# 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 glucoamylase enzyme preparation produced by Novozymes.

**Proposed change to Australia New Zealand Food Standards Code – Schedule 18—Processing aids**

Schedule 18—Processing aids is proposed to be amended to include a genetically modified strain of *Aspergillus niger* expressing a glucoamylase from *Gloeophyllum sepiarium* as permitted source for glucoamylase.

The application is applied for assessment by the general procedure.

**Description of enzyme preparation**

The enzyme is a glucan 1,4-alpha-glucosidase (EC 3.2.1.3), commonly known as glucoamylase.

Glucoamylase catalyses the hydrolysis of (1→4)-α- as well as (1→6)-α-linkages in the starch polysaccharides amylose and amylopectin.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing a glucoamylase from *Gloeophyllum sepiarium*.

The glucoamylase enzyme preparation is available as a liquid preparation complying with the JECFA recommended purity specifications for food-grade enzymes.

The producing microorganism, *Aspergillus niger*, is absent from the commercial enzyme product.

**Use of the enzyme**

The glucoamylase enzyme preparation is used as a processing aid in brewing processes, distilled alcohol processes, and starch processing for glucose syrups production and other starch hydrolysates, and baking processes. Generally, glucoamylase degrade starch into D-glucose.

- during brewing processes the glucoamylase degrades starch into fermentable sugars.
- during beverage alcohol (distilling) processes the glucoamylase is used in order to degrade gelatinised starch and dextrins into glucose and other fermentable sugars.
- during starch processing to produce syrups the glucoamylase degrades polysaccharides into glucose.
- during baking and other cereal-based processes the glucoamylase degrades starch and dextrins into glucose that can be fermented by yeast.

**Benefits**

The benefits of the action of the glucoamylase in brewing processes are:

- More uniform and predictable production process and brewing yield including the possibility to control the desired level of fermentable sugars at every production

The benefits of the action of the glucoamylase in distilled alcohol production are:

- Efficient degradation of dextrins and production of fermentable sugar
- High alcohol yields due to a more complete conversion of starch and thereby less use of raw materials
- Reduced risk of infection due to high operating temperature (65°C)
- Reduced risk of infection due to low operating pH

The benefits of the action of the glucoamylase in starch processing for glucose syrups production and other starch hydrolysates are:

- Efficient degradation of dextrins and production of glucose
- Reduced risk of contamination because the enzyme can be used at high operating temperature
- Stable process allowing for variations in temperature

The benefits of the action of the glucoamylase in baking and other cereal-based processes are:

- Reduced baking time and yeast boosting
- Uniform and slightly increased volume and enhanced crust colour of the bakery product
- More uniform and predictable production of glucose
- Improved fermentability
- Uniform colour

**Safety evaluation**

The safety of the production organism and the enzyme product has been thoroughly assessed:

- The production organism has a long history of safe use as production strain for food-grade enzyme preparations and is known not to produce any toxic metabolites.
- The genetic modifications in the production organism are well-characterised and safe and the recombinant DNA is stably integrated into the production organism and unlikely to pose a safety concern.
- The enzyme preparation complies with international specifications ensuring absence of contamination by toxic substances or noxious microorganisms
- Sequence homology assessment to known allergens and toxins shows that oral intake of the glucoamylase does not pose food allergenic or toxic concern.
- Two mutagenicity studies *in vitro* showed no evidence of genotoxic potential of the enzyme preparation.
- An oral gavage administration study in rats for 13-weeks showed that all dose levels were generally well tolerated and no evidence of toxicity.

Furthermore, the safety of the glucoamylase preparation was confirmed by external expert groups, as follows:

- Denmark: The enzyme preparation was safety assessed resulting in the authorisation of the enzyme product by the Danish Veterinary and Food Administration.

**Conclusion**

Based on the Novozymes safety evaluation, confirmed by the above-mentioned body, we respectfully request the inclusion of the glucoamylase in Schedule 18—Processing aids.