

Annex J: RP955 - 6-phytase produced by *Trichoderma reesei* as a feed additive for all pigs and poultry

Annex J: RP955 - 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for all pigs and poultry (Finase® EC) (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 RP955 for the renewal of use of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) (Finase® EC) as a feed additive for pigs and poultry, from Roal Oy.

FSA/FSS has reviewed the EFSA opinion ([EFSA Journal 2020;18\(12\):6336](#)) and confirm that it is adequate for UK considerations and therefore a full safety assessment of this application was not performed by FSA and FSS. Please see the earlier section titled 'Our safety assessment process' to understand how and when we make use of EFSA opinions.

It is the FSA/FSS opinion that 6-phytase (EC 3.1.3.26) (Finase® EC), 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(c) 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 6-phytase produced by *Trichoderma reesei* (CBS 122001) in animal feed as detailed in the EURL analytical method evaluation report ([FAD-2008-0040](#)). Valid analytical methods exist for:

- the quantification of 6-phytase 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	6-phytase (EC 3.1.3.26)
ID No	4a12
Target species	All pigs and poultry
Authorisation Holder	Roal Oy
Authorisation period	10 years from the date of authorisation

2: Additive composition

Preparation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) having a minimum activity of 4×10^4 PPU/g for the solid form and 5×10^3 PPU/g for the liquid forms:

Form	Activity (PPU = phytase units)*
Solid form	40 000 PPU/g
Liquid forms	5 000 PPU/g (new formulation) 10 000 PPU/g

* Enzyme activity is expressed in PPU units, where one PPU is the amount of enzyme which liberates 1 micromole (μmol) of inorganic phosphate from sodium phytate per minute at pH 5.0 and 37°C]

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

6-phytase (EC 3.1.3.26) produced by fermentation with *Trichoderma reesei* (CBS 122001)

- EC (IUBMB) no: 3.1.3.26

- CAS no: 9001-89-2
- EINECS no: 232-630-9

4: Conditions of use

Species or category of animal?	Maximum age?	Content of 6-phytase?(units of activity/kg of complete feed with a moisture content of 12%)?
Pigs Poultry for fattening, poultry for breeding.	n/a	Minimum level: 250 PPU Maximum level: No maximum
Poultry for laying	n/a	Minimum level: 125 PPU 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 phytase activity in the feed additive, premixtures, feed materials and compound feed:??

Colorimetric method quantifying the activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex.

7: Transition period arrangements

As regards the feed additive composition, minor improvements were made during manufacturing which do not affect safety, however it is our view that it is appropriate to provide transitional periods to meet new requirements (i.e., on labelling).

A proposal for transitional arrangements is set out below for the existing feed additive authorisation for pigs and poultry (where all pig and poultry sub-groups are defined as food-producing animals).

Proposal: Feed containing this additive may continue to be placed on the market and used under the conditions of its prior authorisation until existing stocks are exhausted where:

- the feed additive or premixture containing the feed additive to be produced and labelled within **six months** from the date of this authorisation?
- **feed materials and compound feed** containing this feed additive to be produced and labelled within **twelve months** from the date of this authorisation for **food-producing animals**

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.
- 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

- The maximum recommended level of 6-phytase in all species/ categories is 1,000 PPU/kg complete feed.
- For use in feed containing more than 0.23% phytin-bound phosphorus.? ?