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► **B** COMMISSION IMPLEMENTING REGULATION (EU) No 1206/2012
of 14 December 2012

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) as a feed additive for poultry for fattening, weaned piglets and pigs for fattening and amending Regulations (EC) No 1332/2004 and (EC) No 2036/2005 (holder of the authorisation DSM Nutritional Products)

(Text with EEA relevance)

(OJ L 347, 15.12.2012, p. 12)

Amended by:

| | | Official Journal | | |
|--------------------|---|------------------|------|-----------|
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| ► <u>M1</u> | Commission Implementing Regulation (EU) 2017/1006 of 15 June 2017 | L 153 | 9 | 16.6.2017 |



**COMMISSION IMPLEMENTING REGULATION (EU)
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concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Aspergillus oryzae* (DSM 10287) as a feed additive for poultry for fattening, weaned piglets and pigs for fattening and amending Regulations (EC) No 1332/2004 and (EC) No 2036/2005 (holder of the authorisation DSM Nutritional Products)

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Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zotechnical 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

Amendments to Regulation (EC) No 1332/2004

Regulation (EC) No 1332/2004 is amended as follows:

(1) Article 1 is replaced by the following:

‘Article 1

The preparation belonging to the group “Enzymes”, as set out in Annex II, is authorised for use without a time limit as additive in animal nutrition under the conditions laid down in that Annex.’;

(2) Annex I is deleted.

Article 3

Amendment to Regulation (EC) No 2036/2005

In Annex III to Regulation (EC) No 2036/2005, the entry for No 5, Endo-1,4-beta-xylanase EC 3.2.1.8, is deleted.

Article 4

Transitional measures

The preparation specified in the Annex and feed containing that preparation, which are produced and labelled before 4 July 2013 in accordance with the rules applicable before 4 January 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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.

ANNEX

| Identification number of the additive | Name of the holder of authorisation | 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 feedingstuff with a moisture content of 12 % | | | |
| Category of zootechnical additives. Functional group: digestibility enhancers | | | | | | | | | |
| 4a1607i | DSM Nutritional Products Ltd | Endo-1,4-beta-xylanase EC 3.2.1.8 | <p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372) having a minimum activity of:</p> <p>Solid form: 1 000 FXU ⁽¹⁾ /g</p> <p>Liquid form: 650 FXU/ml</p> <p><i>Characterisation of the active substance</i></p> <p>endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372)</p> <p><i>Analytical method</i> ⁽²⁾</p> <p>For quantification of endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM 26372) in a feed additive:</p> <p>— colorimetric method measuring coloured compound produced by the dinitro salicylic acid (DNSA) and the xylosylic moieties released by the action of xylanase on arabinoxylan.</p> | Poultry for fattening Weaned piglets Pigs for fattening | — | 100FXU 200FXU 200FXU | — | <p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. Recommended maximum dose per kilogram of complete feedingstuff for:</p> <p>— poultry for fattening: 200 FXU;</p> <p>— piglets (weaned): 400 FXU;</p> <p>— pigs for fattening: 400 FXU.</p> <p>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection and skin protection.</p> <p>4. For use in weaned piglets up to approximately 35 kg.</p> | 4 January 2023 |

▼ **M1**

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|---------------------------------------|-------------------------------------|----------|--|-------------------------------|-------------|---|-----------------|------------------|--------------------------------|
| | | | | | | Units of activity/kg of complete feedingstuff with a moisture content of 12 % | | | |
| | | | For quantification of endo-1,4-beta-xylanase produced by <i>Aspergillus oryzae</i> (DSM26372) in premixtures and feedingstuffs: — colorimetric method measuring water soluble dye released by action of xylanase from dye-labelled oat spelt azo-xylan. | | | | | | |

⁽¹⁾ 1 FXU is the amount of enzyme which liberates 7,8 micromole of reducing sugars (xylose equivalents) from azo-wheat arabinoxylan per minute at pH 6,0 and 50 °C.

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.