

EXECUTIVE SUMMARY:

IFF Health and Biosciences (IFF) is seeking approval for a “Xylanase (EC 3.2.1.8)” enzyme for use as a processing aid in potable alcohol production and starch processing applications. The enzyme is designated as “Xylanase” throughout the dossier.

The enzyme/food Xylanase is derived from a selected non-pathogenic, non-toxicogenic strain of *Trichoderma reesei* (formerly *Trichoderma longibrachiatum*) with reduced viscosity (LVS) during fermentation, which is genetically modified by IFF to produce a variant xylanase from *Fusarium verticillioides*.

The enzyme is intended for use in starch processing to improve gluten and starch purity and yield. It is also used to facilitate the process of raw materials when dealing with Potable alcohol production and alcohol fermentation.

In all 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, 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 *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 967.8 mg total protein/kg bw/day or 1000 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 0.011 mg TOS/kg body weight/day. This still offers a 90,909-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 production potable alcohol and in starch processing by lowering manufacturing costs and improving yields and purity.