EXECUTIVE SUMMARY:

This application seeks to amend Schedule 18—Processing aids of the Australia New Zealand Food Standards Code to permit a glucoamylase enzyme preparation (EC 3.2.1.3) produced by a genetically modified strain of *Trichoderma reesei* (production strain *T. reesei* GICC03474). The enzyme, designated Glucoamylase A, is intended for use as a processing aid in brewing, starch and carbohydrate processing (including the manufacture of corn sweeteners such as high fructose corn syrup), and potable alcohol production.

Schedule 18 is proposed to be amended to include the genetically modified strain *T. reesei* GICC03474, expressing a glucoamylase gene from *Fusarium verticillioides*, as a permitted source microorganism for glucoamylase (EC 3.2.1.3). The application is submitted for assessment under the General Procedure.

Glucoamylase A (systematic name: 4-alpha-D-glucan glucohydrolase) catalyses the hydrolysis of terminal (1→4)-linked alpha-D-glucose residues from non-reducing ends of polysaccharides, releasing glucose. It is produced by submerged fermentation and formulated as a liquid food-grade enzyme preparation that complies with internationally recognised purity specifications for enzymes used in food processing. The production organism is not present in the final commercial enzyme product.

The enzyme is used to saccharify liquefied starch and maximise conversion of starchy substrates to fermentable carbohydrates in brewing, sweetener manufacture and potable alcohol production. Glucoamylase A functions as a processing aid and performs its technological role during food processing only. Depending on the application, the enzyme is inactivated or removed through downstream processing steps such as heating, clarification, filtration, purification and distillation, such that it is not present or is present only as inactive residues in negligible amounts in the final food.

The production organism *Trichoderma reesei* has a long history of safe use in industrial enzyme manufacture and is considered non-pathogenic and non-toxigenic. The genetic modifications introduced into the production strain are well characterised and stable, with no antibiotic resistance markers or bacterial vector DNA present. Safety evaluation of Glucoamylase A included bioinformatic analyses for toxin and allergenicity potential, genotoxicity studies, and a 90-day oral toxicity study in rats. The enzyme was not mutagenic, clastogenic or aneugenic, and a no-observed-adverse-effect level (NOAEL) of 1000 mg TOS/kg body weight/day was established.

Dietary exposure was conservatively estimated using the Budget Method, resulting in a theoretical maximum daily intake of 0.33 mg TOS/kg body weight/day and a margin of safety of 3579. Glucoamylase A has also been assessed and authorised for use as a processing aid in other jurisdictions, including the United States, Brazil and Mexico.

Based on the technical, toxicological and dietary exposure information provided, Glucoamylase A produced by *T. reesei* GICC03474 is considered safe for its intended use as a processing aid. This application therefore requests inclusion of this enzyme source in Schedule 18—Processing aids of the Australia New Zealand Food Standards Code.