

EXECUTIVE SUMMARY:

IFF Health & Biosciences (IFF) are seeking approval for a “Aminopeptidase (EC 3.4.11.15)” enzyme for use as processing aid in bakery application. The enzyme is designated as “Aminopeptidase” throughout the dossier.

The enzyme Aminopeptidase is derived from a selected non-pathogenic, non-toxicogenic strain of *Trichoderma reesei* which is genetically modified to overexpress the Aminopeptidase gene from *Aspergillus clavatus*.

The enzyme is intended to be used in protein processing to produce protein hydrolysates of animal plant origin which can be further processed to provide liquid or powdered ingredients for use in a wide range of food products. Aminopeptidase can be added at the protein hydrolysis step.

In application, Aminopeptidase will be used as a processing aid where the enzyme is either not present in the final food or present in insignificant quantities having no function or technical effect in the final food.

To assess the safety of the Aminopeptidase for use in these applications, IFF vigorously applied the criteria identified in the guidelines as laid down by Food Standards Australia New Zealand (FSANZ) and U.S. Food and Drug Administration (FDA) utilising enzyme toxicology/safety data, the safe history of use of enzyme preparations from *T. reesei* and of other Aminopeptidase enzymes in food, the history of safe use of the *T. reesei* production organism for the production of enzymes used in food, an allergenicity evaluation, and a comprehensive survey of the scientific literature.

In addition, different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, Aminopeptidase is not mutagenic, clastogenic or aneugenic. Daily oral administration of Aminopeptidase up to and including a dose level of 1000 mg TOS/kg bw/day does not result in any manifestation of systemic, hematologic, or histopathologic adverse effects.

Based on a worst-case scenario that a person is consuming Aminopeptidase in food, the calculated Theoretical Maximum Daily Intake (TMDI) will be 2.26 mg TOS/kg body weight/day. This still offers a 442-fold margin of safety.

Based on the results of safety studies and other evidence, Aminopeptidase has been demonstrated as safe for its intended applications and at the proposed usage levels. Approval of this application would provide manufacturers and/or consumers with countless benefits including, flavour improvement, processing efficiencies, and improved functional or nutritional properties.