

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 triacylglycerol lipase enzyme preparation produced by Chr. Hansen.

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 *Komagataella phaffii* expressing a triacylglycerol lipase from *Yarrowia lipolytica* as a permitted source for triacylglycerol lipase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a triacylglycerol lipase (EC 3.1.1.3), commonly known as lipase.

The lipase catalyses the hydrolysis of triglycerides, diglycerides and monoglycerides to yield free fatty acids and monoglycerides, diglycerides and glycerol.

The enzyme is produced by submerged fermentation of a *Komagataella phaffii* microorganism expressing a lipase from *Yarrowia lipolytica*.

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

The producing microorganism, *Komagataella phaffii*, is absent from the commercial enzyme product.

Use of the enzyme

The lipase enzyme preparation is used as a processing aid in cheese production, production of flavouring preparations from dairy products (enzyme-modified dairy ingredients), and production of plant-based analogues of milk and milk products. The lipase catalyses the hydrolysis of triglycerides, diglycerides and monoglycerides to yield free fatty acids and monoglycerides, diglycerides and glycerol.

Benefits

The benefit of using the lipase in cheese production is:

- Helping develop the flavour of specific cheeses

The benefit of using lipase in the production of flavouring preparations from dairy products is:

- To develop the characteristic flavour

The benefits of using lipase in the production of production of plant-based analogues of milk and milk products are:

- Helping plant-based products develop a dairy-like flavour.

- Helping plant-based products achieve a desirable texture while limiting the addition of saturated or hydrogenated fat.

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 a production strain in the food industry 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 the absence of contamination by toxic substances or noxious microorganisms.
- Sequence homology assessment to known allergens and toxins shows that oral intake of the lipase is unlikely to pose food allergenic or toxic concern.

Furthermore, the safety of the lipase 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 safety evaluation, confirmed by the above-mentioned bodies, we respectfully request the inclusion of the lipase in Schedule 18—Processing aids.