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 phosphoinositide phospholipase C 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 a phosphoinositide phospholipase C from *Pseudomonas sp-62186* as permitted source for phosphoinositide phospholipase C.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a phosphoinositide phospholipase C (EC 3.1.4.11), commonly known as phosphoinositide phospholipase C.

Phosphoinositide Phospholipase C catalyses the hydrolysis of phosphatidylinositol to 1,2-diacylglycerol and inositolphosphate.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing a phosphoinositide phospholipase C from *Pseudomonas sp-62186*.

The phosphoinositide phospholipase C 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 phosphoinositide phospholipase C enzyme preparation is used as a processing aid in degumming of fats and oils. Generally, phosphoinositide phospholipase C hydrolyses the phosphodiester bond of phosphatidylinositol at *sn-3* position, resulting in the formation of 1,2-diacylglycerol and inositolphosphate.

Benefits

The benefits of the action of the phosphoinositide phospholipase C in degumming of fats and oils are:

- Robust and simple process
- Cost-efficient process with low water consumption and reduced need for bleaching earth
- Reduced gum fraction and higher total oil yield
- Adequate storage stability and facilitation of further processing of the oil due to efficient removal of impurities such as phosphatides, also called gums

- Higher oil yields due to significantly reduced loss of oils to gums, close to zero formation of soaps and no hydrolysis of the oil
- Cleaner oil products due to efficient removal of impurities that affect the taste, smell and visual appearance of the oil such as gums

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 phosphoinositide phospholipase C 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 phosphoinositide phospholipase C 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.

- Brazil: The enzyme was evaluated, approved and included in the Brazilian positive list – RDC 26/2009.

- 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 the phosphoinositide phospholipase C in Schedule 18—Processing aids.