Safety evaluation of the food enzyme thermolysin from the non-genetically modified Anoxybacillus caldiproteolyticus strain DP-Fzj32

1 Report

Status Finished
EFSA question number EFSA-Q-2015-00682
Adopted 20-05-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme thermolysin from G. caldoproteolyticus strain (DP-Fzj32). The dossier was updated on 8 February 2016. Additional information, requested from the applicant during the assessment phase on 4 January 2016, 27 March 2023 and 18 March 2026, was received on 8 February 2016, 27 January 2026 and 13 April 2026, respectively. Following the request for additional data sent by EFSA on 27 March 2023, the applicant requested a clarification teleconference on 18 September 2023, after which the applicant provided additional data on 27 January 2026.

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 membrane and is discarded
Average TOS (w/w) 8.2 %
Average activity/TOS 5.3 XS/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, 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 /

Pathogens

Microbiological quality indicators

Metals

Coments LoDs: Pb = 5 mg/kg; Cd, Hg = 0.5 mg/kg each; As = 3 mg/kg.