

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 mannanase 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 *Aspergillus niger* expressing a mannanase from *Evansstolkia leycettanus* as a permitted source for mannanase.

The application is submitted for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a mannanase (EC 3.2.1.78), commonly known as mannanase.

Mannanase catalyses the random hydrolysis of 1,4-beta-mannosidic linkages in the mannan polymer and other hemicelluloses.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing a mannanase from *Evansstolkia leycettanus*.

The mannanase 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

In principle, the enzymatic conversion of mannans and other hemicelluloses with the help of the food enzyme can be used in the processing of all food raw materials which naturally contain this substrate. The food enzyme that is the subject of this dossier is typically used in the following food manufacturing processes:

- During processing of coffee beans for instant coffee production, the enzyme object of the present dossier is typically used to hydrolyse mannans and other hemicelluloses during extraction in order to increase extraction yield.

Benefits

The benefit of the action of the food enzyme in coffee processing is an increased extraction yield during instant coffee production.

Safety evaluation

The safety of the production organism and the enzyme product have 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 mannanase 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 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 mannanase 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.

Conclusion

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