

# Safety evaluation of the food enzyme serine endopeptidase from the genetically modified *Aspergillus niger* strain NZYM-MG

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2025-00017](#)

**Adopted** 04-02-2026

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the food enzyme serine endopeptidase from *A. niger* strain NZYM-MG. Additional information, requested from the applicant during the assessment phase on 19 December 2025, and on 21 January 2026, and they were received on 5 January and on 26 January 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 and 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)** 6.7 %

**Average activity/TOS** 4.0 PROT(B)/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.

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

**Antifoam agents** /

**Other** The presence of ochratoxin A and fumonisin B2 was examined in all food enzyme batches and were below the limits of detection (LoDs) of the applied analytical methods.

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoQ: Pb = 0.5 mg/kg. LoDs: fumonisin B2 = 0.3 µg/kg; ochratoxin A = 0.3 µg/kg.