



# Safety evaluation of the food enzyme protein-glutamine $\gamma$ -glutamyltransferase from the genetically modified *Bacillus licheniformis* strain NZYM-TR

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2024-00545](#)

**Adopted** 03-02-2026

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the food enzyme transglutaminase from a genetically modified *B. licheniformis* strain NZYM-TR. 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 enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded.

**Average TOS (w/w)** 8.6 %

**Average activity/TOS** 11.8 TGHU(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 preparation 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, but that the likelihood is low. The Panel concluded that a risk of contribution to coeliac disease cannot be excluded

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

**Antifoam agents** /

**Other** /

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoQ Pb = 0.5 mg/kg