Safety evaluation of the food enzyme glutaminase from the genetically modified Bacillus subtilis strain Glu3-3

1 Report

Status Finished
EFSA question number EFSA-Q-2025-00232
Adopted 15-04-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glutaminase from B. subtilis Glu3-3. 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 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. Finally, the food enzyme is freeze-dried in the presence of a stabiliser prior to analysis
Average TOS (w/w) 39.9 %
Average activity/TOS 1.0 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. The Panel could not conclude on the absence of recombinant DNA in the food enzyme.
Allergenicity The Panel considered that under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that 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 LoQs: Pb = 0.04 mg/kg; As = 0.01 mg/kg