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Assessment of the feed additive consisting of endo-1,4-β-xylanase produced by *Trichoderma reesei* CBS 114044 (ECONASE® XT) for piglets (weaned), chickens reared for laying, chickens for fattening, turkeys for fattening and turkeys reared for breeding for the renewal of its authorisation (Roal Oy)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the ECONASE® XT, an enzyme based on endo-1,4-β-xylanase produced by a genetically modified strain of *Trichoderma reesei* CBS 114044. The additive is currently authorised for use in chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned) and pigs for fattening. ECONASE® XT is currently authorised in two forms, a solid and a liquid form with activities of 4,000,000 and 400,000 BXU/g, respectively. In a previous opinion, the FEEDAP Panel could not exclude the potential presence of recombinant DNA derived from the production organism in recent batches of the additive. The applicant has submitted data to support the absence of recombinant DNA derived from the production organism in recent product batches. The FEEDAP Panel confirms that the data provided support the absence of recombinant DNA of *Trichoderma reesei* CBS 114044 in the additive and thus, no safety concern was identified.

Keywords: zootechnical additives, digestibility enhancers, ECONASE® XT, xylanase, safety, recombinant DNA

Requestor: European Commission

Question number: EFSA-Q-2020-00653

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, Roal Oy,[2] is seeking a Community authorisation of beta-1,4-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive to be used as digestibility enhancers for piglets (weaned), chickens reared for laying, chickens for fattening, turkeys for fattening, and turkeys reared for breeding (Table 1).

Table 1: Description of the substances

Category of additive	Zootechnical additives
Functional group of additive	Digestibility enhancers
Description	Beta-1,4-xylanase produced by *Trichoderma reesei* (CBS 114044)
Target animal category	Piglets (weaned); chickens reared for laying; chickens for fattening; turkeys for fattening and turkeys reared for breeding
Applicant	Roal Oy
Type of request	New opinion

On 28 November 2019, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, could not conclude on the identification of additive containing beta-1,4-xylanase produced by *Trichoderma reesei* (CBS 114044). Due to the lack of the analysis on recent batches, EFSA was unable to conclude on the absence of rDNA in the final product.

The Commission gave 60 days to the applicant to submit complementary information, in particular analysis to confirm the absence of the residues of rDNA in the final product, in order to complete the assessment. The new data have been received on 22 April 2020.

In view of the above, the Commission asks the Authority to deliver a new opinion on beta-1,4-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for chickens reared for laying, turkeys for fattening, piglets (weaned), chickens for fattening and turkeys reared for breeding, based on the additional data submitted by the applicant.

1.2. Additional information

The additive is a preparation of endo-1,4-β-xylanase produced by a strain of *Trichoderma reesei* (CBS 114044), available in solid and liquid formulations, with the trade name ECONASE® XT. The additive (4a8) is authorised in the European Union for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, minor poultry species, piglets (weaned) and pigs for fattening.[3,4]

The FEEDAP Panel adopted two opinions on the safety and efficacy of ECONASE® XT solid and liquid as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned) (EFSA, 2008, 2009), which included the assessment of the safety for the consumer, the user and the environment as well as the safety aspects of the genetic modification of the production strain. The FEEDAP Panel adopted another opinion on the safety and efficacy of ECONASE® XT when used as a feed additive for laying hens, minor poultry species and

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Roal Oy, Tyykkimäentie 15, 05200 Rajamäki, Finland.
[3] Commission Regulation (EC) No 902/2009 of 28 September 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy. OJ L 256, 29.9.2009, p. 23.
[4] Commission Implementing Regulation (EU) No 1110/2011 of 3 November 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy). OJ L 287, 4.11.2011, p. 27 and amending by Commission Implementing Regulation (EU) 2018/1569 of 18 October 2018.

pigs for fattening (EFSA FEEDAP Panel, 2011), an opinion on the modification of the authorisation for laying hens (EFSA FEEDAP Panel, 2018a) and an opinion on the assessment of the application for renewal of authorisation for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (EFSA FEEDAP Panel, 2019). In the latter, the FEEDAP Panel could not exclude the potential presence of recombinant DNA derived from the production organism in recent batches of the additive.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[5] to a previous application on the same product.[6]

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of ECONASE® XT (endo-1,4-β-xylanase) is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b).

