EXECUTIVE SUMMARY:

IFF Health & Biosciences (IFF) is seeking approval for a "Dextransucrase (EC 2.4.1.5)" enzyme for use as processing aid in the conversion of the sucrose in foods to oligosaccharides, polysaccharides. The enzyme is designated as "Dextransucrase" throughout the dossier.

The enzyme Dextransucrase is derived from a selected non-pathogenic, non-toxigenic strain of *Bacillus subtilis* which is genetically modified to overexpress the dextransucrase gene from *Streptococcus salivarius.*

The enzyme is intended for use in sucrose containing foods. Dextransucrase performs its technological function (breakdown of sucrose into oligosaccharides, polysaccharides) during the food manufacturing process only with the result being reduced sugar content and improved texture.

In all of these applications, Dextransucrase 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 Dextransucrase 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 *B. subtilis* and of other dextransucrase 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, Dextransucrase is not mutagenic, clastogenic or aneugenic. Daily oral administration of Dextransucrase 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.

Based on a worst-case scenario that a person is consuming Dextransucrase; the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.64 mg TOS/kg body weight/day. This still offers a 1563-fold margin of safety.

Based on the results of safety studies and other evidence, Dextransucrase 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 reduced sugar processed foods with potentially improved texture.