EXECUTIVE SUMMARY:

Danisco New Zealand Ltd (IFF) is seeking approval for a "an alpha-glucosidase (EC 3.2.1.20)" enzyme for use as processing aid in brewing application. The enzyme designated as "an α-glucosidase" or "Alpha-glucosidase" throughout the dossier is already approved for use in other food applications by FSANZ.

In October 2019, following an evaluation of DuPont's Application A1169, FSANZ recommended to the Ministerial Forum on Food Regulation this enzyme be approved for use in the manufacture and/or processing of potable alcohol, lysine, organic acids, monosodium glutamate and other biochemicals, and isomalt-oligosaccharides (IMO) and other sweeteners. The Ministerial Forum granted approval in these food applications, and this was subsequently Gazetted to the Joint Australia New Zealand Food Standards Code in January 2020.

The enzyme in this application is the identical to the α-glucosidase in A1169, derived from the same selected non-pathogenic, non-toxigenic strain of *Trichoderma reesei* which has been genetically modified to overexpress the Alpha-glucosidase gene from *Aspergillus niger.*

The enzyme as it is presented in this application is intended for use in brewed beverages. In brewing, Alpha-glucosidase is used by adding it to the mash, to will create IMOs and reduce the share of fermentable sugars in wort. Further to this, by adding Alpha-glucosidase to fermentation, it will eventually break down IMOs and limit dextrins during the fermentation, and this way increase the conversion from starch to alcohol.

In brewing, Alpha-glucosidase is used as a processing aid where the enzyme is either not present in the final beverage or present in insignificant quantities having no function or technical effect in the final beverage.

To assess the safety of the Alpha-glucosidase for use in this application, IFF H&B vigorously applied the criteria identified in the guidelines as laid down by Food Standards Australia New Zealand (FSANZ) utilising enzyme toxicology/safety data, the safe history of use of enzyme preparations from *T. reesei* and of other Alpha-glucosidase 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 A1169 different endpoints of toxicity were investigated, and the results are evaluated and assessed in this document. In genotoxicity studies, Alpha-glucosidase is not mutagenic, clastogenic or aneugenic.

Based on a worst-case scenario that a person is consuming Alpha-glucosidase from beer products, the calculated Theoretical Maximum Daily Intake (TMDI) will be 0.255 mg TOS/kg body weight/day. This submission describes that this TMDI still offers a 110.6-fold margin of safety.

Based on the results of safety studies and other evidence, Alpha-glucosidase has been demonstrated as safe for its intended applications, including brewing and at the proposed usage levels. Approval of this application would provide manufacturers and/or consumers with benefits of facilitating the brewing process and providing differentiated brewed beer products.