Safety evaluation of the food enzyme cellulase from the genetically modified Trichoderma reesei strain NZYM-FS

1 Report

Status Finished
EFSA question number EFSA-Q-2025-00591
Adopted 08-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme cellulase from T. reesei strain NZYM-FS. Additional information was 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, 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) 12.4 %
Average activity/TOS 13.6 CNU(CL)/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 In conclusion, 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 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoDs/LoQs: Pb = 0.5 mg/kg.