Safety evaluation of a food enzyme containing cellulase and endo-1,3(4)-β-glucanase activities from the non-genetically modified Trichoderma reesei strain DP-Nzc104

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00229
Adopted 09-09-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing cellulase and endo-1,3(4)-β-glucanase from a non-genetically modified T. reesei DP-Nzc104. Additional information was requested from the applicant during the assessment process on 22 January 2024, 23 April 2025, 27 April 2026 and 3 July 2026 and received on 22 October 2024, 31 October 2025, 1 May 2026 and 8 July 2026.

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 then further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded.
Average TOS (w/w) 13.7 %
Average activity/TOS 45.5 IU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The presence of viable cells of the production strain in the food enzyme was analysed. Upon request to provide molecular identification of the contaminants, the applicant submitted another study using three new batches analysed under the same conditions, in which no colonies were detected and a positive control was included. Although the Panel could not assess the identity of the contaminants in the first study provided, in view of the results of the second study, the Panel considers reasonable to conclude that the food enzyme is free of viable cells of the production strain.

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 food enzyme, particularly for salmon-and egg-allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after salmon and egg consumption.

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

Antifoam agents /

Other The presence of aflatoxin, T2 toxin, zearalenone, ochratoxin, sterigmatocystin and fumonisin was examined in all food enzyme batches and were below the limit of detection (LoD) of the applied method.

Pathogens

Microbiological quality indicators

Metals

Coments LoD: Pb = 0.01 mg/kg. LoDs: As = 0.01 mg/kg, Hg = 0.01 mg/kg, Cd = 0.01 mg/kg. LoDs Aflatoxin = 1.4 µg/kg; T2-Toxin < 10 µg/kg, Zearalenone = 10 µg/kg each; Ochratoxin = 1 µg/kg; Sterigmatocystin = 100 µg/kg; Fumonisin = 50 µg/kg.