Official Journal
of the European Union

EN
L series

2026/356

19.2.2026

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)

(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) 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 such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 as a feed additive for gestating sows, requesting that additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 June 2025 ([2]) that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 is safe for gestating sows, as well as for consumers and the environment. The Authority also concluded that the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 in both formulations, solid and liquid, is considered a skin and eye irritant and respiratory sensitiser, and any exposure to this preparation is considered a risk. The Authority further concluded that the preparation of endo-1,4-beta-xylanase produced with *Bacillus subtilis* LMG S-15136 has the potential to be efficacious as a zootechnical additive in sows during the gestation period at 10 IU/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 2016 ([3]) are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ([4]), an evaluation report of the Reference Laboratory was therefore not required.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) *EFSA Journal* 2025;23:e9552, https://doi.org/10.2903/j.efsa.2025.9552.
([3]) *EFSA Journal* 2016;14(9):4562, https://doi.org/10.2903/j.efsa.2016.4562.
([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).

(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 use of that preparation should be authorised for gestating sows. 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.

(7) 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 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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, 18 February 2026.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the additive	Name of the holder of authorisation	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers.									
4a1606i	Puratos NV	Endo-1,4-beta-xylanase (EC 3.2.1.8)	*Additive composition* Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced with *Bacillus subtilis* LMG S-15136 having a minimum activity of: 400 IU ([1])/g. Solid form and liquid form *Characterisation of the active substance* Endo-1,4-beta-xylanase (EC 3.2.1.8) produced with *Bacillus subtilis* LMG S-15136 *Analytical method* ([2]) For the quantification of xylanase activity in the feed additive: — colorimetric method measuring reducing sugars released by action of xylanase on birchwood xylan substrate in the presence of 3,5-dinitrosalicylic acid (DNS).	Gestating sows	—	10 IU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. 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, skin and eye protective equipment.	11 March 2036

Identification number of the additive	Name of the holder of authorisation	Name of the additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feed with a moisture content of 12 %			
			For the quantification of xylanase activity in premixtures, compound feed: — colorimetric method measuring water soluble dye released by action of xylanase from azurine cross-linked wheat arabinoxylan substrates.						

([1]) 1 IU is defined as the amount of enzyme which liberates one micromole of reducing sugars (xylose equivalents) from birchwood xylan per minute at pH 4,5 and 30 °C.
([2]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

ELI: http://data.europa.eu/eli/reg_impl/2026/356/oj