

## 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 xylanase 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 *Bacillus licheniformis* expressing a xylanase from *Chryseobacterium cucumeris* (*Chryseobacterium sp-10696*) as permitted source for xylanase.

The application is applied for assessment by the general procedure.

### Description of enzyme preparation

The enzyme is an endo-1,4- $\beta$ -xylanase (EC 3.2.1.8), commonly known as xylanase.

Xylanase catalyses the hydrolysis of (1 $\rightarrow$ 4)- $\beta$ -D-xylosidic linkages in xylans.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing a xylanase from *Chryseobacterium cucumeris* (*Chryseobacterium sp-10696*).

The xylanase 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 xylanase enzyme preparation is used as a processing aid in distilled alcohol production and the production of starch and gluten fractions. Generally, xylanases hydrolyse xylosidic linkages in xylans, including arabinoxylan present in grains for the production of several products, e.g., gluten, starch, potable alcohol, beer, and fats and oils.

- during beverage alcohol (distilling) processes the xylanase is used in order to degrade gelatinised starch and dextrans into glucose and other fermentable sugars.
- during the production of starch and gluten fractions the xylanase degrades xylans, including arabinoxylans (also called pentosans), into oligosaccharides of variable.

### Benefits

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

- Higher solid concentration during mashing (energy efficiency).
- Improved heat exchange.
- Improved centrifugal separation.
- Improved mass transfer in fermentation.

- Increased fermentable sugars from beta glucan hydrolysis.

The benefits of the action of the xylanase in the production of starch and gluten fractions are:

- Higher gluten and starch yield due to efficient targeted degradation of the highly branched arabinoxylans of the cereal/grain fibre.
- More efficient removal of trapped water from the fibre, resulting in reduced evaporation load, leading to energy savings.
- Smoother operations and increased plant capacity.

### 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 xylanase does not pose food allergenic or toxic concern.
- Two mutagenicity studies 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 xylanase 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 preparation was evaluated and approved by the competent authorities in France (Sous-direction de la sécurité sanitaire des aliments, Bureau des établissements et produits des industries alimentaires spécialisées).

### Conclusion

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