Safety evaluation of the food enzyme endo-1,3(4)-β-glucanase from the non-genetically modified Trichoderma reesei strain TG-M5-337

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00295
Adopted 12-11-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme endo-1,3(4)-β-glucanase from a non-genetically modified Trichoderma reesei (strain TG-M5-337). Additional information, requested from the applicant during the assessment process on 06 June 2024 and 21 October 2025, was received on 16 July 2024 and 24 October 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 enzyme is extracted with, and the solid biomass is removed from the fermentation broth by centrifugation and filtration. The filtrate containing the enzyme is 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) 15.1 %
Average activity/TOS 1.1 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 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 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), sterigmatocystin, zearalenone, ochratoxin A and T-2 toxin was examined in all food enzyme batches and was below the limits of quantification (LoQ) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 5 mg/kg; As = 3 mg/kg. LoQs: aflatoxins (B1, B2, G1, G2) = 0.5 µg/kg each; sterigmatocystin = 100 µg/kg; zearalenone = 100 µg/kg; ochratoxin A = 0.5 µg/kg; T-2 toxin = 100 µg/kg.