EXECUTIVE SUMMARY:

DuPont Nutrition & Biosciences (DuPont N&B) is seeking approval for a "β-Galactosidase (EC 3.2.1.23)" enzyme for use as processing aid in dairy food applications. The enzyme is designated as "β-Galactosidase or lactase" throughout the dossier, and also referred to as 'lactase' or 'Sweet Dream' in some references. The enzyme β-Galactosidase is derived from a selected non-pathogenic, non-toxigenic strain of *Bacillus subtilis* which is genetically modified to overexpress the β-Galactosidase gene from *Lactobacillus delbrueckii bulgaricus.*

The enzyme is intended for use in dairy processing for production of lactose reduced dairy products including but not limited to milk, yogurt, cheese. In dairy products the β-Galactosidase catalyses the hydrolysis of terminal non-reducing β-D-galactose residues in β-D-galactosides. The lactose in these dairy products is hydrolysed into galactose and glucose.

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

To assess the safety of the β-Galactosidase 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. subtilis* and of other β-Galactosidase enzymes in food, the history of safe use of the *B. subtilis* 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, β-Galactosidase is not mutagenic or clastogenic. Daily oral administration of β-Galactosidase 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. This NOAEL is equivalent to 752 mg total protein/kg body weight/day in males and females.

Based on a worst-case scenario that a person is consuming β-Galactosidase from baking application, the calculated Theoretical Maximum Daily Intake (TMDI) will be 11.29 mg TOS/kg body weight/day. This still offers a 125.5-fold margin of safety.

Based on the results of safety studies and other evidence, β-Galactosidase 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 facilitating the lowering of lactose content in many processed dairy-based food applications.