Safety evaluation of a food enzyme containing endo-polygalacturonase, pectinesterase and pectin lyase activities from the non-genetically modified Aspergillus niger strain CCTCC M 2023236

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00227
Adopted 11-03-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the pectinase complex containing three claimed activities produced by a non-genetically modified A. niger CCTCC M 2023236. Additional information, requested from the applicant during the assessment process on 9 December 2024, was received on 29 April 2025 (see 'Documentation provided to EFSA'). Following the reception of additional data, EFSA requested a clarification teleconference on 23 February 2026, after which the applicant provided Spontaneous information on 25 February 2026

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 a filtration step in which the enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 92.2 %
Average activity/TOS 395.1 U/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, particularly in pollen-allergic individuals, cannot be excluded

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

Antifoam agents /

Other The presence of aflatoxins (B1, B2, G1 and G2), deoxynivalenol (DON), fumonisins (B1 and B2), ochratoxin A, sterigmatocystin, T2-toxin, HT2-toxin and zearalenone was examined in all food enzyme batches and was below the LoQs of the applied analytical methods, except for DON. Using the highest estimated dietary exposure of 1.221 mg TOS/kg bw per day as the reference, European consumers could be exposed to DON up to 0.106 ng/kg bw per day. As this estimate is below the tolerable daily intake (TDI) for DON (1 µg/kg bw per day, EFSA CONTAM Panel, 2017), the Panel considered this concentration as of no concern. Since the production strain is not able to produce DON, the occurrence of DON in the food enzyme is likely to have originated from a contamination of the raw material. Adverse effects caused by the possible presence of other secondary metabolites are addressed by the toxicological examination of the food enzyme. The Panel considered that the information provided on the purity of the food enzyme is sufficient.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As, Cd and Hg = 0.005 mg/kg each. LoQs: aflatoxins (B1, G1) = 0.1 µg/kg each; aflatoxins (B2, G2) = 0.03 µg/kg each; deoxynivalenol = 5 µg/kg (dried food enzyme batches) and 20 µg/kg (liquid food enzyme batches); fumonisins (B1, B2) = 20 µg/kg each; HT-2 toxin, T-2 toxin, sterigmatocystin = 10 µg/kg each; zearalenone = 1 kg (dried food enzyme batches) and 10 µg/kg (liquid food enzyme batches); ochratoxin A = 0.2 µg/kg.