EUROPEAN
COMMISSION

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[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, the authorisation of that preparation as a feed additive for use in feed and in water for drinking for chickens reared for breeding, turkeys for fattening and turkeys reared for breeding (holder of authorisation: Biomin GmbH) and repealing Implementing Regulations (EU) No 544/2013 and (EU) 2015/1105

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, the authorisation of that preparation as a feed additive for use in feed and in water for drinking for chickens reared for breeding, turkeys for fattening and turkeys reared for breeding (holder of authorisation: Biomin GmbH) and repealing Implementing Regulations (EU) No 544/2013 and (EU) 2015/1105

(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 and renewing such authorisation.

(2) A preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 (previously taxonomically identified as *Lactobacillus salivarius* ssp. *salivarius* DSM 16351) and *Enterococcus faecium* DSM 21913 was authorised for 10 years as a feed additive for use in feed for chickens for fattening by Commission Implementing Regulation (EU) No 544/2013[2] and, by Commission Implementing Regulation (EU) 2015/1105[3] for use in feed and water for

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

2 Commission Implementing Regulation (EU) No 544/2013 of 14 June 2013 concerning the authorisation of a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens for fattening (holder of authorisation Biomin GmbH) (OJ L 163, 15.6.2013, p. 13, ELI: http://data.europa.eu/eli/reg_impl/2013/544/oj).

3 Commission Implementing Regulation (EU) 2015/1105 of 8 July 2015 concerning the authorisation of a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens reared for laying and minor poultry species other than laying, the authorisation of that feed additive for use in water for drinking for chickens for fattening and amending Regulation (EU) No 544/2013 as regards the maximum content of that feed additive in complete feedingstuff and its compatibility with coccidiostats (holder of the authorisation Biomin GmbH) (OJ L 181, 9.7.2015, p. 65, ELI: http://data.europa.eu/eli/reg_impl/2015/1105/oj).

drinking for chickens reared for laying and minor poultry species other than laying, as well as for use in water for drinking for chickens for fattening.

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species other than laying, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the authorisation of new uses of the same preparation as a feed additive for use in feed and in water for drinking for chickens reared for breeding, turkeys for fattening and turkeys reared for breeding. 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 15 November 2023[4] that the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 is safe for the target species, the consumers and the environment under the authorised conditions of use and considered that this conclusion also applies to the target species for which a request for new uses was made. It also concluded that that preparation is non-irritant to skin or eyes but should be considered a respiratory sensitiser. The Authority indicated that there was no need for assessing the efficacy of the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 in the context of the renewal of the authorisation for chickens for fattening, chickens reared for laying and minor poultry species other than laying. It further concluded that that preparation was considered to be efficacious in feed and water for drinking for all growing poultry species, including as regards the compatibility of the use of 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 (c), of Commission Regulation (EC) No 378/2005[5], an evaluation report of the Reference Laboratory is therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that preparation should be renewed for use in feed and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, and the use of that preparation should be authorised for use in feed and water for drinking for chickens reared for breeding, turkeys for fattening and turkeys reared for breeding. It is appropriate to indicate the compatibility of the use of that preparation with the coccidiostats maduramicin ammonium, diclazuril, robenidine hydrochloride, decoquinate, narasin, nicarbazin, a combination of narasin with

[4] EFSA Journal 2023;21(12):8356.

[5] 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).

nicarbazin. In addition, considering that those coccidiostats may not be authorised as feed additives for each of the species or categories listed in the Annex, their simultaneous use with the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 should only be possible in accordance with their respective conditions of authorisation as feed additives. 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 preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 as a feed additive for use in feed and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species reared for laying or breeding, Implementing Regulations (EU) No 544/2013 and (EU) 2015/1105 should be repealed.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 for use in feed and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, 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 the authorisation

The authorisation 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 and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, is renewed subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised for use in feed and water for chickens reared for breeding, turkeys for fattening and turkeys reared for breeding, subject to the conditions laid down in that Annex.

