

Annex I: RP954 - Endo-1,4-beta-xylanase produced by *Trichoderma reesei* as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding

Annex I: RP954 - Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (Econase® XT) (Roal Oy) (renewal)

Background

Name of applicant:

Roal Oy

Address of applicant:

Tykkimäentie 15b
05200
Rajamäki
Finland

FSA/FSS Safety Assessment

FSA/FSS has undertaken a safety assessment of application RP954 for the renewal of use of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding, from Roal Oy.

FSA/FSS has reviewed the EFSA opinions ([EFSA Journal 2021;19\(2\):6458](#) and [EFSA Journal 2019;17\(11\):5880](#)) and confirms that it is adequate for UK considerations and, therefore, a full safety assessment of this application was not performed. 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) (Econase® XT), as described in this application, is safe and is not liable to have an adverse effect on the target species, worker safety, 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 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 produced by *Trichoderma reesei* (CBS 114044) (Econase® XT) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2018-0071](#)). Valid analytical methods exist for:
 - the quantification of endo-1,4-beta-xylanase 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	4a8
Target species	Piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding
Authorisation Holder	Roal Oy
Authorisation	10 years from the date of authorisation period

2: Additive composition

Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with *Trichoderma reesei* (CBS 114044) having a minimum activity of 1.6 x 10⁵ BXU/g for both solid and liquid forms:

Form	Activity (BXU = endo-1,4-beta-xylanase units)*
Solid (P) forms	800 000 BXU/g (new formulation)
	160 000 BXU/g (new formulation)
	4 000 000 BXU/g
Liquid (L) forms	160 000 BXU/g (new formulation)
	400 000 BXU/g

*[Enzyme activity expressed in birchwood xylanase units (BXU), where one BXU is the amount of enzyme which liberates 1 nanomole of reducing sugars as xylose from birch xylan per second at pH 5.3, and 50°C.

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

Endo-1,4-beta-xylanase produced by fermentation of *Trichoderma reesei* (CBS 114044)

- EC (IUBMB) number: 3.2.1.8
- EINECS number: 232-800-2

- CAS number: 9025-57-4

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%)
Chickens for fattening, chickens reared for laying	n/a	Minimum level: 8,000 BXU Maximum level: No Maximum
Turkeys for fattening, turkeys reared for breeding	n/a	Minimum level: 16,000 BXU Maximum level: No Maximum
Piglets (weaned)	n/a	Minimum level: 24,000 BXU Maximum level: No Maximum

5: Other Provisions

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

6: Analytical methods

For the quantification of endo-1,4-beta-xylanase in the feed additive and premixtures:
Colorimetric method based the enzymatic reaction of endo-1,4-beta-xylanase on the birch xylan substrate at pH 5.3 and 50°C.

For the quantification of endo-1,4-beta-xylanase in feed materials and compound feed:
Colorimetric method based the enzymatic reaction of endo-1,4-beta-xylanase on the azurine cross-linked wheat arabinoxylan substrate at pH 5.3 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 a: respiratory sensitiser.
- for use in feed for piglets (weaned) up to 35 kg body weight.
- 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 compound feed rich in non-starch polysaccharides, mainly arabinoxylans (e.g., containing more than 20% wheat).