

Safety evaluation of the food enzyme endo-1,4- β -xylanase from the non-genetically modified *Aspergillus luchuensis* strain DP-Azd103

1 Report

Status Finished

EFSA question number [EFSA-Q-2023-00225](#)

Adopted 09-10-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme endo-1,4- β -xylanase from a non-genetically modified *A. luchuensis* (strain DP-Azd103). Additional information was requested from the applicant during the assessment phase on 18 September 2023 and received on 19 January 2024

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch or 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 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) 7.0 %

Average activity/TOS 3983.0 FXU/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 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 The presence of aflatoxins, fumonisins, ochratoxin A, sterigmatocystin, T-2 toxin and zearalenone was examined in all batches and all were below the limit of detection (LoD) of the applied methods

Pathogens

Microbiological quality indicators

Metals

Comments LoD: Pb = 0.05 mg/kg and 0.01 mg/kg (batch 4). LoDs: aflatoxins total = 2 µg/kg; ochratoxin A = 2 µg/kg; fumonisins total = 200 µg/kg; sterigmatocystin = 10 µg/kg; zearalenone = 5 µg/kg.