Article 3

Repeals

Implementing Regulations (EU) No 544/2013 and (EU) 2015/1105 are repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for use in feed and water for drinking for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, 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 preparation specified in the Annex, which are intended for chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying or breeding, 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

ANNEX

Identi-fication number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi-mum age	Mini-mum content	Maxi-mum content	Mini-mum content	Maxi-mum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12%		CFU/l of water for drinking			
Category: zootechnical additives. Functional group: gut flora stabilisers											
4b1890	Biomin GmbH	*Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913	***Additive composition*** Preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 containing a minimum of 10×10^9 CFU/g additive (3:1:6 ratio) Solid form ***Characterisation of the active substance*** Viable cells of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Ligilactobacillus salivarius* DSM 16351 and *Enterococcus*	All poultry species for fattening All poultry species reared for laying All poultry species reared for breeding	-	1×10^8	-	5×10^7	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: maduramicin ammonium, diclazuril, robenidine hydrochloride, decoquinate, narasin, nicarbazin, a combination of narasin with nicarbazin. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publica-tion]*

			faecium DSM 21913 ***Analytical method*** **(1)** Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697. Enumeration in the feed additive, premixtures, compound feed and water of: - *Bifidobacterium animalis* ssp. *animalis* DSM 16284: spread plate method EN 15785 - *Ligilactobacillus salivarius* DSM 16351: spread plate method EN 15787 - *Enterococcus faecium* DSM 21913: spread plate method EN 15788							risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

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Brussels, XXX
SANTE/11026860/2023
[…](2023) XXX draft

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)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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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)

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 and renewing such authorisation.

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

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

[2] 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).

[3] 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).

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

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the 'micro-encapsulated form' and the 'micro-encapsulated 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 'micro-encapsulated form', the 'micro-encapsulated form with shellac' and the 'non-coated granulated 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 'non-coated granulated 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 'micro-encapsulated form', the 'micro-encapsulated form with shellac' and the 'non-coated granulated 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 'micro-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 'zootechnical 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[6] 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 'micro-encapsulated form' and

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4 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).

5 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).

6 EFSA Journal 2023;21(10):8347.

the ‘micro-encapsulated 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 ‘non-coated granulated 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[7], 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 ‘micro-encapsulated form’ and the ‘micro-encapsulated 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 ‘micro-encapsulated form’, the ‘micro-encapsulated form with shellac’ and the ‘non-coated granulated 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 ‘micro-encapsulated form’ and the ‘micro-encapsulated 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 ‘micro-encapsulated form’, the ‘micro-encapsulated form with shellac’ and the ‘non-coated granulated 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 amended,

[7] 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).

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 'micro-encapsulated form' and the 'micro-encapsulated 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 'micro-encapsulated form', the 'micro-encapsulated form with shellac' and the 'non-coated granulated 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 'micro-encapsulated form' and the 'micro-encapsulated 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 'micro-encapsulated form', the 'micro-encapsulated form with shellac' and the 'non-coated granulated 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 'non-coated granulated 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 'micro-encapsulated form', the 'micro-encapsulated form with shellac' and the 'non-coated granulated 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 'micro-encapsulated form' and the 'non-coated granulated 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 ‘micro-encapsulated form’ and the ‘micro-encapsulated 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 ‘micro-encapsulated form’, the ‘micro-encapsulated form with shellac’ and the ‘non-coated granulated 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 ‘micro-encapsulated form’ or the ‘micro-encapsulated 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 ‘micro-encapsulated form’, the ‘micro-encapsulated form with shellac’ or the ‘non-coated granulated 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

ANNEX

Part I

Identification number of the feed 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	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12%		CFU/l of water for drinking			
Category: zootechnical additives. Functional group: gut flora stabilisers											
4b1705	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	*Enterococcus lactis* NCIMB 10415	***Additive composition*** Preparation of *Enterococcus lactis* NCIMB 10415 containing a minimum of: —micro-encapsulated form: 1×10^{10} CFU/g additive, or —non-coated granulated form: 3.5×10^{10} CFU/g additive. Solid forms ***Characterisation of the active substance*** Viable cells of *Enterococcus lactis* NCIMB 10415	All poultry species for fattening	–	3×10^8	-	1.5×10^8	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used via water for drinking. 3. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: decoquinate, monensin sodium, robenidine hydrochloride, diclazuril, semduramicin, lasalocid A sodium, maduramicin ammonium, narasin, a	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]*
				All poultry species reared for laying							
				All poultry species reared for breeding							
				Ornamental birds							
				Sows of all *Suidae* species		7×10^8		3.5×10^8			
				Suckling piglets of		1×10^9		0.5×10^9			

