Safety evaluation of the food enzyme papain, a cysteine endopeptidase complex from the latex of Carica papaya L.

1 Report

Status Finished
EFSA question number EFSA-Q-2023-00441
Adopted 03-02-2026
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme papain from Carica papaya L. as a new food enzyme. Additional information was requested four times during the risk assessment phase.

2 Production method

Manufacturing The food enzyme is obtained by aqueous extraction from papaya latex provided by a third-party supplier
Formulation Unknown
Downstream processing After the dried latex is rehydrated, the liquid containing the enzyme is filtrated and 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. Finally, the food enzyme is spray-dried. Around 5 kg of dry latex is needed to produce 1 kg of papain. Taken into account the weight loss during drying (about 7 times), this corresponds to a yield factor of 0.03 (w/w, papain/fresh latex). The applicant provided information on the identity of the substances used in the extraction and in the subsequent downstream processing of the food enzyme.
Average TOS (w/w) 91.3 %
Average activity/TOS 904.7 TU/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA /
Allergenicity /
Antimicrobial resistance /

Antifoam agents /

Other The presence of aflatoxin B1, B2, G1, G2, deoxynivalenol, zearalenone and ochratoxin A was examined in three food enzyme batches. All were below the LoQ of the applied analytical methods.

Pathogens

Microbiological quality indicators

Metals

Coments LoQs: Pb, As, Cd = not provided; Hg = 0.005 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 1 µg/kg each; ochratoxin A = 1 µg/kg; deoxynivalenol = 100 µg/kg; zearalenone = 5 µg/kg.