Safety evaluation of the food enzyme pectin lyase from the non-genetically modified Aspergillus luchuensis strain CBS 141530

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00020
Adopted 16-06-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Pectin lyase from a non-genetically modified Aspergillus luchuensis (strain CBS 141530). Additional information was requested from the applicant during the assessment process on 28 June 2023, and 9 February 2026 and was consequently provided. Following the reception of additional data by EFSA on 28 September 2023, EFSA requested a clarification teleconference on 12 January 2024, after which the applicant provided the clarification required.

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 food enzyme is extracted with [...]. The solid biomass is then removed from the suspension by [...]. The supernatant containing the enzyme is then further purified and concentrated, including an [...] in which enzyme protein is retained while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 20.1 %
Average activity/TOS 5.5 UPL/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, when used for the production of distilled alcoholic beverages, 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 aflatoxins (B1, B2, G1 and G2), deoxynivalenol, fumonisins (B1 and B2), ochratoxin A, T2-toxin and HT2-toxin, and zearalenone was examined in all food enzyme batches and all were below the LoQs of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.01 mg/kg; As = 0.01 mg/kg; Cd = 0.01 mg/kg; Hg = 0.005 mg/kg. LOQs: aflatoxins B1, B2, G1 and G2 = 0.1 µg/kg each; deoxynivalenol = 100 µg/kg, fumonisins B1 and B2 = 250 µg/kg; ochratoxin A = 2.5 µg/kg; T-2 toxin, HT2 toxin = 10 µg/kg; zearalenone = 6 µg/kg.