European Food Safety Authority

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Opinion on a request from the European Commission related to the enzyme preparation of trade name 'Econase XT P/L (endo-1,4-beta-xylanase) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned)[1]

Updated Scientific Opinion of the Panel on Genetically Modified Organisms

(Question No EFSA-Q-2008-775)

Adopted on 21 April 2009

PANEL MEMBERS[*]

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SUMMARY

The European Commission has requested the European Food Safety Authority (EFSA) to deliver a scientific opinion on the enzyme preparation of trade name "Econase XT P/L (endo-1,4-beta-xylanase)" as a feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned), based on new data provided by the applicant in the supplementary dossier.

The presence of recombinant DNA from the production microorganism in the Econase XT P/L feed additive was assessed by two PCR tests. For the semifinal liquid product, the detection limits were 20 pg mL^{-1} and 20 ng mL^{-1} for the 663 bp and the larger fragment of 1974 bp, respectively. For the final liquid product, the detection limits were 20 pg mL^{-1} and 2 ng mL^{-1} for the 663 bp and the larger fragment of 1974 bp, respectively. No recombinant DNA was detected in any of the products tested.

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[*] (minority opinion) This opinion is not shared by 0 members of the Panel. / (conflict of interest) 0 members of the Panel did not participate in (part of) the discussion on the subject referred to above because of possible conflicts of interest.

Request from the European Commission related to "Econase XT P/L" as a feed additive

Key words: zootechnical additive, digestibility enhancer, enzyme, xylanase, chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding, piglets (weaned), safety, efficacy, Econase XT, genetically modified microorganisms

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BACKGROUND AS SUBMITTED BY EC

Regulation (EC) No. 1831/2003 establishes rules governing the Community authorisation of additives for animal nutrition and, in particular, defines the conditions that a substance/product should meet to be granted the authorisation.

The Scientific Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority adopted on 21st May 2008 an opinion on the safety and efficacy of enzyme preparation with the trade name "Econase XT L and Econase XT P," as feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned). The opinion was adopted in cooperation with the Panel on Genetically Modified Organisms (GMO Panel). In the opinion it was concluded that "the presence of recombinant DNA in the final product was not examined and, therefore, the presence of recombinant DNA cannot be excluded". Therefore, the European Commission gave the possibility to the company to submit complementary information to complete the assessment.

The European Commission received supplementary information from the applicant company, Roal Oy.

TERMS OF REFERENCE AS SUBMITTED BY EC

The European Commission requests the European Food Safety Authority to issue an opinion on the enzyme preparation with the trade name "Econase XT L and Econase XT P," as feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding and piglets (weaned), taking into account its earlier opinion on 21st May 2008 and the new data provided.

ACKNOWLEDGEMENTS

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ASSESSMENT

1. Introduction

The European Food Safety Authority has received a request from the European Commission to update the opinion on the Econase XT L and Econase XT P (Econase XT P/L) adopted in May, 2008 (EFSA, 2008). The designations L and P refer to the liquid and powdered formulations, respectively, of the same product Econase XT (endo-1,4-beta-xylanase). The opinion concluded that the presence of recombinant DNA in the final product was not examined and, therefore, the presence of recombinant DNA could not be excluded. The GMO Panel assessed the potential transfer of the recombinant DNA to other organisms and its consequences and concluded that the sequences introduced do not pose safety concerns. However, the European Commission considered that leaving open the question about the possible presence of recombinant DNA in the product was not in compliance with Article 7(3)(i) of Regulation (EC) No. 1831/2003 and gave the company the possibility to submit additional information.

The company provided information concerning the presence of recombinant DNA in five lots of Econase XT: one lot of the dry form; one lot of semifinal liquid product before addition of stabilising agents; one lot of the final liquid product; one lot of a diluted final liquid product; one lot of a premixed dry enzyme concentrate. The present opinion is based on the information provided in the report of 25 September 2008. Additional data provided in response to a request by the GMO Panel and received on 17 February 2009 has also been considered.

2. Assessment of the presence of recombinant DNA

The purification process of the product involves several filtration steps and no inactivation of the production microorganism. Therefore, the absence of culturable fungal propagules is an acceptable indicator of the removal of the production microorganism from the product.

The presence of recombinant DNA released from the production microorganism in the Econase XT P/L feed additive was assessed by two PCR tests, each amplifying a different fragment of the recombinant DNA present in the final production strain *Trichoderma reesei* RF5427. One PCR amplified a 663 bp fragment of the gene encoding β-1,4-xylanase (*xyn11A*), reaching a quantification limit of 0.1 fg plasmid DNA and 100 fg genomic DNA. The second PCR amplified a 1974 bp fragment of the selectable marker gene acetamidase (*amdS*), reaching a quantification limit of 1 fg plasmid DNA and 1 pg genomic DNA. The limits of detection of both PCRs for DNA added to the final product before extraction were determined in two lots of Econase XT, the semifinal liquid product before addition of stabilising agents and the final liquid product. The *xyn11A*-PCR amplifying a 663 bp fragment reached a detection limit of 20 pg mL^{-1} in both Econase products; the *amdS*-PCR amplifying a fragment of 1974 bp reached a detection limit of 20 ng mL^{-1} in the semifinal liquid product and of 2 ng mL^{-1} in the final liquid formula. No recombinant DNA was detected in the five products tested with the *xyn11A* primers or in the two products (the semifinal and final liquid products) tested with the *amdS* primers.

3. Safety for the environment

The production microorganism is removed from the product and the recombinant DNA in the final commercial product is below the limit of detection. No further environmental risk assessment is required.

CONCLUSIONS

No recombinant DNA was detected in the commercial enzyme preparations tested. For the semifinal liquid product, the detection limits were 20 pg mL^{-1} and 20 ng mL^{-1} for the 663 bp and the larger fragment of 1974 bp, respectively. For the final liquid product, the detection limits were 20 pg mL^{-1} and 2 ng mL^{-1} for the 663 bp and the larger fragment of 1974 bp, respectively. No recombinant DNA was detected in any of the products tested.

DOCUMENTATION PROVIDED TO EFSA

1. Enclosure. November 2008. Submitted by European Commission.

   Company supplementary comment on the EFSA opinion for Econase XT P/L as feed additive. September 2008. Roal Oy.

2. Supplementary information on Econase XT P/L. February 2009. Submitted by Roal Oy.

REFERENCES

EFSA 2008. 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). (Summary). The EFSA Journal 712, 1-2.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902004731.htm