

# Safety evaluation of a food enzyme containing endo-polygalacturonase and pectin lyase activities from the non-genetically modified *Aspergillus luchuensis* strain NZYM-XA

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2022-00536](#)

**Adopted** 16-06-2026

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing polygalacturonase and pectin lyase that is produced with a strain of *A. luchuensis* (NZYM-XA). Additional information, requested from the applicant during the assessment phase on 18 September 2023, was received on 29 April 2025.

## 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 enzyme is extracted with [...] and the solid biomass is removed from the suspension by filtration. The filtrate containing the enzyme is 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)** 22.7 %

**Average activity/TOS** 98.4 PGNU(PL)/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.



**Allergenicity** In conclusion, the Panel considered that, under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly for papaya- and pollen-allergic individuals, cannot be excluded. The likelihood of papaya-related reactions will not exceed the risk of reactions after papaya consumption.

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

**Antifoam agents** /

**Other** The presence of fumonisin B2 and ochratoxin A was examined in the food enzyme batches intended for commercialisation and was below the LoDs of the applied methods

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoDs: Pb = 0.5 mg/kg; As = 0.1/0.3 mg/kg; Cd = 0.05 mg/kg; Hg = 0.03/0.05 mg/kg. LoDs: fumonisin B2, ochratoxin A = 0.3 µg/g each.