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 beta-amylase enzyme preparation produced by Novozymes A/S.

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 *Bacillus licheniformis* expressing a beta-amylase from *Bacillus flexus* as permitted source for beta-amylase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a beta-amylase (EC 3.2.1.2).

Beta-amylases catalyse the hydrolysis of (1→4)-α-D-glucosidic linkages in polysaccharides so as to remove successive maltose units from the non-reducing ends of the chains.

The enzyme is produced by submerged fermentation of an *Bacillus licheniformis* microorganism expressing a beta-amylase from *Bacillus flexus*.

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

The producing microorganism, *Bacillus licheniformis*, is absent from the commercial enzyme product.

Use of the enzyme

The beta-amylase preparation is used as a processing aid in starch processes to produce syrups where it degrades starch into maltose.

Benefits

The benefits of the action of the beta-amylase in starch processing are:

- More consistent and efficient production of maltose syrups from starch compared to the use of enzymes present in malt

- Consistent maltose content in the syrup product
- Reduced risk of contamination because the enzyme can be used at high operating temperature
- Stable process allowing for variations in pH and temperature

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 beta-amylase 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 feeding 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 beta-amylase 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.
- France: The enzyme is included in the French positive list for processing aids, including food enzymes (The French order of October 19, 2006 on use of processing aids in the manufacture of certain foodstuff), as amended.
- Brazil: The enzyme was evaluated, approved and included in the Brazilian positive list – RDC 26/2009.

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

Conclusion

Based on the Novozymes A/S safety evaluation (confirmed by the above-mentioned bodies), we respectfully request the inclusion of the beta-amylase in Schedule 18—Processing aids.