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

of **XXX**

concerning the renewal of the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for laying hens and minor poultry species for laying, the authorisation of a preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for other birds kept for egg production or breeding (holder of authorisation: Kemin Europa N.V.) and repealing Implementing Regulation (EU) 2015/1020

(Text with EEA relevance)

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(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 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 *Bacillus velezensis* ATCC PTA-6737, previously taxonomically identified as *Bacillus subtilis* ATCC PTA-6737, was authorised for a period of 10 years as a feed additive for laying hens and minor poultry species for laying by Commission Implementing Regulation (EU) 2015/1020².
- (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 *Bacillus velezensis* ATCC PTA-6737 as a feed additive for laying hens and minor poultry species for laying, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. That application included a proposal for amending the conditions of the original authorisation, consisting in an increase of the minimum concentration of the active agent in the preparation from 1×10^{10} CFU/g additive to 8×10^{10} CFU/g additive. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the authorisation of a new use of the same preparation as a feed additive for other birds kept for egg production or breeding, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'gut flora stabilisers'. That application was accompanied by the particulars and

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

² Commission Implementing Regulation (EU) 2015/1020 of 29 June 2015 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying (holder of the authorisation Kemin Europa NV) (OJ L 163, 30.6.2015, pp. 22, ELI: http://data.europa.eu/eli/reg_impl/2015/1020/oj).

documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 May 2025³ that, under the current authorised conditions of use and considering the fact that the composition and manufacturing process of the additive has not been substantially modified, the preparation of *Bacillus velezensis* ATCC PTA-6737 remains safe for laying hens, minor poultry species for laying, as well as for the consumers and the environment. The requested modifications to the specifications of the additive do not introduce additional concerns. The Authority also concluded that the additive is safe for birds kept for egg production or breeding, and that the use of the additive in these new species/categories is safe for the consumers and the environment. It also concluded that the preparation is not irritant to skin and eyes but should be considered a skin and respiratory sensitiser, and inhalation and dermal exposure is considered a risk. The Authority considered that there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation as the application does not include a proposal for amending or supplementing the conditions of use that would have an impact on the efficacy of the additive for those species/categories for which there is an authorisation. It also considered that the conclusions reached for those species can be extended to other species and therefore concluded that the additive has the potential to be efficacious in other birds kept for egg production or breeding at the minimum inclusion level of 1×10^8 CFU/kg complete feed. The Authority did not consider that there is a need for specific requirements for a post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of *Bacillus velezensis* ATCC PTA-6737 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), points (a), (b) and (c), of Commission Regulation (EC) No 378/2005⁴, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers that the preparation of *Bacillus velezensis* ATCC PTA-6737 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for laying hens and minor poultry species for laying. Furthermore, the use of the additive should be authorised for other birds kept for egg production or breeding. 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. Those protective measures should be without prejudice to other workers' safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 as a feed additive for laying hens and minor poultry species for laying, Implementing Regulation (EU) 2015/1020 should be repealed.

³ EFSA Journal. 2025;23:e9457. <https://doi.org/10.2903/j.efsa.2025.9457>.

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

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of *Bacillus velezensis* ATCC PTA-6737 for laying hens and minor poultry species for laying, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal or the modification of that 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 Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed for laying hens and minor poultry species for laying, subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in 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 other birds kept for egg production or breeding, subject to the conditions laid down in that Annex.

Article 3

Repeal

Implementing Regulation (EU) 2015/1020 is repealed.

Article 4

Transitional measures

1. The feed additive *Bacillus velezensis* ATCC PTA-6737, as authorised by Implementing Regulation (EU) 2015/1020, and premixtures containing that additive, which are intended for laying hens and minor poultry species 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 laying hens and minor poultry species 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
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