RP955 Assessment of the application for renewal of Finase EC produced by Trichoderma reesei CBS 122001 as a feed additive

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Authors: Risk Assessment Unit Science, Evidence and Research Division, FSA
Conducted by: Risk Assessment Team Science Division, FSS

1.Executive summary

The FSA/ FSS have undertaken a safety assessment of application RP 955 for the renewal of use of Finase EC produced by *Trichoderma reesei* CBS 122001 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. In line with the principles for making use of EFSA opinions in their decision making on regulated products, the FSA/FSS opinion is that the conclusions of the EFSA opinion are valid for the UK and therefore 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.

2.Background and purpose of review

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Question number: EFSA-Q-2019-00333

In accordance with Retained EU Regulation 1831/2003 on feed additives, the application RP 955 for the renewal and extension of use of Finase EC produced by *Trichoderma reesei* (CBS 122001) as a feed additive for for pigs and poultry, from Roal Oy has been submitted for authorisation in each nation of Great Britain (GB).

Whilst it was a Member State of the EU, the UK accepted the assessments of EFSA in support of authorisations for regulated food and feed products. Since the end of the transition period, FSA/ FSS has adopted equivalent technical guidance and quality assurance processes to make independent GB safety assessments.

A number of applications have been received by GB where EFSA, prior to the end of the transition period, evaluated an application for the product. FSA/FSS has decided to make use of

the EFSA risk assessment, where this is appropriate, in forming its own independent opinion. Therefore, FSA/FSS safety assessors have reviewed the EFSA opinions for the application below in the context of intended GB use and have concluded that the intended uses are safe.

In reviewing the output of the EFSA risk assessment the reviewers have verified that the standard approach as outlined in the relevant guidance has been followed and the arguments made are consistent with the data summarised. Consideration has been given to the processes undertaken to ensure the outcome is robust and whether there are and aspects that would require further review such as specific issues for the countries of the UK. The result of the assessment is that the EFSA scientific opinion is adequate also for UK considerations. Therefore, a full safety assessment has not been performed by FSA/ FSS.

3.Details of the EFSA assessment

Methodology applied in the EFSA opinion

EFSA FEEDAP guidance: Guidance on the renewal of the authorisation of feed additives **(2013)**, Guidance on the characterisation of microorganisms used as feed additives or as production organisms **(2018)**, and principles in Regulation (EC) No 429/2008 (not explicitly stated whether applicable SC guidance applied).

3.1 Source/organism

The additive contains 6-phytase which is produced by a genetically modified strain of *T.reesei* (CBS 122001). The trade name is Finase EC and is available in two forms, a solid (P) and a liquid form (L).

The applicant describes 3 formulations of varying enzyme activity in both solid and liquid formulations, two of which were previously authorised, one each of a solid (40,000 PPU/g) and liquid (10,000 PPU/g) formulation. These two formulations were fully characterised and described in previous opinions **(EFSA, 2009, 2010 and 2011)**. The third new formulation is in a liquid form at lower activity (5,000 PPU/g).

Finase®EC is currently authorised for use in pigs and poultry for fattening and breeding at a minimum recommended dose of 250 PPU/kg complete feed and for use in poultry for laying at a minimum recommended dose of 125 PPU/kg of complete feed. The maximum recommended level for all species/categories is 1,000 PPU/kg complete feed. Authorisation is for feed containing more than 0.23% phytin-bound phosphorus.

3.2 Genetic modification step

The assessment of the genetic modification of the production strain was performed in a previous evaluation **(EFSA, 2009)**, and has not been modified.

3.3 Specification

Information provided on the identity, composition and specifications of the bacteria does not raise safety concerns.
Characterisation, homogeneity and stability were evaluated in a previous EFSA opinion **(EFSA, 2009)**.

3.4 Exposure assessment

Not relevant

3.5 Toxicological data

This application is for the renewal of use of Finase EC as a feed additive for pigs and poultry for fattening and breeding. Previous EFSA evaluations exist for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows **(EFSA 2009, 2010 and 2011)**.

Literature searches from Agris, PubMed, Scifinder and Web of Science were undertaken for this application to prove there has been no further data since the past opinions that could render the additive unsafe for the target species, consumers, workers or the environment.

4. EFSA assessment and conclusions

Finase EC raises no concerns for the consumer of the products obtained from animals fed the additive.

The additive, in either form, is not a skin irritant or eye-irritant. Due to the proteinaceous nature of the active substance it should be considered a respiratory sensitiser in both forms.

No risks to the environment are expected and no further environmental risk assessment is required. The application does not raise safety concerns for the environment with regard to the genetic modification of the production strain *T.reesei*.

No new data has been provided which would lead the Panel to revise the previous conclusions. Therefore, the FEEDAP Panel concludes that Finase EC has the potential to be efficacious as a zootechnical additive in the species presented at inclusion rates up to 1,000 PPU/kg complete feed. The new formulation was considered equivalent to the previously authorised formulations.

Viable cells of the production strain and its DNA were not detected in a sample representative of both final formulations.

5. Caveats and uncertainties

FSA/FSS accepts the EFSA conclusion on data protection since FSA/FSS could not have assessed the product without all proprietary data and detailed information on production process, composition, and specification.

6. FSA Conclusion on reliability and applicability

The application has been assessed in line with the applicable guidance (although it should be noted the FEEDAP guidance differs in approach to all other EFSA guidance on toxicological testing and does not provide the best 3Rs approach) and is partially based on considerations of detailed proprietary information available to the Panel, whilst this is only briefly summarised this description is consistent with the conclusions. The conclusions for this renewal and extensions of use are based on previous opinions in 2008 and 2009 on both the feed additive and the genetic modification and its subsequent authorisation. The basis for these previously accepted conclusions has not been re-examined. The conclusions are appropriate and consistent within the identified caveats and uncertainties and would be applicable to the UK.

7. Outcome of assessment

FSA/FSS has reviewed the EFSA opinion and consider it adequate also for UK considerations. Therefore, a full safety assessment of this application was not performed by the FSA and FSS.

FSA/FSS has had access to all supporting documentation as provided to EFSA for forming the EFSA opinion. FSA/FSS agree with the safety conclusions outlined in the opinion.

Following the principles outlined in the background for making use of the EFSA opinion, the FSA/FSS opinion is that 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.

8. References

Finase® EC (6-phytase) as a feed additive for chickens for fattening and reared for laying, laying hens, turkeys for fattening and reared for breeding, ducks and other minor poultry species, piglets (weaned), pigs for fattening and sows. EFSA Journal 2009;7(11):1380, 27 pp. doi.org/10.2903/j.efsa.2009.1380 https://www.efsa.europa.eu/en/efsajournal/pub/1380

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2010. Scientific Opinion on the safety of Finase® EC (6-phytase) as a feed additive for turkeys for fattening. EFSA Journal 2010;8(3):1553, 4 pp. https://doi.org/10.2903/j.efsa.2010.1553

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Scientific Opinion on the safety of Finase®EC (6-phytase) as feed additive for sows. EFSA Journal 2011;9(3):2111, 5 pp. https://doi.org/10.2903/j.efsa.2011.2111

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. https://doi.org/10.2903/j.efsa.2013.3431

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018a. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206