

# Safety evaluation of the food enzyme cellulase from the genetically modified *Trichoderma reesei* strain AR-715

## 1 Report

**Status** Finished

**EFSA question number** [EFSA-Q-2023-00422](#)

**Adopted** 13-11-2025

**Previous authorisations** The applicant has submitted a dossier in support of the application for authorisation of the endo-1,4- $\beta$ -glucanase from the genetically modified *Trichoderma reesei* strain AR-715. Additional information was requested from the applicant during the assessment process on 24 November 2023 and received on 28 May 2025. Following the request for additional data sent by EFSA on 24 November 2023, the applicant requested a clarification teleconference on 08 January 2024, after which the applicant provided additional data on 28 May 2025.

## 2 Production method

**Manufacturing** The production strain is grown as a pure culture using a typical industrial medium in a submerged, 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 purified and concentrated, including an ultrafiltration step in which the enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded.

**Average TOS (w/w)** 21.6 %

**Average activity/TOS** 2365.0 BU/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 a risk of allergic reactions upon  dietary exposure can be excluded.

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

**Antifoam agents** /

**Other** The presence of T-2 and HT-2 toxins, deoxynivalenol and zearalenone was examined in three food enzyme batches, and all were below the LoQ of the applied method, except for deoxynivalenol, found at a level of 26 µg/kg in one of the tested batches. The Panel considered this concentration as of no concern. In addition, the presence of aflatoxins B1, B2, G1 and G2; fumonisins B1, B2 and B3; ochratoxin A; and sterigmatocystin was examined in one food enzyme batch, and all were below the LoQ of the applied method.<sup>24,25</sup> Adverse effects caused by the possible presence of other secondary metabolites are addressed by the toxicological examination of the food enzyme. The Panel considered that the information provided on the purity of the food enzyme was sufficient.

**Pathogens**

**Microbiological quality indicators**

**Metals**

**Comments** LoQs: Pb = 0.05 mg/kg; As = 0.5 mg/kg; Cd = 0.05 mg/kg; Hg = 0.05 mg/kg. LoQs: aflatoxins B1, B2, G1 and G2 = 0.01 µg/kg each; fumonisins B1, B2 and B3 = 20 µg/kg each; ochratoxin A = 2 µg/kg; sterigmatocystin = 10 µg/kg; T-2 and HT-2 toxins = 10 µg/kg each; zearalenone = 10 µg/kg; deoxynivalenol = 20 µg/kg.