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

**of **XXX****

**concerning the renewal of the authorisation of a preparation of *Enterococcus lactis* NCIMB 10415 as a feed additive for certain animal species, the authorisation of that preparation as a feed additive for certain other animal species (holder of authorisation: DSM Nutritional Products Ltd.), amending Implementing Regulation (EU) No 1061/2013 and repealing Implementing Regulations (EU) No 361/2011, (EU) 2015/518 and (EU) 2019/11**

(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 nutrition<sup>1</sup>, 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 authorisation.
- (2) Two forms of a preparation of *Enterococcus lactis* NCIMB 10415 (previously taxonomically identified as *Enterococcus faecium* NCIMB 10415), the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’, were authorised for 10 years as a feed additive for use in feed for chickens for fattening by Commission Implementing Regulation (EU) No 361/2011<sup>2</sup>, and for chickens reared for laying, minor poultry species for fattening and reared for laying by Commission Implementing Regulation (EU) No 2015/518<sup>3</sup>. The ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’, as well as a ‘granulated non-coated form’ of that preparation, were authorised for 10 years as a feed additive for use in feed for

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<sup>1</sup> OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

<sup>2</sup> 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 (OJ L 100, 14.4.2011, p. 22, ELI: [http://data.europa.eu/eli/reg\\_impl/2011/361/2015-04-16](http://data.europa.eu/eli/reg_impl/2011/361/2015-04-16)).

<sup>3</sup> Commission Implementing Regulation (EU) 2015/518 of 26 March 2015 concerning the authorisation of the preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying and amending Implementing Regulation (EU) No 361/2011 as regards the compatibility with coccidiostats (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. z o.o) (OJ L 82, 27.3.2015, p. 75, ELI: [http://data.europa.eu/eli/reg\\_impl/2015/518/oj](http://data.europa.eu/eli/reg_impl/2015/518/oj)).

calves and kids by Commission Implementing Regulation (EU) No 1061/2013<sup>4</sup>, and for sows, suckling piglets, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) No 2019/11<sup>5</sup>.

- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of the preparation of *Enterococcus lactis* NCIMB 10415 for use in feed for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying and for the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation for use in feed for calves for fattening, calves for rearing, kids for fattening, kids for rearing, sows, suckling piglets, weaned piglets and pigs for fattening. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application was also submitted for the authorisation of new uses of the preparation of *Enterococcus lactis* NCIMB 10415, namely the use of the ‘granulated non-coated form’ in feed for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying, the use of the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ in feed for chickens reared for breeding, turkeys for fattening, turkeys reared for breeding, minor poultry species reared for breeding, ornamental birds, lambs for rearing, lambs for fattening, minor ruminant species for rearing, minor ruminant species for fattening, pigs reared for breeding and all categories of minor porcine species, the use of the ‘encapsulated form’ and the ‘granulated non-coated form’ in water for drinking for chickens for fattening, chickens reared for laying, chickens reared for breeding, turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening, minor poultry species reared for laying, minor poultry species reared for breeding, ornamental birds, calves for rearing, calves for fattening, kids for rearing, kids for fattening, lambs for rearing, lambs for fattening, minor ruminant species for rearing, minor ruminant species for fattening, pigs reared for breeding and all categories of pigs and of minor porcine species (‘the target species’). The application requested that additive to be classified in the category ‘zotechnical additives’ and in the functional group ‘gut flora stabilisers’. The application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of that Regulation.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 27 September 2023<sup>6</sup> that all three forms of the preparation of *Enterococcus lactis* NCIMB 10415 are safe for the target species, the consumers and the environment under the proposed conditions of use. It also concluded that the ‘encapsulated form’ and the

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<sup>4</sup> Commission Implementing Regulation (EU) No 1061/2013 of 29 October 2013 concerning the authorisation of a preparation of *Enterococcus faecium* NCIMB 10415 as a feed additive for calves, kids, cats and dogs and amending Regulation (EC) No 1288/2004 (holder of the authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o.) (OJ L 289, 31.10.2013, p. 38, ELI: [http://data.europa.eu/eli/reg\\_impl/2013/1061/oj](http://data.europa.eu/eli/reg_impl/2013/1061/oj)).

<sup>5</sup> 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.) (OJ L 2, 4.1.2019, p. 17, ELI: [http://data.europa.eu/eli/reg\\_impl/2019/11/oj](http://data.europa.eu/eli/reg_impl/2019/11/oj)).

<sup>6</sup> EFSA Journal 2023;21(10):8347.

