
EXECUTIVE SUMMARY

The present application seeks to amend Schedule 18—Processing aids of the Australia New Zealand Food Standards Code (the Code) to approve an alpha-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 *Aspergillus niger* expressing an alpha-amylase from *Rhizomucor pusillus* as permitted source for alpha-amylase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is an alpha-amylase (EC 3.2.1.1).

Alpha-amylases catalyse the hydrolysis of 1,4-alpha-D-glucosidic linkages in starch polysaccharides.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing an alpha-amylase from *Rhizomucor pusillus*.

The alpha-amylase 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 alpha-amylase preparation is used as a processing aid during starch processing and beverage alcohol (distilling) processes. Generally, alpha-amylases degrade starch into maltose, glucose and dextrans.

- During starch processing to produce syrups the alpha-amylase degrades starch into dextrans.
- In beverage alcohol (distilling) processes the alpha-amylase converts liquified starch into fermentable sugars.

Benefits

The benefits of the action of the alpha-amylase during starch processing are:

- Efficient degradation of starch and production of the suited substrate (dextrins) for further processing and production of syrups.

The benefits of the action of the alpha-amylase in beverage alcohol (distilling) processes:

- Higher ethanol yields
- Fast fermentation
- Efficient production of the suited substrate (dextrins) for saccharification
- Efficient production of fermentable sugars for fermentation

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

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.