

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 acetolactate decarboxylase 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 an acetolactate decarboxylase from *Bacillus brevis* as permitted source for acetolactate decarboxylase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is an acetolactate decarboxylase (EC 4.1.1.5), commonly known as ALDC.

Acetolactate decarboxylase catalyses the decarboxylation of alpha-acetolactate to acetoin formed by yeast during fermentation.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing an acetolactate decarboxylase from *Bacillus brevis*.

The acetolactate decarboxylase 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 acetolactate decarboxylase enzyme preparation is used as a processing aid in brewing processes and beverage alcohol (distilling) processes. Generally, acetolactate directly into acetoin, thereby by-passing the formation of diacetyl (unwanted due to off-flavour formation), which is formed during yeast fermentation.

- during brewing processes and beverage alcohol (distilling) processes, the acetolactate decarboxylase converts acetolactate into acetoin.

Benefits

The benefits of the action of the acetolactate decarboxylase in brewing processes and beverage alcohol (distilling) processes are:

- Reduced formation of diacetyl during fermentation and thereby a reduction of the off-flavours caused by this substance
- A faster maturation process and thereby a shorter production time, e.g. to meet peak season capacity demands.

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 acetolactate decarboxylase 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 acetolactate decarboxylase 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 body, we respectfully request the inclusion of the acetolactate decarboxylase in Schedule 18—Processing aids.