



Safety evaluation of the food enzyme subtilisin from the genetically modified *Bacillus paralicheniformis* strain AP-GKY

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00552](#)

Adopted 04-02-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme subtilisin from *Bacillus paralicheniformis* strain AP-GKY. 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 filtration membrane and is discarded

Average TOS (w/w) 7.6 %

Average activity/TOS 4674.0 DAPU/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 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, particularly in natto, melon and pomegranate allergic individuals. However, the likelihood of such reactions will not exceed the risk of reactions after natto, melon and pomegranate consumption.

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches.

Antifoam agents /

Other /

Pathogens

Microbiological quality indicators

Metals

Comments LoD Pb = 0.00138 mg/L.