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

of **XXX**

concerning the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for poultry for laying (holder of authorisation: Evonik Operations GmbH), amending Implementing Regulation (EU) 2020/1395 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for chickens for fattening and reared for laying and amending Implementing Regulation (EU) 2021/2050 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction)

(Text with EEA relevance)

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

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concerning the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for poultry for laying (holder of authorisation: Evonik Operations GmbH), amending Implementing Regulation (EU) 2020/1395 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for chickens for fattening and reared for laying and amending Implementing Regulation (EU) 2021/2050 as regards the terms of the authorisation of a preparation of *Bacillus velezensis* CECT 5940 as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction)

(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 Articles 9(2) and 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 an authorisation.
- (2) A preparation of *Bacillus amyloliquefaciens* CECT 5940 was authorised for a period of 10 years as a feed additive for use in feed for chickens for fattening and reared for laying by Commission Implementing Regulation (EU) 2020/1395².
- (3) A preparation of *Bacillus velezensis* CECT 5940 was authorised for a period of 10 years as a feed additive for use in feed for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction) by Commission Implementing Regulation (EU) 2021/2050³.

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

² Commission Implementing Regulation (EU) 2020/1395 of 5 October 2020 concerning the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of the authorisation Evonik Operations GmbH) (OJ L 324, 6.10.2020, pp. 3, ELI: http://data.europa.eu/eli/reg_impl/2020/1395/2021-05-26).

³ Commission Implementing Regulation (EU) 2021/2050 of 24 November 2021 concerning the authorisation of the preparation of *Bacillus velezensis* CECT 5940 as a feed additive for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction) (holder of authorisation: Evonik Operations GmbH) (OJ L 420, 25.11.2021, pp. 16, ELI: http://data.europa.eu/eli/reg_impl/2021/2050/2021-11-25).

- (4) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Bacillus velezensis* CECT 5940. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The application concerns the authorisation of the preparation of *Bacillus velezensis* CECT 5940 as a feed additive for laying hens and other bird species kept for egg production purposes, requesting that additive to be classified in the additive category ‘zootechnical additives’ and in the functional group ‘gut flora stabilisers’.
- (6) At the same time, the applicant requested modification of the terms of the authorisations granted by Commission Implementing Regulation (EU) 2020/1395 and Commission Implementing Regulation (EU) 2021/2050 in accordance with Article 13(3) of Regulation (EC) No 1831/2003, in order to consolidate the authorisations of *Bacillus velezensis* (CECT 5940), including to update the taxonomic identification of the strain from *Bacillus amyloliquefaciens* CECT 5940 to *Bacillus velezensis* CECT 5940.
- (7) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 25 June 2025⁴ that, under the proposed conditions of use, the preparation of *Bacillus velezensis* CECT 5940 is considered safe for the target species, as well as for consumers and the environment. The Authority also concluded that the preparation of *Bacillus velezensis* CECT 5940 is not irritant to eyes but should be considered a skin and respiratory sensitiser and any exposure through skin and respiratory tract is considered a risk. The Authority further concluded that the preparation of *Bacillus velezensis* CECT 5940 has the potential to be efficacious in all laying hens and other bird for egg production when supplemented at 1.0×10^9 CFU/kg complete feed. Furthermore, the Authority confirmed the conclusions reached in its opinion of 5 May 2021⁵ that the active agent originally identified as *Bacillus amyloliquefaciens* was reclassified as *Bacillus velezensis*. The Authority did not consider that there is a need for specific requirements of post-market monitoring.
- (8) 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 16 July 2008⁶ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁷, an evaluation report of the Reference Laboratory was therefore not required.
- (9) Following a request from the Commission, the Authority, in its reply dated January 9, 2026, confirmed that the conclusion on user safety of its opinion of 25 June 2025

⁴ EFSA Journal. 2025;23:e9554, <https://doi.org/10.2903/j.efsa.2025.9554>.

⁵ EFSA Journal 2021;19(6):6620. <https://doi.org/10.2903/j.efsa.2021.6620>

⁶ EFSA Journal (2008) 773, 1-13, <https://doi.org/10.2903/j.efsa.2008.773>.

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>).

applies to the opinions of 28 January 2020⁸ and 5 May 2021⁹ and should be reflected in the relevant authorisations.

- (10) In view of the above, the Commission considers that the preparation of *Bacillus velezensis* CECT 5940 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for poultry for laying. 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.
- (11) The Commission also considers that the preparation of *Bacillus velezensis* CECT 5940 still satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms of the authorisation laid down in Implementing Regulation (EU) 2020/1395 as regards the use for chickens for fattening and reared for laying, by the modification of the taxonomic identification of the strain from *Bacillus amyloliquefaciens* CECT 5940 to *Bacillus velezensis* CECT 5940 and the protective measures for users.
- (12) The Commission further considers that the preparation of *Bacillus velezensis* CECT 5940 still satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms of the authorisation laid down in Implementing Regulation (EU) 2021/2050 as regards the use for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction), by the modification of the protective measures for users.
- (13) Implementing Regulations (EU) 2020/1395 and (EU) 2021/2050 should therefore be amended accordingly.
- (14) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bacillus amyloliquefaciens* CECT 5940 for chickens for fattening and reared for laying, and of the preparation of *Bacillus velezensis* CECT 5940 for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction), 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.
- (15) 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 **Authorisation**

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.

⁸ EFSA Journal 2020;18(2):6014, <https://doi.org/10.2903/j.efsa.2020.6014>.

⁹ EFSA Journal 2021;19(6):6620, <https://doi.org/10.2903/j.efsa.2021.6620>.

Article 2

Amendment to Implementing Regulation (EU) 2020/1395

Implementing Regulation (EU) 2020/1395 is amended as follows:

(1) the title is replaced by the following:

‘Commission Implementing Regulation (EU) 2020/1395 of 5 October 2020 concerning the renewal of the authorisation of *Bacillus velezensis* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of the authorisation Evonik Operations GmbH)’

(2) the Annex is amended as follows:

- (a) in the column ‘Additive’, the expression ‘*Bacillus amyloliquefaciens* CECT 5940’ is replaced by ‘*Bacillus velezensis* CECT 5940’;
- (b) in the column ‘Composition, chemical formula, description, analytical method’, and in the sections ‘Additive composition’ and ‘Characterisation of the active substance’ thereof, the expression ‘*Bacillus amyloliquefaciens* CECT 5940’ is replaced by ‘*Bacillus velezensis* CECT 5940’;
- (c) in the column ‘Other provisions’, provision 3 is replaced by ‘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 such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment’.

Article 3

Amendment to Implementing Regulation (EU) 2021/2050

The Annex to Implementing Regulation (EU) 2021/2050 is amended as follows:

- (a) in the column ‘Identification number of the additive’ the Identification number is replaced by ‘4b1822’;
- (b) in the column ‘Other provisions’, provision 3 is replaced by ‘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 such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment’.

Article 4

Transitional measures related to the amendment to Implementing Regulation (EU) 2020/1395

1. The feed additive *Bacillus amyloliquefaciens* CECT 5940, as authorised by Implementing Regulation (EU) 2020/1395 and premixtures containing that additive, which are intended for chickens for fattening and reared for laying, 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 and reared for laying, 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 5

Transitional measures related to the amendment to Implementing Regulation (EU) 2021/2050

1. The feed additive *Bacillus velezensis* CECT 5940, as authorised by Implementing Regulation (EU) 2021/2050 and premixtures containing that additive, which are intended for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction), 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 turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and reared for breeding and ornamental birds (except for reproduction), 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 6

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