Safety evaluation of the food enzyme aminopeptidase Y from the genetically modified Trichoderma reesei strain DP-Nyf80

1 Report

Status Finished
EFSA question number EFSA-Q-2024-00089
Adopted 25-06-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme aminopeptidase Y from a genetically modified Trichoderma reesei DP-Nyf80. Additional information, requested from the applicant during the assessment phase on 28 November 2024 and 5 May 2025, was received on 9 April 2025 and 9 May 2025, respectively. Following the request for additional data sent by EFSA 28 November 2024, the applicant requested a clarification teleconference on 27 February 2025, after which the applicant provided additional data on 9 April 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a 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 filtration membrane and is discarded.
Average TOS (w/w) 26.5 %
Average activity/TOS 21.0 KAPU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The possible presence of viable cells of

the production strain in the food enzyme was assessed in three independent batches analysed in triplicate. (...) Contaminating colonies were observed on the agar plates from all three batches. The applicant declared that the contaminating colonies were not the production strain based on visual inspection. However, based on the submitted data and the absence of confirmatory analyses (e.g. wet mount microscopy, molecular identification, mass spectrometry), the Panel could not unambiguously differentiate one of the isolates from the production strain. The applicant stated that this isolate could no longer be detected at the replate event. In the absence of molecular data for this isolate, the Panel concludes that the presence of viable cells of the production strain in the food enzyme cannot be definitively ruled out. The absence of recombinant DNA in the food enzyme was analysed (...) of three additional batches in triplicate. (...) The Panel noted that the DNA analysis was not carried out with the batch from which the above mentioned colony was found

Allergenicity the Panel considered that under the intended 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 The presence of aflatoxins (B1, B2, G1 and G2), ochratoxin A, fumonisins (B1 and B2), zearalenone, T2-toxin and sterigmatocystin was examined in the food enzyme batch used for the toxicological studies and all were below the LoQ of the applied methods

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 5 mg/kg; As = 0.3 mg/kg; Cd = 0.003 mg/kg; Hg = 0.015 mg/kg. LoQs: aflatoxins (B1, B2, G1 and G2) = 5 µg/kg each; T-2 toxin = 25 µg/kg; zearalenone = 25 µg/kg; fumonisins (B1, B2) = 100 µg/kg each; ochratoxin A = 2 µg/kg; sterigmatocystin = 100 µg/kg.