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►**B** **COMMISSION IMPLEMENTING REGULATION (EU) No 361/2011**

of 13 April 2011

concerning the authorisation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional products Ltd represented by DSM Nutritional Products Sp. z o.o) and amending Regulation (EC) No 943/2005

(Text with EEA relevance)

(OJ L 100, 14.4.2011, p. 22)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Regulation (EU) 2015/518 of 26 March 2015	L 82	75	27.3.2015

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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 in accordance with Directive 70/524/EEC as a feed additive without a time limit for use on calves up to 6 months by Commission Regulation (EC) No 1288/2004 ([3]), for use on chickens for fattening and pigs for fattening by Commission Regulation (EC) No 943/2005 ([4]), for use on sows by Commission Regulation (EC) No 1200/2005 ([5]), for use on piglets by Commission Regulation (EC) No 252/2006 ([6]) and for use on cats and dogs by Commission Regulation (EC) No 102/2009 ([7]). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1)(b) 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 *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens for

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 243, 15.7.2004, p. 10.
([4]) OJ L 159, 22.6.2005, p. 6.
([5]) OJ L 195, 27.7.2005, p. 6.
([6]) OJ L 44, 15.2.2006, p. 3.
([7]) OJ L 34, 4.2.2009, p. 8.

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fattening, requesting that additive be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 22 June 2010 ([1]) that, under the proposed conditions of use, *Enterococcus faecium* NCIMB 10415 does not have an adverse effect on animal health, human health or on the environment, and that that additive has the potential to increase the final body weight of chickens for fattening. 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 European Union Reference Laboratory for Feed Additives set up by Regulation (EC) No 1831/2003.

(5) The assessment 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 Annex I to this Regulation.

(6) As a consequence of a new authorisation being granted by this Regulation, the entry concerning *Enterococcus faecium* NCIMB 10415 for chickens for fattening in Regulation (EC) No 943/2005 should be deleted.

(7) Since the modifications to the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of premixtures and compound feed.

(8) 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 Annex I, 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

Annex I to Regulation (EC) No 943/2005 is replaced by the text in Annex II to this Regulation.

([1]) EFSA Journal 2010; 8(7):1661.

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Article 3

Premixtures and compound feed containing *Enterococcus faecium* NCIMB 10415 labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until stocks are exhausted.

Article 4

This Regulation shall enter into force on the 20th day following 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.

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 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 of additive; Other microencapsulated forms: 1×10^{10} CFU/g additive *Characterisation of the active substance* *Enterococcus faecium* NCIMB 10415 *Analytical method* (1) Enumeration: spread plate method using bile esculin azide agar Identification: Pulsed- Field Gel Electrophoresis (PFGE)	Chickens for fattening		3×10^{8}	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. ►**M1** 2. The use is permitted in feed containing the authorised coccidiostats: decoquinate, monensin sodium, robenidine hydrochloride, diclazuril, semduramycin, lasalocid A sodium, maduramycin ammonium, narasin, narasin/nicarbazin or salinomycin sodium. ◄	4 May 2021

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives

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ANNEX II

Annex I to Regulation (EC) No 943/2005 is replaced by the following:

'ANNEX I

EC No		Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feeding-stuff			
Micro-organisms									
E 1705		*Enterococcus faecium* NCIMB 10415	Preparation of *Enterococcus faecium* containing a minimum of: Microencapsulated form: $1,0 \times 10^{10}$ CFU/g of additive; Granulated form: $3,5 \times 10^{10}$ CFU/g additive	Pigs for fattening	—	$0,35 \times 10^{9}$	$1,0 \times 10^{9}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	Without a time limit'