Safety evaluation of the food enzyme acid prolyl endopeptidase from the genetically modified Aspergillus niger strain GEP

1 Report

Status Finished
EFSA question number EFSA-Q-2014-00852
Adopted 03-02-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme acid prolyl endopeptidase from a genetically modified strain of A. niger (strain GEP). The dossier was updated on 8 June 2021 with an application for extension of use of the food enzyme. Additional information, requested from the applicant during the assessment phase on 15 December 2022 and 31 January 2022, was received on 22 April 2022 and 6 September 2023, respectively. Spontaneous additional information was received from the applicant on 1 December 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, fed-batch 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) 25.0 %
Average activity/TOS 0.1 PPU/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 alcohol, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining intended uses, the risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but the likelihood is low.

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

Antifoam agents /

Other The presence of zearalenone, fumonisins, trichothecenes, aflatoxins and ochratoxin A was examined in three food enzyme batches and was below the limit of detection (LoD) of the applied method.

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.08–2 mg/kg. LoD: zearalenone = 3 µg/kg; fumonisins = 10 µg/kg each; trichothecenes = 10 µg/kg each; aflatoxins = 0.1 µg/kg each; ochratoxin A = 0.1 µg/kg.