

EXECUTIVE SUMMARY:

IFF Health & Biosciences (IFF) are seeking approval for a “Thermolysin protease (EC 3.4.24.27)” enzyme for use as processing aid in protein processing. The enzyme is designated as “Thermolysin” throughout the dossier.

The enzyme Thermolysin is derived from the selected non-pathogenic, non-toxicogenic, non-genetically modified strain *Anoxybacillus caldoproteolyticus* Rokko.

The enzyme’s intended use is to catalyse the hydrolysis of peptide bonds during the manufacture and/or processing of protein containing foods. Thermolysin has broad substrate specificity, and it will efficiently hydrolyse animal and vegetable proteins including but not limited to dairy proteins, gelatin, soy proteins, wheat gluten (e.g., in brewing), fish proteins. Using Thermolysin in for protein hydrolysis imparts numerous benefits including processing efficiencies and better utilisation of resources in the processed food chain.

Thermolysin 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 Thermolysin for use in these applications, IFF vigorously applied the criteria identified in the guidelines as laid down by Food Standards Australia New Zealand (FSANZ) utilising enzyme toxicology/safety data, the safe history of use of enzyme preparations from *A. caldoproteolyticus* and of other thermolysin enzymes in food, the history of safe use of the *A. caldoproteolyticus* 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, Thermolysin from *A. caldoproteolyticus* Rokko is not mutagenic, clastogenic or aneugenic. Daily oral administration of Thermolysin up to and including a dose level of 21.50 mg total protein/kg bw/day corresponding to 337.50 mg TOS /kg/day, respectively does not result in any manifestation of systemic, hematologic, or histopathologic adverse effects.

Based on a worst-case scenario that a person is consuming Thermolysin in food, the calculated Theoretical Maximum Daily Intake (TMDI) will be 1.83 mg TOS/kg body weight/day. This still offers a 184-fold margin of safety.

The results of safety studies and other evidence demonstrate that Thermolysin from *A. caldoproteolyticus* Rokko is safe for its intended applications and at the proposed usage levels. Approval of this application would provide manufacturers and/or consumers with countless benefit including, flavour improvement, processing efficiencies, improved physical properties, improved nutritional quality, and utilisation of food waste streams.