Safety Assessment RP709 protease (subtilisin) produced by Bacillus licheniformis DSM 33099 (ProAct 360)

Area of research interest: Research projects

Project status: Completed Project code: RP709

Conducted by: Regulated Products Risk Assessment Unit FSA and Risk Assessment Team FSS

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Summary

An application was submitted to the Food Standards Agency in March 2021 from DSM Nutritional Products LTD ("the applicant") for the new authorisation of an additive (ProAct 360) containing protease (subtilisin), under the category of "zootechnical additives" and functional group "digestibility enhancers". The additive is proposed to be used in growing poultry, with a proposed inclusion rate of 30,000 NFP/kg of complete feed (12% moisture).

The Advisory Committee on Animal Feedingstuffs (ACAF) was asked to review the dossier and the supplementary information submitted by the Applicant, and to advise the Food Standards Agency and Food Standards Scotland (FSA/FSS) in evaluating the dossier.

The FSA/FSS concluded, based on the ACAF's advice, that the additive was correctly identified and characterised. No causes for concern were raised in this section of the dossier.

The feed additive is safe for consumers, the target animal and the environment. The additive should be considered a potential respiratory sensitiser, dermal sensitiser and eye irritant. It is not a skin irritant.

Based on data from three efficacy studies in broilers, it was concluded that the additive ProAct 360 is efficacious in growing poultry when included in feed at a dose of 30,000 NFP/kg.

The views of ACAF have been taken into account in this safety assessment which represents the opinion of the FSA/FSS.

Safety assessment

PDF

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