



Safety evaluation of the food enzyme endo-1,4- β -xylanase from the genetically modified Bacillus subtilis strain DP-Ezd119

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00079](#)

Adopted 11-02-2025

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 genetically modified Bacillus subtilis strain DP-Ezd119. Additional information, requested from the applicant during the assessment process on 4 November 2024, was received on 4 December 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) 3.7 %

Average activity/TOS 66.2 DXU/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, 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.01 mg/kg.