RP954 Assessment of the application for renewal of ECONASE XT produced by Trichoderma reesei CBS 114044 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
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1.Executive summary

The FSA/ FSS have undertaken a safety assessment of application RP 954 for the renewal of use of ECONASE XT 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, from Roal Oy.

FSA/FSS has reviewed the EFSA opinions (**EFSA Journal 2021**;19(2):6458 and **EFSA Journal 2019**;17(11):5880) 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 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.

2.Background and purpose of review

EFSA Journal 2021; 19(2):6458, **EFSA Journal 2019**;17(11):5880;

Question number: EFSA-Q-2018-00824

In accordance with Retained EU Regulation 1831/2003 on feed additives, the application RP 954 for the renewal and extension of use of ECONASE XT 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, 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 endo-1,4-beta-xylanase which is produced by a genetically modified strain of *T.reesei* (CBS 114044). The trade name is ECONASE XT and is available in two forms, a solid (P) and a liquid form (L).

ECONASE XT is currently authorised for use in weaned piglets at a minimum recommended dose of 24,000 BXU/kg complete feed and for use in chickens and turkeys for fattening and rearing (for laying / breeding) at a minimum recommended dose of 8,000 and 16,000 BXU/kg of complete feed respectively. The additive is authorised for use in compound feed containing large amounts of non-starch polysaccharides, for example containing more than 20% wheat.

3.2 Genetic modification step

The assessment of the genetic modification of the production strain was performed in a previous evaluation **(EFSA, 2008 and 2009)**, and has not been modified.

The second EFSA opinion (2021) relating to this application considered data to support absence of recombinant DNA derived from the production organism.

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 previous EFSA opinions, however the applicant did provide recent batch to batch variation data for five formulations in the current application.

3.4 Exposure assessment

Not relevant

3.5 Toxicological data

This application is for the renewal of use of ECONASE XT as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding. Previous EFSA evaluations exist for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned) **(EFSA, 2008 and 2009)**.

A literature search from Agris, PubMed and Web of Science was 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

ECONASE XT 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 and the liquid form is not an 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 ECONASE® XT has the potential to be efficacious as a zootechnical additive in the species presented at inclusion rates as a minimum of between 8,000 and 24,000 BXU/kg of complete feed (species dependant). The three new formulations were considered equivalent to the previously authorised formulations provided they deliver the same enzyme activity.

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 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.

8. References

EFSA (European Food Safety Authority), 2008. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and of the Panel on Genetically Modified Organisms (GMO) on the safety and efficacy of Econase XT P/L as feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned). EFSA Journal 2008;6(6):712, 19 pp. https://doi.org/10.2903/j.efsa.2008.712

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission related to the enzyme preparation of trade name ‘Econase XT P/L
(endo-1,4 b-xylanase) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned). EFSA Journal 2009;7(4):1058, 6 pp. https://doi.org/10.2903/j.efsa.2009.1058

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