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## 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 glucoamylase 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 *Aspergillus niger* expressing a glucoamylase from *Trametes cingulata* as permitted source for glucoamylase.

The application is applied for assessment by the general procedure.

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

The enzyme is a glucan 1,4-alpha-glucosidase (EC 3.2.1.3), commonly known as glucoamylase.

Glucoamylases catalyse the hydrolysis of 1,4-alpha and 1,6-alpha-D-glucosidic linkages in starch polysaccharides.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing a glucoamylase from *Trametes cingulata*.

The glucoamylase 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 glucoamylase preparation is used as a processing aid in starch processing and beverage alcohol (distilling) processes. Generally, glucoamylases degrade starch into D-glucose.

- During starch processing to produce syrups the glucoamylase degrades polysaccharides into glucose.
- In beverage alcohol (distilling) processes the glucoamylase is used in order to degrade gelatinised starch and dextrans into glucose and other fermentable sugars.

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## **Benefits**

The benefits of the action of the glucoamylase in starch processing are:

- Efficient degradation of dextrans and production of glucose
- Reduced risk of contamination, because the enzyme can be used at high operating temperature
- Stable process allowing for variations in temperature

The benefits of the action of the glucoamylase in beverage alcohol (distilling) processes:

- Efficient degradation of dextrans and production of fermentable sugars
- High alcohol yields due to a more complete conversion of starch and thereby less use of raw materials
- Reduced risk of contamination, because the enzyme can be used at high operating temperature and low operating pH

## **Safety evaluation**

The safety of the strain 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 strain 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 glucoamylase 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 glucoamylase 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.

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**Conclusion**

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