Safety evaluation of the food enzyme subtilisin from the genetically modified Bacillus licheniformis strain NZYM-PD

1 Report

Status Finished
EFSA question number EFSA-Q-2025-00016
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme subtilisin from B. licheniformis strain NZYM-PD. Additional information, requested from the applicant during the assessment process on 5 December 2025 and was received on 4 March 2026, respectively

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) 14.9 %
Average activity/TOS 5.7 PROT(A)/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 alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded.
Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches
Antifoam agents /
Other /
Pathogens
Microbiological quality indicators
Metals
Coments LoQ: Pb = 0.5 mg/kg.