



# Safety evaluation of the food enzyme trypsin from the genetically modified *Fusarium venenatum* strain NZYM-FG

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2014-00412](#)

**Adopted** 03-02-2026

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Serine protease (with trypsin specificity) from the genetically modified *Fusarium venenatum* strain NZYM-FG. The dossier was updated in March 2021. Additional information, requested from the applicant during the assessment process on 18 September 2023 and 16 October 2025, was received on 18 December 2023 and 11 November 2025, respectively.

## 2 Production method

**Manufacturing** The production strain is grown as a pure culture using a typical industrial medium in a [...] 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)** 18.0 %

**Average activity/TOS** 2.1 KMTU/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, but that the likelihood is low.

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

**Antifoam agents** /

**Other** Mycotoxins known to be produced by Fusarium species (diacetoxyscirpenol, fusarin C and butanolide) were below the LoD in four batches of the food enzyme.

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoDs: Pb = 0.5 mg/kg; As = 0.3 mg/kg; Cd = 0.05 mg/kg; Hg = 0.05 mg/kg. LoDs: diacetoxyscirpenol = 20 µg/kg, fusarin C = 20 µg/kg, and butanolide = 500 µg/kg.