

# 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 subtilisin 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 subtilisin from *Pyrococcus furiosus* as permitted source for subtilisin.

The application is applied for assessment by the general procedure.

### ***Description of enzyme preparation***

The enzyme is a subtilisin (EC 3.4.21.62).

Subtilisin hydrolyses peptide bonds in proteins with broad specificity.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing a subtilisin from *Pyrococcus furiosus*.

The subtilisin 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 subtilisin preparation is used as a processing aid in potable alcohol production. During production subtilisin hydrolyses protein peptide bonds. In potable alcohol production the subtilisin is used in order to degrade proteins into peptides and amino acids.

### ***Benefits***

The benefits of the action of the subtilisin in potable alcohol production:

- lowering viscosity
- release of peptides and amino acids used as nutrients for yeast for fast and complete fermentation

## **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 subtilisin does not pose food allergenic or toxic concern.
- A mutagenicity study *in vitro* showed no evidence of genotoxic potential of the enzyme preparation.
- An oral feeding study in rats for 14 days showed that all dose levels were generally well tolerated and no evidence of toxicity.

## **Conclusion**

Based on the Novozymes A/S safety evaluation, we respectfully request the inclusion of this enzyme in Schedule 18—Processing aids.