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

of **XXX**

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, the extension of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all porcine species (holder of authorisation: Puratos NV), and repealing Implementing Regulations (EU) 2017/211, (EU) 2020/1377, (EU) 2021/1413 and (EU) 2026/356

(Text with EEA relevance)

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concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, the extension of the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all porcine species (holder of authorisation: Puratos NV), and repealing Implementing Regulations (EU) 2017/211, (EU) 2020/1377, (EU) 2021/1413 and (EU) 2026/356

(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 endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 was authorised for a period of 10 years as a feed additive for poultry, weaned piglets and pigs for fattening by Commission Implementing Regulation (EU) 2017/211², for suckling piglets, all minor porcine species other than reproductive animals by Commission Implementing Regulation (EU) 2020/1377³, for lactating sows by Commission Implementing Regulation (EU) 2021/1413⁴ and for gestating sows by Commission Implementing Regulation (EU) 2026/356⁵.

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

² Commission Implementing Regulation (EU) 2017/211 of 7 February 2017 concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Bacillus subtilis* (LMG-S 15136) as a feed additive for poultry, weaned piglets and pigs for fattening, and amending Regulations (EC) No 1259/2004, (EC) No 1206/2005, and (EC) No 322/2009 and repealing Regulation (EC) No 516/2007 (holder of authorisation Beldem, a division of Puratos NV) (OJ L 33, 8.2.2017, pp. 23). ELI: http://data.europa.eu/eli/reg_impl/2017/211/oj.

³ Commission Implementing Regulation (EU) 2020/1377 of 1 October 2020 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) as a feed additive for suckling piglets, all minor porcine species other than reproductive animals (holder of authorisation Beldem, a division of Puratos NV) (OJ L 319, 2.10.2020, pp. 29). ELI: http://data.europa.eu/eli/reg_impl/2020/1377/oj.

⁴ Commission Implementing Regulation (EU) 2021/1413 of 27 August 2021 concerning the authorisation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* LMG-S 15136 as a feed additive for lactating

- (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 endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. In accordance with Article 7 of Regulation (EC) No 1831/2003, that application also concerned the extension of the authorisation as a new use of the same preparation as a feed additive to all porcine species, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. That application was accompanied by the particulars and 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 27 January 2026⁶ that, under the current authorised conditions of use and considering the fact that the manufacturing and composition of the additive have not been modified, the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 remains safe for the target species, consumers and the environment. In addition, the Authority concluded that, regarding the extension of use to all porcine species, the additive is safe for the target species, consumers, and the environment. It further concluded that the two formulations of the preparation are considered skin and eye irritants, and respiratory sensitisers. Any exposure is considered a risk. The Authority stated that the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, it concluded that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. It also considered that the conclusions reached in the original authorisation can be extended to other species and therefore concluded that the additive, in both forms, has the potential to be efficacious in all porcine species/categories at the minimum use level of 10 IU endo-1,4-beta-xylanase/kg complete feed. The Authority did not consider that there is a need for specific requirements of 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 13 July 2016⁷ are valid and applicable for the current application. In accordance with Article 5(4), points (a) and (c), of Commission Regulation (EC) No 378/2005⁸, an evaluation report of the Reference Laboratory is therefore not required.

sows (holder of the authorisation Beldem, division of Puratos NV) (OJ L 304, 30.8.2021, pp. 18). ELI: http://data.europa.eu/eli/reg_impl/2021/1413/oj.

⁵ Commission Implementing Regulation (EU) 2026/356 of 18 February 2026 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for gestating sows (holder of authorisation: Puratos NV) (OJ L, 2026/356, 19.2.2026). ELI: http://data.europa.eu/eli/reg_impl/2026/356/oj.

⁶ EFSA Journal. 2026;24:e9925. <https://doi.org/10.2903/j.efsa.2026.9925>.

⁷ EFSA Journal 2016;14(9):4562. <https://doi.org/10.2903/j.efsa.2016.4562>.

⁸ 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

- (6) In view of the above, the Commission considers that the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals. Furthermore, the extension of use of that preparation should be authorised for all porcine species. 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 endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, Implementing Regulations (EU) 2017/211, (EU) 2020/1377, (EU) 2021/1413 and (EU) 2026/356 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 endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the 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 the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, 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 'digestibility enhancers', is authorised as an additive in animal nutrition for all porcine species, subject to the conditions laid down in that Annex.

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>.

Article 3

Repeal

Implementing Regulations (EU) 2017/211, (EU) 2020/1377, (EU) 2021/1413 and (EU) 2026/356 are repealed.

Article 4

Transitional measures

1. The feed additive of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136, as authorised by Implementing Regulations (EU) 2017/211, (EU) 2020/1377, (EU) 2021/1413 and (EU) 2026/356, and premixtures containing that additive, which are intended for all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals 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 all poultry species, suckling and weaned piglets, pigs for fattening, lactating sows, gestating sows and all minor porcine species other than reproductive animals, 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