EXECUTIVE SUMMARY

The present application seeks to amend Schedule 18 - Processing Aids of the Australia New Zealand Food Standards Code (the Code) to approve a cellulase enzyme preparation produced by AB Enzymes GmbH.

Proposed change to Standard 1.3.3 - Processing Aids

The table **Schedule 18—9(3) Permitted processing aids — various purposes (section 1.3.3—11)**, is proposed to be amended to include a genetically modified strain of *Trichoderma reesei* expressing a cellulase from *Aspergillus niger* as permitted source for **Cellulase** (EC 3.2.1.4). This application is submitted under a general assessment procedure.

Description of Enzyme Preparation

The main activity of the *T. reesei* AR-852 enzyme preparation is a cellulase (IUBMB 3.2.1.4). Cellulase chemical reaction is the endohydrolysis of (1 → 4)-beta-D-glucosidic linkages in cellulose, lichenin and cereal beta-D-glucans, the initial breakdown produces oligosaccharides.

The enzyme is produced by submerged fermentation of a genetically modified strain of *T. reesei* expressing a cellulase gene from *A. niger*.

Use of the Enzyme and Benefits

The enzyme is to be used in the production of bakery products, brewing and malting.

The benefits of hydrolysis with the help of cellulases in baking processing are:

- Ensured a uniform structure and increased volume
- Improved crumb structure of the bakery product
- Reduced the roughness of dough

The benefits of hydrolysis with the help of cellulase in brewing and malting processing are:

- Quick run-off due to reduced wort viscosity
- Increased wort lautering and beer filtration
- Reduced haze formation

- Less process delay, increasing brewhouse efficiency

Safety Evaluation

The safety of the cellulase enzyme and the production organism, genetically modified *Trichoderma reesei* AR-852 have been thoroughly assessed:

- Strains from the *T. reesei* microorganism are generally recognized as safe, with long history of safe use and are recognized and permitted to produce a variety of enzymes
- The enzyme product from *T. reesei* AR-852 complies with JECFA specifications for chemical and microbiological purity of food enzymes
- The product is free of production strain and production strain DNA
- The toxicological studies conducted showed negative findings demonstrating the AR-852 production strain to be non-mutagenic, to not induce structural and/or numerical chromosomal damage, and to not cause toxigenic
- With the NOAEL value of 1000 mg TOS/kg bw/day for the cellulase and Total Theoretical Maximum Daily Intake (TMDI) of the food enzyme of 0.099 mg TOS/kg body weight/day, a Margin of Exposure (MOE) value of 10,152 was calculated
- Allergenicity and toxin analysis assessment on the amino acid sequence of food enzyme show no food allergenicity or toxicity concern
- The cellulase has an established history of safe use. The toxicological safety of the notified cellulase has been evaluated by the following authorities with positive opinions: Brazilian Health Regulatory Agency (ANVISA), European Food Safety Authority (EFSA), Danish Veterinary and Food Administration, France's Ministère de L'Agriculture et de la Souveraineté Alimentaire Direction générale de l'alimentation, Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS) and USA GRAS.

Conclusion

Based on the safety evaluation, AB Enzymes GmbH respectfully request the inclusion of **Cellulase** (EC 3.1.1.3) from *Aspergillus niger* expressed in a genetically modified strain of *Trichoderma reesei* AR-852 in the table of **Schedule 18—9(3) Permitted processing aids — various purposes (section 1.3.3—11)**.