# 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) (Text with EEA relevance)

## 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)

(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) and Article 13(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 modifying such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new use of a preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 and for an amendment of the terms of the current authorisation for chickens for fattening granted by Commission Implementing Regulation (EU) No 544/2013[(2)]. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003, and by the relevant data to support that amendment request.

(3) The application concerns the authorisation of a new use of the 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, to be classified in the additive category 'zootechnical additives', the authorisation of a new use of that preparation via water for drinking for chickens for fattening and the modification of the terms of the current authorisation for chickens for fattening to allow simultaneous use with the additional coccidiostats: decoquinate, narasin, nicarbazin or narasin/nicarbazin, and to remove the limit for the maximum content of that preparation in complete feedingstuff.

(4) The use of that preparation was authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 544/2013.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 9 December 2014[3] that, under the proposed conditions of use, the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 does not have an adverse effect on animal health, human health and the environment and has the potential to be efficacious when used in chickens reared for laying and minor poultry species other than laying. The Authority also concluded that delivery of the additive via water for drinking is as safe for chickens for fattening as delivery via feed and that there would be no safety implications if the current maximum dose for chickens for fattening were withdrawn. The conclusions on safety for chickens for fattening, as regards delivery via water for drinking and maximum dose, would also apply to chickens reared for laying and minor avian species. The Authority further concluded that the additive is compatible with the coccidiostats decoquinate, narasin, nicarbazin or narasin/nicarbazin. 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.

(6) The assessment of the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 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.

(7) In order to allow for the use of coccidiostats compatible with the preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 also for chickens for fattening and to allow for the same content of that preparation in complete feedingstuff for chickens for fattening as for chickens reared for laying and minor poultry species it is appropriate to amend Regulation (EU) No 544/2013.

(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*

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*

The Annex to Regulation (EU) No 544/2013 is amended as follows:

(1) In the eighth column, ‘Maximum content’, the text ‘$1 \times 10^9$’ is deleted.

(2) In the ninth column, ‘Other provisions’, paragraph 2 is replaced by the following:

2. The use is permitted in feed containing the authorised coccidiostats: maduramicin ammonium, diclazuril, robenidine hydrochloride, decoquinate, narasin, nicarbazin or narasin/nicarbazin.

*Article 3*

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, 8 July 2015.

*For the Commission*

*The President*

Jean-Claude JUNCKER

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1105. (See end of Document for details)*

ANNEX

PART A

| 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 | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | **CFU[a]/kg of complete feedingstuff with a moisture content of 12 %** | | **CFU[a] l of water for drinking** | | | |
| Category of zootechnical additives. Functional group: gut flora stabilisers. | | | | | | | | | | | |
| 4b1890 | Biomin GmbH | *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 and *Enterococcus faecium* DSM 21913 | *Additive composition* Preparation of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 containing a minimum of $5 \times 10^9$ CFU/g additive *Lactobacillus salivarius* ssp. *salivarius* DSM 16351 containing a minimum of $1 \times 10^9$ CFU/g additive *Enterococcus faecium* DSM 21913 containing a minimum of $5 \times 10^9$ CFU/g additive *Bifidobacterium animalis* ssp. *animalis* DSM 16284 containing a minimum of $1 \times 10^9$ CFU/g additive | Chickens reared for laying, other than laying poultry species | — | $1 \times 10^8$ | — | $5 \times 10^7$ | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. The use is permitted in feed containing the following coccidiostats: maduramicin ammonium, diclazuril, robenidine | 29 July 2025 |

**a** As total content of the mixture.

**b** 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

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2015/1105. (See end of Document for details)*

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | a minimum of $6 \times 10^9$ CFU/g additive Solid preparation (ratio 3:1:6) *Characterisation of the active substance* Viable cells of *Bifidobacterium animalis* ssp. *animalis* DSM 16284, *Lactobacillus salivarius* ssp. *salivarius* DSM 16351, and *Enterococcus faecium* DSM 21913 *Analytical method*[b] For the enumeration of: *Bifidobacterium animalis* ssp. *animalis* DSM 16284: spread plate method EN 15785 *Lactobacillus salivarius* | | | | | hydrochloride, decoquinate, narasin, nicarbazin or narasin/nicarbazin.<br>3. For safety: breathing protection, glasses and gloves shall be used during handling.<br>4. The additive may be used also via water for drinking.<br>5. For use of the additive in water for drinking the homogeneous dispersion of the additive shall be ensured.<br>6. The simultaneous |

**a** As total content of the mixture.

**b** 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