Safety evaluation of a food enzyme containing cellulase, endo-1,3(4)-β-glucanase and endo-1,4-β-xylanase activities from the non-genetically modified Trichoderma reesei strain AR-999

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00194
Adopted 12-11-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing cellulase, endo-1,3(4)-β-glucanase and endo-1,4-β-xylanase activities from non-genetically modified Trichoderma reesei AR-999. The dossier was updated in March 2023. Additional information, requested from the applicant during the assessment process on 22 June 2023, 21 October and 5 November 2025, was received on 21 September 2023, 31 October and 10 November 2025, respectively.

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 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) 92.3 %
Average activity/TOS 75.8 ECU/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, particularly for salmon-allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after salmon consumption.

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

Antifoam agents /

Other The presence of T-2 toxin and HT-2 toxin was examined in all food enzyme batches. Additionally, aflatoxins (B1, B2, G1, G2), fumonisins (B1, B2), ochratoxin A, sterigmatocystin, zearalenone and deoxynivalenol were analysed in the batch used for toxicological testing. All were below the LoQ of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments "LoQs: Pb = 0.05 mg/kg; As = 0.5 mg/kg; Cd = 0.05 mg/kg; Hg = 0.05 mg/kg. LoQs:aflatoxins (B1, B2, G1 and G2) = 0.1 µg/kg each; deoxynivalenol = 20 µg/kg; fumonisins (B1, B2) = 20 µg/kg each; HT-2 toxin, T-2 toxin, sterigmatocystin and zearalenone = 10 µg/kg each; ochratoxin A = 2 µg/kg."