



EXECUTIVE SUMMARY:

DuPont Industrial Biosciences (IB) is seeking approval for a “Xylanase (EC 3.2.1.8)” enzyme for use as processing aid in bakery application. The enzyme is designated as “Xylanase” throughout the dossier.

The enzyme Xylanase is derived from a selected non-pathogenic, non-toxigenic strain of *Trichoderma reesei* which is genetically modified to overexpress the xylanase gene from *Aspergillus niger* (*var. tubingensis*).

The enzyme is intended for use in baking for the production of bread, buns, cakes, sweet goods and tortillas and other bakery products. In baking, Xylanase performs its technological function during the dough or batter handling to improve the dough stability and dough handling properties.

In all of these applications, Xylanase 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 Xylanase for use in these applications, Dupont IB 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 xylanase 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.

In addition, different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, Xylanase is not mutagenic, clastogenic or aneugenic. Daily oral administration of Xylanase up to and including a dose level of 1000 mg total protein/kg bw/day or 1214.4 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 Xylanase from baking application, the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.488 mg TOS/kg body weight/day. This still offers a 2489 fold margin of safety.

Based on the results of safety studies and other evidence, Xylanase 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 baking process, lowering the manufacturing cost, and improving quality of final foods.