Safety evaluation of the food enzyme pectin lyase from the non-genetically modified Aspergillus luchuensis strain LC-07

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00266
Adopted 11-03-2026
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 LC-07). Additional information, requested from the applicant during the assessment process on 08 December 2023 and 26 January 2026, was received on 07 June 2024 and 2 February 2026, respectively. Following the reception of additional data, EFSA requested a clarification teleconference on 25 February 2026, after which the applicant provided additional data on 25 February 2026

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 enzyme is extracted with [...] and the solid biomass is removed from the suspension by centrifugation followed by filtration. The filtrate containing the enzyme is further purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded
Average TOS (w/w) 18.6 %
Average activity/TOS 52.7 U/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 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, G2), ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone and fumonisins (B1, B2) was examined in all food enzyme batches and was below the LoQs of the applied methods.

Pathogens

Microbiological quality indicators

Metals

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