Commission Implementing Regulation (EU) 2019/11 of 3 January 2019 concerning the authorisation of the preparation of Enterococcus faecium NCIMB 10415 as a feed additive for sows, suckling piglets, weaned piglets, pigs for fattening, and amending Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 (holder of authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/11

of 3 January 2019

concerning the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, suckling piglets, weaned piglets, pigs for fattening, and amending Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 (holder of authorisation DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.)

(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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) The preparation of *Enterococcus faecium* NCIMB 10415 was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for piglets by Commission Regulation (EC) No 252/2006[(3)], for pigs for fattening by Commission Regulation (EC) No 943/2005[(4)] and for sows by Commission Regulation (EC) No 1200/2005[(5)]. That preparation was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for sows, weaned piglets, suckling piglets and pigs for fattening. The applicant requested that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 June 2015[6] and 21 February 2018[7] that, under the proposed conditions of use, the preparation of *Enterococcus faecium* NCIMB 10415 does not have an adverse effect on animal health, human health or the environment. The Authority considered that the additive has the potential to improve performance parameters in suckling piglets, weaned piglets, pigs for fattening and sows. 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 *Enterococcus faecium* NCIMB 10415 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) Therefore, Regulations (EC) No 252/2006, (EC) No 943/2005 and (EC) No 1200/2005 should be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Regulation (EC) No 252/2006

Regulation (EC) No 252/2006 is amended as follows:

(1) Article 1 is deleted;

(2) Annex I is deleted.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/11. (See end of Document for details)*

Article 3

Amendment to Regulation (EC) No 943/2005

Regulation (EC) No 943/2005 is amended as follows:

(1) Article 1 is deleted;

(2) Annex I is deleted.

Article 4

Amendment to Regulation (EC) No 1200/2005

In Annex II to Regulation (EC) No 1200/2005, the entry E 1705 on *Enterococcus faecium* NCIMB 10415 is deleted.

Article 5

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 24 July 2019 in accordance with the rules applicable before 24 January 2019 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 6

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, 3 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/11. (See end of Document for details)*

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 zootechnical additives. Functional group: gut flora stabilisers.									
4b1705	DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.	*Enterococcus faecium* NCIMB 10415	*Additive composition* Preparation of *Enterococcus faecium* NCIMB 10415 containing a minimum of: — coated form (with shellac): 2×10^{10} CFU/g additive, or — other coated forms: 1×10^{10} CFU/g additive, or — granulated non-coated form:	Sows Suckling piglets Weaned piglets Pigs for fattening	—	7×10^{8} 1×10^{9} $3{,}5 \times 10^{8}$	— — —	1. the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. additive shall be administered to pregnant and lactating sows and simultaneously to the suckling piglets 3. For use in weaned piglets until	24 January 2029 The For

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports