

Safety evaluation of the food enzyme aspergillopepsin I from the non-genetically modified *Aspergillus* sp. strain AE-PRHF

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00205](#)

Adopted 25-06-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme aspergillopepsin I from a non-genetically modified *A. oryzae* strain AE-PRHF. Additional information, requested from the applicant during the assessment phase on 21 January 2025, were received on 18 April 2025

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in fermentation system with conventional process controls in place

Formulation Unknown

Downstream processing After completion of the fermentation, the enzyme is and the solid biomass is removed from the suspension broth by filtration. The filtrate containing the enzyme is then further purified and concentrated, including (...) in which the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded

Average TOS (w/w) 94.5 %

Average activity/TOS 262.7 UNIT/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.

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 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 aflatoxin B1, B2, G1, G2, deoxynivalenol, T-2 toxin, HT-2 toxin, zearalenone, ochratoxin A, sterigmatocystin was examined in all food enzyme batches and all were below the limit of quantification (LoQ) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQ: Pb = 0.05 mg/kg. LoQs: aflatoxin B1, B2, G1, G2 = 1 µg/kg each; deoxynivalenol = 0.05 mg/kg; T-2 toxin = 0.01 mg/kg, HT-2 toxin = 0.05 mg/kg; zearalenone = 0.05 mg/kg; ochratoxin A = 5 µg/kg; sterigmatocystin = 0.05 mg/kg.