RP215 Assessment of the application for renewal and extension of use of Xylanase 40000 G/L as a feed additive for pigs and poultry

Maes o ddiddordeb ymchwil: Research projects
Statws y prosiect: Wedi'i gwblhau
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Awduron: Risk Assessment Unit, Science, Evidence and Research Division, FSA
Cynhaliwyd gan: Risk Assessment Team Science Division, FSS
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1. Executive summary

The FSA/ FSS have undertaken a safety assessment of application RP 215 for the renewal and extension of use of Xylanase 40000 G/L produced by *Trichoderma reesei* ATCC 5588 as a feed additive for pigs and poultry, 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 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 Xylanase 40000 G/L, 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;0(0):6539 **Question number:** EFSA-Q-2018-01039

In accordance with Retained EU Regulation 1831/2003 on feed additives, the application RP 215 for the renewal and extension of use of Xylanase 40000 G/L produced by *Trichoderma reesei* (ATCC 5588) as a feed additive for pigs and poultry, from Danisco Animal Nutrition 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 assessment of the safety of feed additives for the target species **(2017)**, Guidance on the characterisation of microorganisms used as feed additives or as production organisms **(2018a)**, Guidance on the assessment of the efficacy of feed additives **(2018b)** 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* (ATCC 5588). The trade name is Danisco Xylanase 40000 G/L and is available in two forms, a powder (G) and a liquid form (L).
These two formulations were fully characterised and described in previous opinions.

3.2 Genetic modification step

The assessment of the genetic modification of the production strain was performed in a previous evaluation **(EFSA, 2007a)**, and has not been modified.

3.3 Specification

Information provided on the identity, composition and specifications of the bacteria does not raise safety concerns (the published version is redacted whilst confidentiality claims are determined. As many of these are directly relevant to the risk assessment it is difficult to see how confidentiality can be justified).

Physiochemical properties, homogeneity and stability were evaluated in previous EFSA opinions, however the applicant did provide recent physiochemical data from recent batches for the current application.
This application included the request to lower the minimum recommended concentrations of the additive to 625 U/kg from 1,250 U/Kg for fattening turkeys.

3.4 Exposure assessment

Not relevant

3.5 Toxicological data

This application is for the renewal and extension of use of Danisco Xylanase 40000 G/L to minor growing porcine species, suckling piglets and all poultry species for fattening, laying and breeding. Previous EFSA evaluations exist for chickens and ducks for fattening **(2007a)**, laying hens **(2007a)**, turkeys for fattening **(2007b)**, weaned piglets **(2011)**, piglets for fattening **(2011)** and all minor poultry species **(2012)**.

A literature search from CAB Abstracts, Veterinary Science Database and Medline 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

Danisco Xylanase 40000 G/L raises no concerns for the consumer of the products obtained from animals fed the additive, this includes the additional species for the extension of use.

The additive, in either form, is not a skin irritant but should be considered a possible eye irritant. Owing to the proteinaceous nature of the active substance it should be considered a respiratory sensitiser.

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* (ATCC 5588).
No new data has been provided which would lead the Panel to revise the previous conclusions. Therefore, the FEEDAP Panel concludes that Danisco Xylanase 40000 has the potential to be efficacious as a zootechnical additive in the poultry and porcine species presented. This is at a minimum inclusion of 625 U/Kg in complete feed for all fattening, laying and breeding poultry and 2000 U/Kg inclusion rate for suckling piglets and all minor growing porcine species.

Viable cells of the production strain and its DNA were not detected in a sample representative of both final formulations.
The panel noted that there were high counts of potential microbiological contamination in at least one of the three liquid formulation batches tested (high total viable counts of 7 x 105 CFU/ml in one batch). And also high counts of *Enterobacteriaceae* (> 15 x 103 CFU/g) and yeasts (370 CFU/g) in the solid form.

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 2007, 2011 and 2012 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 Xylanase 40000 G/L, 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 safety extensions to younger animals was supported by extrapolation of existing studies in older animals rather than a specific study in younger animals.

8. References

EFSA (European Food Safety Authority), 2007a. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and of the Scientific Panel on Genetically Modified Organisms (GMO) on a request from the European Commission on the safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) as a feed additive for chickens for fattening, laying hens and ducks for fattening. EFSA Journal 2007;5(10):548, 18 pp. https://doi.org/10.2903/j.efsa.2007.548

EFSA (European Food Safety Authority), 2007b. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) as a feed additive for turkeys for fattening. EFSA Journal 2007;5(12):586, 12 pp. https://doi.org/10.2903/j.efsa.2007.586

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Scientific Opinion on the safety and efficacy of Danisco Xylanase G/L (endo-1,4-beta-xylanase) for weaned piglets and pigs for fattening. EFSA Journal 2011;9(2):2008, 13 pp. https://doi.org/10.2903/j.efsa.2011.2008

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Scientific Opinion on the safety and efficacy of Danisco Xylanase 40000 G/L (endo-1,4-beta-xylanase) for laying hens and poultry minor species. EFSA Journal 2012;10(6):2739, 11 pp. https://doi.org/10.2903/j.efsa.2012.2739

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021

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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018b. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274