

Safety evaluation of the food enzyme 6-Phytase from the genetically modified *Trichoderma reesei* strain AR-766

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00525](#)

Adopted 15-01-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme 6-Phytase from a genetically modified *Trichoderma reesei* AR-766. Additional information was requested from the applicant during the assessment process on 16 January 2024, 21 October 2024 and received on 12 July 2024, and 12 November 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 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) 22.9 %

Average activity/TOS 354.3 FTU/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 alcohols, the Panel considered that a risk of allergic reactions upon dietary exposure can be excluded. For the



remaining intended uses, the risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but the likelihood is low.

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

Antifoam agents /

Other The presence of T-2 and HT-2 toxins was examined in three food enzyme batches, and both were below the LoQ of the applied method

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 0.5 mg/kg; Cd = 0.03 mg/kg; Hg = 0.05 mg/kg.
LoQs: T-2 and HT-2 toxins = 10 µg/kg each.