Safety evaluation of the food enzyme endo-1,4-β-xylanase from the genetically modified Bacillus licheniformis strain NZYM-FX

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00453
Adopted 15-04-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme xylanase from a genetically modified B. licheniformis strain NZYM-FX. 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, 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 further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded
Average TOS (w/w) 6.5 %
Average activity/TOS 7.1 FXU(TB)/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The presence of viable cells of the production strain in the food enzyme was analysed in triplicate. No colonies of the production strain were detected. 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 /
Pathogens
Microbiological quality indicators
Metals
Coments Pb: Limit of quantification (LoQ) = 0.5 mg/kg.