Annex A: RP215 - Endo-1,4-beta-xylanase produced by Trichoderma reesei

RP215 - Endo-1,4-beta-xylanase produced by Trichoderma reesei as a feed additive for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species.

Annex A: RP215 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 143953, previously deposited as ATCC 5588) as a feed additive for all poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species (Danisco Xylanase 40000 G/L) (Danisco (UK) Limited) (renewal, modification and new use)

Background

Name of applicant:

Danisco (UK) Ltd (trading as Danisco Animal Nutrition)

Address of applicant:

PO Box 777
Marlborough
Wiltshire
SN8 1XN
United Kingdom

FSA/ FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP215 for the renewal, modification and extension of use of endo-1,4-beta-xylanase (EC 3.2.1.8) (Xylanase 40000 G/L) produced by *Trichoderma reesei* (CBS 143953), previously deposited as ATCC 5588) as a feed additive for poultry and pigs, from Danisco Animal Nutrition.

FSA/FSS has reviewed the EFSA opinion (EFSA Journal 2021;0(0):6539) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA/FSS. Please see the earlier section titled ‘Our safety assessment process’ to understand how and when we make use of EFSA opinions.

The FSA/FSS opinion is that endo-1,4-beta-xylanase (EC 3.2.1.8) (Xylanase 40000 G/L), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health at the intended concentrations of use. The proposed terms of authorisation are set out below.

Any relevant provisions of Retained EU Law

Under the requirements of Retained EU Regulation 1831/2003 (‘the Regulation’) for feed additives:

1. Article 16 and points 1(a) and 1(b) of Annex III: Labelling and packaging requirements apply, if authorised.
2. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (CBS 143953) in animal feed as detailed in the EURL analytical method evaluation report (FAD-2010-0007). Valid analytical methods exist for: the quantification of endo-1,4-beta-xylanase activity in the feed additive, premixtures, feed materials and compound feed.
3. Annex IV: The general conditions of use must be complied with, where applicable for the individual feed additive authorisation.

Proposed terms of authorisation

1: Additive details

Additive category	(4) Zootechnical additives
Functional group	(a) Digestibility enhancers
Feed additive	Endo-1,4-beta-xylanase (EC 3.2.1.8)
ID No	4a11
Target species	All poultry species, piglets (suckling and weaned), pigs for fattening and minor porcine species.
Authorisation Holder	Danisco (UK) Limited
Authorisation period	10 years from the date of authorisation

2: Additive composition

Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 143953) with a minimum activity of 40 000 U/g

3: Characterisation / identification of the active substance(s)

Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 143953)

- EC (IUBMB) no: 3.2.1.8
- CAS no: 9025-57-4
- EINECS no: 232-800-2

4: Conditions of use

Species or category of animal	Maximum age	Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%)
All poultry species	n/a	Minimum level: 625 U Maximum level: No maximum?
Piglets (suckling and weaned), pigs for fattening and minor porcine species	n/a	Minimum level: 2 000 U Maximum level: No maximum?

5: Other Provisions

1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.

6: Analytical methods

For quantification of endo-1,4-beta-xylanase activity in the feed additive, premixtures, feed materials and compound feed:
Colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrate.

One Unit is the amount of enzyme which releases 0.48 micromoles (?mol) of reducing sugar (xylose equivalent) per minute from wheat arabinoxylan at pH 4,.2 and 50°C.

Other relevant information (separate to terms of authorisation)

1: Supplementary information

- feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as an: eye irritant, respiratory sensitiser.
- major animal species and their subgroups are defined in Annex IV of Retained EU Regulation 429/2008.
- the FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in Retained EU Regulation 183/2005 ‘Feed Hygiene Regulation’ and Good Manufacturing Practice.

2: Recommendations

For use in feed rich in starch and non-starch polysaccharides (mainly beta- arabinoxylans).