Safety evaluation of the food enzyme endo-polygalacturonase from the genetically modified Trichoderma reesei strain AR-414

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00372
Adopted 20-05-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Polygalacturonase from Trichoderma reesei AR-414. Additional information, requested from the applicant during the assessment process on 25 March 2024 and 4 December, were received on 9 October 2024 and 11 December 2024

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a (. . .) fermentation system with conventional process controls in place.
Formulation Unknown
Downstream processing After completion of the fermentation, the solid biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded.
Average TOS (w/w) 21.8 %
Average activity/TOS 251.4 PGX/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production strain in the food enzyme was demonstrated. The absence of recombinant DNA in the food enzyme was demonstrated
Allergenicity when used for the production of distilled alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining

intended uses, the Panel considered that a risk of allergic reactions upon dietary exposure to this food enzyme, particularly in papaya and pollen-allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after papaya consumption

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batche

Antifoam agents /

Other The presence of HT2-toxin and T-2 toxin was examined in all food enzyme batches, and all were below the limit of quantification (LoQ) of the applied method

Pathogens

Microbiological quality indicators

Metals

Coments LoD Pb: 0.025 mg/kg; LoQ Pb: 0.05 mg/kg. LOQs: HT2 toxin = 10 µg/kg; T-2 toxin = 10 µg/kg.