



2024/1200

22.4.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1200

of 18 April 2024

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 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

⁽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 feedstuff 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).

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 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.

⁽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>).

- (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 12 November 2024 in accordance with the rules applicable before 12 May 2024 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 May 2025 in accordance with the rules applicable before 12 May 2024 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, 18 April 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

4b1890	Biomin GmbH	<i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus faecium</i> DSM 21913	<p><i>Additive composition</i> Preparation of <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus faecium</i> DSM 21913 containing a minimum of 10×10^9 CFU/g additive (3:1:6 ratio) Solid form</p> <p><i>Characterisation of the active substance</i> Viable cells of <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284, <i>Ligilactobacillus salivarius</i> DSM 16351 and <i>Enterococcus faecium</i> DSM 21913</p> <p><i>Analytical method</i> ⁽¹⁾ Identification: DNA sequencing methods or Pulsed Field Gel Electrophoresis (PFGE) - CEN/TS 17697.</p> <p>Enumeration in the feed additive, premixtures, compound feed and water of:</p> <p>— <i>Bifidobacterium animalis</i> ssp. <i>animalis</i> DSM 16284: spread plate method EN 15785</p>	All poultry species for fattening All poultry species reared for laying All poultry species reared for breeding	-	1×10^8	-	5×10^7	-	<ol style="list-style-type: none"> 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. 	12.5.2034
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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			
			<div><div>— <i>Ligilactobacillus salivarius</i> DSM 16351: spread plate method EN 15787</div><div>— <i>Enterococcus faecium</i> DSM 21913: spread plate method EN 15788</div></div>							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.	

(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.