Safety evaluation of the food enzyme containing endo-1,4-β-xylanase and endo-1,3(4)-β-glucanase from the non-genetically modified Aspergillus tubingensis strain CBS 138353

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00230
Adopted 04-02-2026
Previous authorisations The applicant has submitted two dossiers in support of the application for authorisation of the food enzyme containing endo-1,4-β-xylanase and endo-1,3(4)-β-glucanase from the non-genetically modified Aspergillus tubingensis strain CBS 138353. Additional information was requested from the applicant during the assessment phase on 21 August 2023 and 25 March 2024 and received on 11 September 2023 and 25 June 2024. Following the reception of additional data by EFSA on 11 September 2023, EFSA requested a clarification teleconference on 17 October 2023.

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 enzyme is extracted with [...] and the solid biomass is removed by centrifugation. The supernatant containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded
Average TOS (w/w) 8.5 %
Average activity/TOS 218.9 AXAU/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 When used for the production of distilled alcohol, 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 aflatoxins (B1, B2, G1 and G2), zearalenone, ochratoxin A, deoxynivalenol, fumonisins (B1 and B2), T2-toxin and HT2-toxin was examined in all food enzyme batches and all were below the LoQ of the applied analytical methods, except for zearalenone which was detected in all batches in concentrations up to 7 µg/kg.
Pathogens
Microbiological quality indicators
Metals
Coments LoQs: Pb = 0.01 mg/kg; As = 0.01 mg/kg; Cd = 0.01 mg/kg; Hg = 0.005 mg/kg. LoQs: aflatoxins (B1, B2, G1 and G2) = 0.1 µg/kg each; zearalenone = 6 µg/kg; ochratoxin A = 2.5 µg/kg; deoxynivalenol = 100 µg/kg; fumonisins (B1, B2) = 250 µg/kg each; T2 and HT2 toxins = 10 µg/kg each.