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 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 cellulase from *Trichoderma reesei* as permitted source for cellulase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a cellulase (EC 3.2.1.4), commonly known as cellulase.

Cellulase catalyses the hydrolysis of (1→4)- β -D-glucosidic linkages in cellulose, lichenin and cereal β -D-glucans.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing a cellulase from *Trichoderma reesei*.

The cellulase 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 cellulase enzyme preparation is used as a processing aid in brewing processes and distilled alcohol production. Generally, cellulases hydrolyse (1,4)-beta-D-glucosidic linkages in cellulose, lichenin and cereal beta-D-glucans which results in the formation of mono- and oligosaccharides composed of glucose residues.

- during brewing processes the cellulase degrades the polymeric beta-glucans present in the endosperm cell wall of grain, into smaller less viscous molecules, thereby lessening the filtration time and reducing haze problems.
- during beverage alcohol (distilling) processes the cellulase is used in order to degrade gelatinised starch and dextrins into glucose and other fermentable sugars.

Benefits

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

- Increase flexibility in the choice of raw materials
- Increase beer filtration rate and reduce need for beer filtration aids

- Improve beer colloid stability as result of reduced haze caused by beta-D-glucans
- Higher brewing yield due to the improved processing, and thereby less use of raw materials
- Decrease wort viscosity and beer turbidity

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

- Increase flexibility in the choice of raw materials
- Better processing (solid/liquid separation)
- Reduction in fouling in the heat exchangers and distilling equipment
- Decrease viscosity
- Potential higher alcohol yield as a result of improved processing, and thereby less use of raw materials

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 cellulase 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 cellulase preparation was confirmed by external expert groups, as follows:

- Mexico: Based on a dossier submitted by Novozymes, the Mexican food authorities, COFEPRIS, have approved the enzyme.

Conclusion

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