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

of XXX

**amending Implementing Regulation (EU) 2021/1411 as regards the terms of the
authorisation of a preparation of *Clostridium butyricum* FERM BP-2789 as a feed
additive for chickens for fattening, chickens reared for laying and minor poultry species
(excluding laying birds) (holder of authorisation: Miyarisan Pharmaceutical Co. Ltd
represented in the Union by Huvepharma NV Belgium)**

(Text with EEA relevance)

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amending Implementing Regulation (EU) 2021/1411 as regards the terms of the authorisation of a preparation of *Clostridium butyricum* FERM BP-2789 as a feed additive for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds) (holder of authorisation: Miyarisan Pharmaceutical Co. Ltd represented in the Union by Huvepharma NV Belgium)

(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 nutrition¹, and in particular Article 13(3) 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) A preparation of *Clostridium butyricum* FERM BP-2789 was authorised for a period of 10 years as a feed additive for use in feed for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets, weaned minor porcine species, chickens for fattening, suckling piglets and suckling minor porcine species by Commission Implementing Regulation (EU) 2021/1411².
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted on 30 April 2021 for the modification of the terms of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 as regards the use for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds). That application concerns the modification of the terms of the existing authorisation to reduce the minimum use level from 2.5×10^8 CFU/kg to 1.25×10^8 CFU/kg complete feed. The request was accompanied by the relevant supporting data.

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Implementing Regulation (EU) 2021/1411 of 27 August 2021 concerning the renewal of the authorisation of *Clostridium butyricum* FERM BP-2789 as a feed additive for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, its authorisation for chickens for fattening, suckling piglets and suckling minor porcine species, and repealing Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium) (OJ L 304, 30.8.2021, pp. 11; ELI: http://data.europa.eu/eli/reg_impl/2021/1411/oj).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 January 2023³ that the proposed modification in the terms of the authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 would not change the conclusions previously drawn regarding the safety of that additive for the target species, consumers and the environment. The Authority also concluded that the preparation of *Clostridium butyricum* FERM BP-2789 is not a skin or eye irritant and that sensitisation via respiratory route cannot be excluded. Furthermore, due to the lack of sufficient data, the Authority could not conclude on the efficacy of the additive at 1.25×10^8 CFU/kg complete feed for chickens for fattening, and, consequently, to extend or extrapolate the efficacy to other minor avian categories and species. After the assessment of newly submitted data by the applicant, the Authority concluded in its opinion of 10 March 2026⁴ that the additive has the potential to be efficacious as a zootechnical additive in chickens for fattening when added to feed at 1.25×10^8 CFU/kg complete feed. This conclusion was extended to chickens reared for laying and extrapolated to minor poultry for fattening and reared for laying. The Authority did not consider that there is a need for specific requirements for post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 8 December 2010⁵ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁶, an evaluation report of the Reference Laboratory was therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Clostridium butyricum* FERM BP-2789 still satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when the terms of the authorisation laid down in Implementing Regulation (EU) 2021/1411 are modified, as regards the use for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds), by reduction of the minimum use level from 2.5×10^8 CFU/kg to 1.25×10^8 CFU/kg complete feed.
- (7) Implementing Regulation (EU) 2021/1411 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Clostridium butyricum* FERM BP-2789 for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds), it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisation concerned.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

³ EFSA Journal 2023;21(2):7818. <https://doi.org/10.2903/j.efsa.2023.7818>.

⁴ EFSA Journal. 2026;24:e10034. <https://doi.org/10.2903/j.efsa.2026.10034>.

⁵ EFSA Journal 2011;9(1):1951. <https://doi.org/10.2903/j.efsa.2011.1951>.

⁶ 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>).

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) 2021/1411

The Annex to Implementing Regulation (EU) 2021/1411 is replaced by the Annex to this Regulation.

Article 2

Transitional measures

1. The feed additive *Clostridium butyricum* FERM BP-2789, as authorised by Implementing Regulation (EU) 2021/1411 and premixtures containing that additive, which are intended for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds), and which are produced and labelled before *[6 months from 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 stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additive referred to in paragraph 1, which are intended for chickens for fattening, chickens reared for laying and minor poultry species (excluding laying birds), and which are produced and labelled before *[12 months from 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 stocks concerned are exhausted.

Article 3

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