

EXECUTIVE SUMMARY:

IFF Health and Biosciences (IFF) is seeking approval for an “Alpha-amylase (EC 3.2.1.1)” enzyme to be used as processing aid in carbohydrate processing. The enzyme is designated as “Alpha-amylase” throughout the dossier.

The enzyme Alpha-amylase is derived from a selected non-pathogenic, non-toxigenic strain of *Bacillus licheniformis* which is genetically modified to express a protein engineered alpha-amylase gene.

The enzyme is intended for use in carbohydrate processing to produce glucose syrups and other starch hydrolysates, and in potable alcohol production. The technological benefits of using Alpha-amylase in the production of glucose syrups and other starch hydrolysates (carbohydrate processing) include more efficient liquefaction, reducing the viscosity of gelatinised starch and increasing in soluble dextrans and oligosaccharides. The technological benefits of using Alpha-amylase to produce distilled alcohol are more efficient liquefaction, energy efficiency, viscosity reduction, and generally improved processing.

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

To assess the safety of the Alpha-amylase 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 *B. licheniformis* and of other Alpha-amylase enzymes in food, the history of safe use of the *B. licheniformis* production organism for the production of enzymes used in food, an allergenicity evaluation, and a comprehensive survey of the scientific literature.

The safety of the food enzyme from *B. licheniformis* has been assessed using toxicology studies conducted on earlier strains of the IFF *B. licheniformis* Safe Strain Lineage. The most suitable standard collection of toxicological tests from the Safe Strain Lineage was identified to support the safety of the food enzyme object of the current dossier. The toxicological tests showed the following results:

1. Negative as a mutagen, clastogen, and aneugen in genotoxicity studies; and
2. 90-day oral toxicity on rats: Under the conditions of the study, the no-observed adverse-effect-level (NOAEL) was established at the high dose 500 mg total organic solids (TOS)/kg body weight/day (corresponding to 272 mg TP/kg bw/day).

Based on a worst-case scenario consumption estimates for Alpha-amylase in the designated applications, the calculated Theoretical Maximum Daily Intake (TMDI) will be 1.14 mg TOS/kg body weight/day. This offers a 439-fold margin of safety.

Based on the results of safety studies and other evidence, Alpha-amylase 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 benefits of mentioned above.