			Analytical method **(1)** Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697. Enumeration in the feed additive, premixtures, compound feed and water: spread plate method using bile esculin azide agar (EN 15788)	all *Suidae* species Calves, kids, lambs and minor ruminant species for rearing Calves, kids, lambs and minor ruminant species for fattening						combination of narasin with nicarbazin, salinomycin sodium. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment, and also eye protective equipment for the granulated non-coated form.	
				Weaned piglets of all *Suidae* species Pigs for fattening of all *Suidae* species		3.5×10^8		2×10^8			

Part II

Identi-fication number of the feed	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maxi-mum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a			

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

additive						**moisture content of 12%**			
Category: zootechnical additives. Functional group: gut flora stabilisers									
4b1705i	DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp. z o.o.	*Enterococcus lactis* NCIMB 10415	***Additive composition*** Preparation of *Enterococcus lactis* NCIMB 10415 containing a minimum of: — micro-encapsulated form with shellac: 2×10^{10} CFU/g additive Solid form ***Characterisation of the active substance*** Viable cells of *Enterococcus lactis* NCIMB 10415 ***Analytical method*** (2) Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697. Enumeration in the feed additive, premixtures, compound feed and water: spread plate method using bile esculin azide agar	All poultry species for fattening All poultry species reared for laying All poultry species reared for breeding Ornamental birds	-	3×10^8	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used simultaneously with the following coccidiostats, in accordance with their respective conditions of authorisation as feed additives: decoquinate, monensin sodium, robenidine hydrochloride, diclazuril, semduramicin, lasalocid A sodium, maduramicin ammonium, narasin, a combination of narasin with nicarbazin, salinomycin sodium. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot	*[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publica-tion]*
				Sows of all *Suidae* species		7×10^8			
				Suckling piglets of all *Suidae* species Calves, kids, lambs and minor ruminant species for rearing Calves, kids, lambs and minor ruminant species for fattening		1×10^9			
				Weaned piglets of all *Suidae* species Pigs for fattening		3.5×10^8			

(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

			(EN 15788)	of all *Suidae* species				be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	

EUROPEAN
COMMISSION

Brussels, XXX
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[…](2023) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs and the authorisation of that preparation for ruminants and repealing Implementing Regulation (EC) No 887/2009

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the renewal of the authorisation of a preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs and the authorisation of that preparation for ruminants and repealing Implementing Regulation (EC) No 887/2009

(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 and renewing such an authorisation.

(2) A preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 was authorised for a period of 10 years as a feed additive by Commission Regulation (EC) No 887/2009[2] for chickens for fattening, turkeys for fattening, other poultry, and pigs.

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for ruminants. Those applications requested that additive to be classified in the category ‘nutritional additives’ and in the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’ and were accompanied by the particulars and documents required respectively under Article 14(2) and Article 7(3) of that Regulation.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 5 July 2023[3] that under the conditions of use currently authorised the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 remains safe for chickens for fattening, turkeys for fattening, other poultry and pigs, and that it is safe for all ruminants. It concluded also that the preparation of 25-

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

[2] Commission Regulation (EC) No 887/2009 of 25 September 2009 concerning the authorisation of a stabilised form of 25-hydroxycholecalciferol as a feed additive for chickens for fattening, turkeys for fattening, other poultry and pigs (OJ L 254, 26.9.2009, p. 68, ELI: http://data.europa.eu/eli/reg/2009/887/oj).

[3] EFSA Journal 2023;21(8):8168 and EFSA Journal 2023;21(8):8169.

hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is safe for the consumers and the environment. It concluded that the preparation of 25-hydroxycholecalciferol produced by Saccharomyces *cerevisiae* CBS 146008 is an efficient source of vitamin D_3 for all ruminants and that, since the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority also concluded that 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is not irritant to the skin or eyes but no conclusion on its potential to be a skin sensitiser or on its effects on the respiratory system can be reached due to absence of data. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

(5) The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003 for the application for renewal of the authorisation for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[4], 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 are valid and applicable for the current application for ruminants.

