Safety evaluation of the food enzyme glucan 1,4-α-glucosidase from the genetically modified Trichoderma reesei strain DP-Nzh109

1 Report

Status Finished
EFSA question number EFSA-Q-2025-00015
Adopted 11-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucan 1,4-α- glucosidase from T. reesei strain DP-Nzh109. Additional information were requested during the risk assessment phase

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) 27.5 %
Average activity/TOS 2.1 GAU/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 When used for the production of distilled alcohol, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the remaining

intended use, 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 aflatoxin (B1, B2, G1, G2), ochratoxin A, fumonisin (B1, B2), zearalenone, sterigmatocystin and T2-toxin was examined in the three food enzyme batches and were below the limits of detection (LoD) of the applied analytical methods

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.01 mg/kg. LoDs: aflatoxins B1, B2, G1 and G2 = 2 µg/kg each; ochratoxin A = 2 µg/kg; fumonisin B1 + B2 = 0.2 mg/kg; zearalenone = 5 µg/kg; sterigmatocystin = 10 µg/kg; T2-toxin = 10 µg/kg.