Safety evaluation of the food enzyme subtilisin from the genetically modified Bacillus subtilis strain DP-Ezx62

1 Report

Status Finished
EFSA question number EFSA-Q-2016-00174
Adopted 12-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme subtilisin from a genetically modified Bacillus subtilis strain DP-Ezx62. Additional information was requested from the applicant during the assessment process on 18 September 2023, 28 June 2024 and 20 June 2025 and received on 15 March 2024, 5 July 2024 and 25 June 2025

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. During the fermentation, another food enzyme is added to the medium.
Formulation Unknown
Downstream processing After the fermentation, the solid biomass is removed from the fermentation broth by centrifugation. The supernatant containing the enzyme is 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) 20.1 %
Average activity/TOS 34.8 GSU/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. The absence of recombinant DNA in the food enzyme was demonstrated.
Allergenicity the Panel considered that, under the intended conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme, particularly for natto or

muskmelon allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after natto or muskmelon consumption

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

Antifoam agents /

Other /

Pathogens

Microbiological quality indicators

Metals

Coments LoQ: Pb = 0.01 mg/kg.