Safety evaluation of the food enzyme β-glucosidase from the genetically modified Trichoderma reesei strain DP-Nyk114

1 Report

Status Finished
EFSA question number EFSA-Q-2025-00235
Adopted 19-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme β-glucosidase from Trichoderma reesei DP-Nyk114. Additional information requested from the applicant during the assessment phase on 16 October 2025 was received on 16 January 2026

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch or fed-batch 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 the enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 19.1 %
Average activity/TOS 130.7 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. The absence of recombinant DNA in the food enzyme was demonstrated

Allergenicity The Panel considered that the results of the sequence homology search and the available literature do not indicate a risk of allergic reactions upon dietary exposure to the food enzyme under assessment

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

Antifoam agents /

Other The presence of aflatoxins, ochratoxin, fumonisins, zearalenone, sterigmatocystin and T2-toxin was examined in three food enzyme batches. All were below the limits of detection (LoDs) of the applied analytical methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.01 mg/kg. LoDs: aflatoxins (B1, B2, G1, G2) = 5 µg/kg each; ochratoxin = 2 µg/kg; T2-toxin = 25 µg/kg; zearalenone = 25 µg/kg; sterigmatocystin = 100 µg/kg; fumonisins (B1, B2) = 1000 µg/kg each.