(6) In view of the above, the Commission considers that the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008[5] satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for chickens for fattening, turkeys for fattening, other poultry and pigs and should be authorised for ruminants. As 25-hydroxycholecalciferol depresses the activity of 1α-hydroxylase in the kidney, the Commission considers that the simultaneous use of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract with that additive should not be allowed. The Commission further considers that the combination of the preparation of 25-hydroxycholecalciferol with cholecalciferol should be limited in order not to exceed the maximum daily intake level for vitamin D_3. The Commission considers that the restriction to use the additive via premixtures should be maintained. In addition, 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 preparation of 25-hydroxycholecalciferol, Implementing Regulation (EC) No 887/2009 should be repealed.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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4 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 additive (OJ L 59, 5.3.2005, p. 8, ELI: http://data.europa.eu/eli/reg/2005/378/oj).

5 EFSA Journal 2023;21(8):8168.

HAS ADOPTED THIS REGULATION:

Article 1
Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, is renewed for chickens for fattening, turkeys for fattening, other poultry and pigs, subject to the conditions laid down in that Annex.

Article 2
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect,’ is authorised as an additive in animal nutrition for ruminants, subject to the conditions laid down in that Annex.

Article 3
Repeal

Implementing Regulation (EC) No 887/2009 is repealed.

Article 4

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

ANNEX

Identification number of the feed additive	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
					mg active substance/kg of complete feed with a moisture content of 12%			
Category: Nutritional additives . Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect								
Sub classification: vitamin D								
3a670a	25-Hydroxy cholecalciferol	**Additive composition:** Preparation with a maximum content of 1.25% of 25-hydroxycholecalciferol. Solid form **Characterisation of the active substance:** 25-Hydroxycholecalciferol. Its precursor compound, 5,7,24-cholestatrienol, is produced with Saccharomyces cerevisiae CBS 146008. After extraction, the precursor is converted chemically to	Chickens for fattening			0,100	1. The additive shall be incorporated in feedingstuffs via the use of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and the stability to heat treatment shall be indicated. 3. Maximum content of the combination of 25-hydroxycholecalciferol with cholecalciferol	[10 years from the date of entry into force of this Regulation – Precise date to be completed by the OP]
			Turkeys for fattening			0,100		
			Other poultry			0,080		
			Pigs			0,050		
			Bovines and ovines			0,100		
			Ruminants other than			0,05		

		25-hydoxy-pro-vitamin D3, which is further transformed photochemically to 25-hydroxycholecalfciferol. $C_{27}H_{44}O_2.H_2O$ CAS number: 63283-36-3 <u>Purity criteria</u> – 25-hydroxycholecalciferol >94% – other sterol derivatives ≤ 1% each – erythrosine < 5 mg/kg **Analytical method[1]** For the determination of 25-hydroxycholecalciferol in the feed additive: Ultra Performance Liquid Chromatography coupled to spectrophotometric detection (UPLC-UV) For the determination of 25-hydroxycholecalciferol in premixtures: High Performance Liquid Chromatography coupled to	bovines and ovines				(vitamin D_3) per kg of complete feedingstuff: – ≤ 0,125 mg [2] (equivalent to 5 000 IU of cholecalciferol) for chickens for fattening and turkeys for fattening, – ≤ 0,080 mg [3] (equivalent to 3 200 IU of cholecalciferol) for other poultry, – ≤ 0,050 mg [4] (equivalent to 2 000 IU of cholecalciferol) for pigs, – ≤ 0,100 mg [5] (equivalent to 4 000 IU of cholecalciferol) for milk replacers for calves,	

[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.
[2] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).
[3] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).
[4] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).
[5] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).

		spectrophotometric detection (HPLC-UV) For the determination of 25-hydroxycholecalciferol in compound feed and in low concentrated premixtures: High Performance Liquid Chromatography coupled to tandem mass spectrometry (HPLC-MS/MS)					– ≤ 0,100 mg [6] (equivalent to 4 000 IU of cholecalciferol) for bovines and ovines, – ≤ 0,05 mg[7] (equivalent to 2 000 IU of cholecalciferol) for ruminants other than bovines and ovines. 4. The simultaneous use of the additive with glycosylated 1,25-dihydroxycholecalciferol from *Solanum glaucophylum* extract shall not be permitted. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by	

[6] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).
[7] 40 IU cholecalciferol (vitamin D3) = 0,001 mg cholecalciferol (vitamin D_3).

							such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	