Safety evaluation of the food enzyme glucan 1,4-α-glucosidase from the non-genetically modified Aspergillus niger strain AN-SHGA-100

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00228
Adopted 08-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucoamylase from Aspergillus niger strain CCTCC M 2023310. Additional information, requested from the applicant during the assessment process on 24 November 2023 and 12 June 2026, was received on 21 May 2024 and 10 September 2026, respectively.

2 Production method

Manufacturing The Panel is not in the position to evaluate the manufacturing process for the food enzyme under assessment.
Formulation Unknown
Downstream processing The Panel is not in the position to evaluate the manufacturing process for the food enzyme under assessment.
Average TOS (w/w) 91.3 %
Average activity/TOS 399.8 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 In conclusion, 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 glucan 1,4-α-glucosidase 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 aflatoxin B1, B2, G1 and G2, deoxynivalenol (DON), fumonisin B1 and B2, ochratoxin A, sterigmatocystin, T2-toxin and HT2-toxin and zearalenone was examined in two food enzyme batches. All were below the LoQ of the applied analytical methods, except for DON (90 µg/kg) and the sum of fumonisins B1 and B2 (800 µg/kg) in the batch produced for toxicological studies, and zearalenone (22 µg/kg) in another batch. Using the highest estimated dietary exposure of 26.829 mg TOS/kg body weight (bw) per day as the reference, the concentration of DON, fumonisins and zearalenone in the food enzyme batches corresponds to 2.64, 23.5 and 0.65 ng/kg bw per day in the regular diet of consumers, respectively. They are several orders of magnitude lower than the tolerable daily intake (TDI) for DON (1 µg/kg bw per day, EFSA CONTAM Panel, 2017), fumonisins (1 µg/kg bw per day, EFSA CONTAM Panel, 2018) and zearalenone (0.25 µg/kg bw per day, EFSA CONTAM Panel, 2011), respectively. The Panel considered that the information provided on the purity of the food enzyme was sufficient.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; Cd, Hg = 0.005 mg/kg each. LoQs: aflatoxin B1 = 0.1 µg/kg, aflatoxin B2 = 0.03 µg/kg, aflatoxin G1 = 0.1 µg/kg, aflatoxin G2 = 0.03 µg/kg, DON = 20 µg/kg, fumonisin B1 = 20 µg/kg, fumonisin B2 = 20 µg/kg, ochratoxin A = 0.2 µg/kg, sterigmatocystin = 10 µg/kg, T2-toxin = 10 µg/kg, HT2-toxin = 10 µg/kg, zearalenone = 10 µg/kg.