‘encapsulated and coated form with shellac’ of that preparation are non-irritant to skin or eyes and that all three forms of the additive are considered a potential respiratory sensitiser. No conclusion could be drawn by the Authority on the potential of the ‘granulated non-coated form’ of that preparation to be skin and eye irritant nor on the skin sensitisation potential of all three forms of the additive. The Authority indicated that there was no need for assessing the efficacy of the preparation of *Enterococcus lactis* NCIMB 10415 in the context of the renewal of the authorisation as the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of use for those species and categories for which there is an authorisation. It further concluded that the efficacy for the new uses can be extrapolated from the previous efficacy studies and that, regarding the compatibility with coccidiostats, the conclusions already reached previously can be extrapolated for the other poultry species and categories at the relevant physiological stage and for the coccidiostats for which an authorisation exists. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

- (5) In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005<sup>7</sup>, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive as regards the method of analysis are valid and applicable for the current application.
- (6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* NCIMB 10415 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of that preparation for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, and of the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows (which include pigs reared for reproduction), suckling piglets, weaned piglets and pigs for fattening, should be renewed. In addition, that preparation should be authorised for the new uses applied for. It is appropriate to extend the indication of the compatibility of use of that preparation with some coccidiostats to chickens reared for breeding, turkeys for fattening and reared for breeding and minor poultry species reared for breeding. Finally, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of the preparation of *Enterococcus lactis* NCIMB 10415 for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, as well as of the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows, suckling piglets, weaned piglets and pigs for fattening, Implementing Regulation (EU) No 1061/2013 should be

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<sup>7</sup> 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 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

amended, and Implementing Regulations (EU) No 361/2011, (EU) 2015/518 and (EU) 2019/11 should be repealed.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of the preparation of *Enterococcus lactis* NCIMB 10415 for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, as well as of the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows, suckling piglets, weaned piglets and pigs for fattening, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from 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 authorisation**

The authorisation of the ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of the preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, as well as of the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows, suckling piglets, weaned piglets and pigs for fattening, is renewed subject to the conditions laid down in that Annex.

#### *Article 2*

##### **Authorisation**

The ‘granulated non-coated form’ of 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 for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, subject to the conditions laid down in that Annex. The ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation are authorised as an additive in animal nutrition for use in feed for chickens reared for breeding, turkeys for fattening and reared for breeding, minor poultry species reared for breeding, ornamental birds, lambs for rearing and for fattening, minor ruminant species for rearing and for fattening, and all categories of minor porcine species, subject to the conditions laid down in that Annex. The ‘encapsulated form’ and the ‘granulated non-coated form’ of that preparation are authorised as an additive in animal nutrition for use in water for drinking for all poultry species for fattening, reared for laying and reared for breeding, ornamental birds, sows of all Suidae species, suckling and weaned piglets of all Suidae species, pigs for fattening of all Suidae species, calves for rearing and for fattening, kids for rearing and for fattening, lambs for rearing and for fattening, and minor ruminant species for rearing and for fattening, subject to the conditions laid down in that Annex.

### Article 3

#### **Amendment to Implementing Regulation (EU) No 1061/2013**

In the Annex to Implementing Regulation (EU) No 1061/2013, the first entry 4b1705 relating to calves and kids is deleted.

### Article 4

#### **Repeals**

Implementing Regulations (EU) No 361/2011, (EU) 2015/518 and (EU) 2019/11 are repealed.

### Article 5

#### **Transitional measures**

1. The ‘encapsulated form’ and the ‘encapsulated and coated form with shellac’ of the preparation specified in the Annex and premixtures containing those forms of that preparation, which are intended for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, as well as the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ and the ‘granulated non-coated form’ of that preparation and premixtures containing those forms of that preparation, which are intended for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows, suckling piglets, weaned piglets and pigs for fattening, and which are produced and labelled before [*6 months after 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 existing stocks are exhausted.
2. Compound feed and feed materials containing the ‘encapsulated form’ or the ‘encapsulated and coated form with shellac’ of the preparation specified in the Annex and premixtures containing those forms of that preparation, which are intended for use in feed for chickens for fattening and reared for laying and minor poultry species for fattening and reared for laying, as well as containing the ‘encapsulated form’, the ‘encapsulated and coated form with shellac’ or the ‘granulated non-coated form’ of that preparation, which are intended for use in feed for calves for rearing and for fattening, kids for rearing and for fattening, sows, suckling piglets, weaned piglets and pigs for fattening, and which are produced and labelled before [*12 months after 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 existing stocks are exhausted.

### Article 5

#### **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*