

# Safety evaluation of the food enzyme triacylglycerol lipase from the genetically modified *Aspergillus oryzae* strain NZYM-PH

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2015-00664](#)

**Adopted** 12-11-2025

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the food enzyme triacylglycerol lipase from a genetically modified *Aspergillus oryzae* (strain NZYM-PH). Additional information, requested from the applicant during the assessment process on 27 March 2023, were received on 26 March 2024.

## 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 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)** 15.9 %

**Average activity/TOS** 839.0 LU/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 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** The presence of kojic acid, 3-nitropropionic acid and cyclopiazonic acid was examined in all food enzyme batches, and all were below the LoD of the applied methods.

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoDs: Pb = 0.5 mg/kg; As = 0.3 mg/kg; Cd, Hg = 0.05 mg/kg each. LoDs: kojic acid < 0.040; mg/kg; 3-nitropropionic acid < 0.707 mg/kg; cyclopiazonic acid < 0.003 mg/kg.