

Safety evaluation of the food enzyme pectinesterase from the non-genetically modified *Aspergillus luchuensis* strain AP2 903-6

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00269](#)

Adopted 18-06-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme pectinesterase from *Aspergillus luchuensis* AP2 903-6. Additional information was requested from the applicant during the assessment process on 21 May 2024 and received on 23 August 2024.

2 Production method

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

Formulation Unknown

Downstream processing After completion of the fermentation, the enzyme is extracted with [...] and the solid biomass is removed from the suspension by centrifugation. The supernatant 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 membrane and is discarded. The ultrafiltered food enzyme is subjected to alkaline treatment to remove the endo-polygalacturonase activity followed by neutralisation and filtration.

Average TOS (w/w) 1.5 %

Average activity/TOS 332.9 PME/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 In conclusion, the Panel considered that, under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly in pollen allergic individuals, cannot be excluded.

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

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1, G2), fumonisins (B1, B2), ochratoxin A, sterigmatocystin, T-2 toxin and zearalenone was examined in three food enzyme batches and was below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2) = 0.5 µg/kg each; sterigmatocystin = 100 µg/kg; zearalenone = 100 µg/kg; ochratoxin A = 0.5 µg/kg; T-2 toxin = 0.1 µg/kg; fumonisins (B1, B2) = 0.5 µg/kg each.