3. Assessment

The additive ECONASE® XT is an enzyme preparation with endo-1,4-β-xylanase (xylanase, EC 3.2.1.8) as the main active agent. It is currently authorised in solid and liquid forms, having a minimum activity of 4,000,000 BXU/g[8] and 400,000 BXU/g, respectively. The endo-1,4-β-xylanase present in the additive (EC 3.2.1.8; xylanase) is produced by a genetically modified strain of *Trichoderma reesei* (CBS 114044) which contains [redacted] The additive is intended to be used as a zootechnical additive (functional group: digestibility enhancers) at the inclusion levels of 8,000 BXU/kg complete feed for chickens for fattening and chickens reared for laying, 16,000 BXU/kg complete feed for turkeys for fattening, turkeys reared for breeding and 24,000 BXU/kg complete feed for weaned piglets.

The additive and the production strain were characterised and described in full in previous assessments (EFSA, 2008, 2009). The genetic modification raised no safety concerns. Although the FEEDAP Panel in its opinion of 2019 could not exclude the presence of recombinant DNA derived from the production organism in recent batches, since no sequences of concern were introduced in the production strain, the FEEDAP Panel concluded that the potential presence of recombinant DNA in the final product did not raise safety concerns.

The applicant has provided supplementary information to address the limitations regarding the potential presence of recombinant DNA of the production strain in the final products.

The presence of recombinant DNA from the production strain was herein analysed in [redacted][9] with an average enzymatic activity of [redacted] BXU/g (ranging from [redacted] BXU/g to [redacted] BXU/g).[10] [redacted][11] The DNA from [redacted] The protocol included a [redacted]

[5] FEED dossier reference: FAD-2020-0074.
[6] FEED dossier reference: FAD-2018-0071.
[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
[8] One BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50°C.
[9] Technical dossier/TentaMedix_Final report.
[10] Technical dossier/Supplementary Information December 2020/Annex 01.
[11] Technical dossier/TentaMedix_Final report and Supplementary Information December 2020/Econase XT_FAD-2020-0074_Supplementary information, Annex 01 and Annex 02.

[redacted] The limit of detection in samples spiked with [redacted] product.

Therefore, it can be concluded that no DNA of the production strain was detected in a dry intermediate product, representative of both final formulations. The FEEDAP Panel confirms its previous conclusion (EFSA FEEDAP Panel, 2019) that ECONASE® XT is safe for the target species, consumers and the environment. ECONASE® XT is non-irritant to the skin, the liquid form is non-irritant to the eyes and is not a dermal sensitiser, but the additive in all forms should be considered a respiratory sensitiser.

4. Conclusions

The data provided in the present assessment supports the absence of recombinant DNA from the production strain in the additive. The FEEDAP Panel confirms its previous conclusions that the ECONASE®XT remains safe for the target species, consumers and the environment. The additive is non-irritant to the skin, whereas should be considered a respiratory sensitiser. The liquid form (only formulation tested) is non-irritant to the eyes and not a dermal sensitiser.

5. Documentation as provided to EFSA/Chronology

Date	Event
08/07/2020	Reception mandate from the European Commission
06/10/2020	Reception of additional data from Roal Oy
16/10/2020	Application validated by EFSA – Start of the scientific assessment
02/12/2020	Request of supplementary information to the applicant in line with Article 7(3) of Regulation (EC) No 1304/2003 – Scientific assessment suspended. *Issues: characterisation of the additive*
07/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
27/01/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CBS	Centraalbureau voor Schimmelcultures
EC	Enzyme Commission
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed