family as a feed additive for pigs, to be classified in the additive category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') in its opinion of 16 April 2013⁽²⁾ concluded that, under the proposed conditions of use, the preparation of a

micro-organism strain DSM 11798 of the *Coriobacteriaceae* family is safe for the target species, for the human health and for the environment. It recognised that it has the capacity to biotransform trichothecenes from contaminated feed for pigs. 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) The assessment of the preparation of a micro-organism 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.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

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 authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(5):3203.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 October 2013.

For the Commission
The President
José Manuel BARROSO

ANNEX

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: Deoxynivalenol (DON)									
1m01	—	Micro-organism strain DSM 11798 of the <i>Coriobacteriaceae</i> family	<p><i>Additive composition</i></p> <p>Preparation of a micro-organism 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: micro-organism strain DSM 11798 of the <i>Coriobacteriaceae</i> family</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>Enumeration of micro-organism strain DSM 11798 of the <i>Coriobacteriaceae</i> family: pour plate method using VM agar supplemented with Oxyrase.</p> <p>Identification of micro-organism 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 premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in animal feed. 3. For safety: it is recommended to use breathing protection and gloves during handling. 	13 November 2023

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: http://www.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx