EXECUTIVE SUMMARY:

DuPont Nutrition & Biosciences (N&B) is seeking approval for a "glucoamylase (EC 3.2.1.3)" enzyme for use as processing aid in bakery, brewing, potable alcohol, and starching processing. The enzyme is designated as "Glucoamylase" throughout the dossier.

The enzyme Glucoamylase is derived from a selected non-pathogenic, non-toxigenic strain of *Trichoderma reesei* which is genetically modified to overexpress the glucoamylase gene from *T. reesei.*

The enzyme is intended for use in baking, brewing, potable alcohol production and starch processing. In all these applications, glucoamylase convert starchy substrate to simple sugars, which can increase fermentation efficiency, and/or be converted to something sweeter in the case of starch processing. In all of these applications, Glucoamylase 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 Glucoamylase 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) utilizing enzyme toxicology/safety data, the safe history of use of enzyme preparations from *T. reesei* and of other Glucoamylase 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.

The safety of the food enzyme from *T. reesei* has been assessed using toxicology studies conducted on earlier strains of the DuPont *T. reesei* Safe Strain Lineage. The most suitable standard package 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:

- Ames test: no mutagenic activity under the given test conditions
- Chromosomal aberrations: no clastogenic activity under the given test conditions
- 90-day oral toxicity on rats: The No Observed Adverse Effect Level (NOAEL) is 1000 mg total organic solid (TOS)/kg bw/day (equivalent to 808 mg total protein/kg bw/ day), which is the high dose in the study

Based on a conservative assumption and a highly exaggerated value consumption data, the NOAEL still offers a 314 fold Margin of Safety.

Based on the results of safety studies and other evidence, Glucoamylase 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 process of bakery, brewing, potable alcohol production and starch processing, lowering the manufacturing cost, and improving quality of final foods.