Safety evaluation of the food enzyme containing aspergillopepsin I and carboxypeptidase C activities from the non-genetically modified Aspergillus sp. strain ACP 112–311

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00246
Adopted 14-04-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme containing aspergillopepsin I and carboxypeptidase activities from a non-genetically modified A. sojae strain ACP 112–311. Additional information, requested from the applicant during the assessment process on 20 December 2023 and 31 March 2026, was received on 19 June 2024 and 9 April 2026, respectively.

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 from the fermentation broth by centrifugation followed 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) 16.1 %
Average activity/TOS 19.5 CFA3/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, particularly for wheat allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after wheat consumption

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

Antifoam agents /

Other Strains of Aspergillus species, in common with most filamentous fungi, have the capacity to produce a range of secondary metabolites. Furthermore, the production strain ACP 112–311 was shown to be capable of producing kojic acid. The presence of aflatoxins (B1, B2, G1, G2), ochratoxin A, sterigmatocystin, T-2 toxin, zearalenone, kojic acid, cyclopiazonic acid and 3-nitropropionic acid was examined in batches 1, 2 and 3 and was below the limit of detection (LoD) of the applied methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb = 0.05 mg/kg; As = 0.1 mg/kg. 29LoD yeast and moulds = 10 CFU/g. LoDs: aflatoxins (B1, B2, G1, G2), ochratoxin A = 0.5 µg/kg each; sterigmatocystin, zearalenone = 100 µg/kg each; T-2 toxin = 0.1 mg/kg; kojic acid, cyclopiazonic acid, 3-nitropropionic = 1 mg/kg each.