

## **Xylanase from *Trichoderma reesei***

**An application to amend the *Australia New Zealand Food Standards Code* with  
a xylanase preparation produced by a genetically modified strain of  
*Trichoderma reesei***

## 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 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 *Trichoderma reesei* expressing a xylanase from *Talaromyces leycettanus* 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.

Xylanases catalyse the endo-hydrolysis of 1,4- $\beta$ -D-xylosidic linkages in xylan.

The enzyme is produced by submerged fermentation of a *Trichoderma reesei* microorganism expressing a xylanase from *Talaromyces leycettanus*.

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

The producing microorganism, *Trichoderma reesei*, is absent from the commercial enzyme product.

### ***Use of the enzyme***

The xylanase enzyme preparation is used as a processing aid in processing of grains, potable alcohol production, brewing, and processing of fats and oils. 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

### ***Benefits***

The benefits of the action of the xylanase in processing of grains are:

- Higher gluten and starch yield due to efficient and targeted degradation of the highly branched arabinoxylans of the grain fibre.

- More efficient removal of trapped water from the fibre, resulting in reduced evaporatin load, leading to energy savings.
- Smoother operations and increased plant capacity.
- Overall reduced net grain cost.

The benefits of the action of the xylanase in potable 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 brewing are:

- Faster and more predictable lautering or mash filtration.
- Increased flexibility in the choice of raw materials.
- Higher brewing yield due to the improved processing, and thereby less use of raw materials.
- Faster beer filtration.
- Reduced consumption of beer filtration aids (e.g. kieselguhr).

The benefits of the action of the xylanase the processing of fats and oils are:

- Higher oil extraction ratio, providing more oil from same amount of raw material (fresh fruit bunches).
- Reduced viscosity in the pressing and separation phase.
- Reduced oil losses.
- Reduced water consumption.
- Reduced waste and thereby less waste handling.

### **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 *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 xylanase preparation was confirmed by external expert groups, as follows:

- Brazil: The enzyme was evaluated, approved and included in the Brazilian positive list – RDC 26/2009.
- Denmark: The enzyme preparation was safety assessed resulting in the authorisation of the enzyme product by the Danish Veterinary and Food Administration.
- 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 xylanase in Schedule 18—Processing aids.