

SCHEDULE 1

Regulation 3

Renewal of authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 143953, formerly ATCC PTA 5588) (identification number 4a11) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks, minor poultry species, weaned piglets and piglets for fattening, and its authorisation extending to the use for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species

The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8), belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, in accordance with the specifications in the following table(1).

<i>Additive</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8)	
<i>Identification number</i>	4a11	
<i>Authorisation holder</i>	Danisco (UK) Ltd	
<i>Additive category</i>	Zootechnical additives	
<i>Functional group</i>	Digestibility enhancers	
<i>Additive composition</i>	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 143953) with a minimum enzyme activity of 40,000 U/g ⁽¹⁾	
<i>Characterisation of the active substance(s)</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 143953) <ul style="list-style-type: none"> • CAS no: 9025-57-4⁽²⁾ • EC (IUBMB) no: 3.2.1.8⁽³⁾ • EINECS no: 232-800-2⁽⁴⁾ 	
<i>Analytical method</i> ⁽⁵⁾⁽⁶⁾	For quantification of endo-1,4-beta-xylanase enzyme activity in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabino xylan substrate 	
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • All poultry species • Piglets (suckling and weaned), • Pigs for fattening • Minor porcine species 	
<i>Maximum age</i>	Not applicable	
<i>Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed)</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • For all poultry species: 625 U/kg • For piglets (suckling and weaned), pigs for fattening and minor porcine species: 2,000 U/kg
	<i>Maximum content</i>	No maximum

(1) This authorisation is a renewal of the authorisations granted under [Commission Regulation \(EU\) No 9/2010](#), Commission Implementing [Regulation \(EU\) No528/2011](#) and Commission Implementing [Regulation \(EU\) No1021/2012](#). Those Regulations are revoked by regulation 7(1) of, and Schedule 14 to these Regulations. This renewal differs from the previous authorisation by updating the bacterial strain from "ATCC PTA 5588" to "CBS 143953". Additionally, the minimum content of the feed additive for turkeys for fattening is reduced from 1,250 to 625 units of activity per kilogram of complete feed (U/kg), to provide that the minimum content is 625 U/kg for all poultry species.

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<i>with a moisture content of 12%</i>		
<i>Other provisions</i>		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

- (1) 1 unit (U) is the amount of enzyme which releases 0.48 micromoles (μmol) of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4.2 and 50°C.
- (2) This is a reference to the CAS Registry Number[®] assigned to this preparation by the Chemical Abstracts Service <https://cas.org/cas-data/cas-registry>.
- (3) This is the identification number adopted by the European Commission which aligns with the numerical system of the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.
- (4) The EINECS number is given in the European Inventory of Existing Commercial Substances, as published in O.J. No. C146A, 15.6.90, p.1.
- (5) Details of the analytical method is set out in the document referenced “JRC.D.5/FSQ/CvH/DM/ag/ARES(2012)353089” and last updated on 6th June 2016, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2011-0030_en.
- (6) The enzyme activity for endo-1,4-beta-xylanase is defined in the document referenced “JRC.DG.D.6/CvH/DM/hn/ARES(2010)-375745” and last on updated 6th June 2016, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en.