

EXECUTIVE SUMMARY:

DuPont Nutrition & Biosciences (DuPont N&B) is seeking approval for a “Maltogenic α -amylase (EC 3.2.1.133)” enzyme for use as processing aid in bakery, potable alcohol, brewing and starch processing applications. The enzyme is designated as “MAA” or “Amylase MAA” throughout the dossier.

The enzyme MAA is derived from a selected non-pathogenic, non-toxigenic strain of *Bacillus licheniformis* which is genetically modified to express the maltogenic α -amylase gene from *G. stearothermophilus*.

The enzyme is intended for use in baking, potable alcohol, brewing and starch processing. In all of these applications the MAA hydrolyses (1 \rightarrow 4)-alpha-D-glucosidic linkages in polysaccharides, to remove successive alpha-maltose residues from the non-reducing ends of the chains.

In these applications, MAA 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 MAA for use in these applications, Dupont N&B 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 MAA 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.

In addition, different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, MAA is not mutagenic or clastogenic or aneugenic. Daily oral administration of MAA up to and including a dose level of 55.6 protein/kg bw/day or 80 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 MAA, the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.266mg TOS/kg body weight/day. This still offers a 300-fold margin of safety.

Based on the results of safety studies and other evidence MAA 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 improving the quality of baked foods, higher brewing yields and flexibility in raw material choice, and efficiencies in potable alcohol production.