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 phospholipase A1 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 a phospholipase A1 from *Talaromyces leycettanus* as permitted source for phospholipase A1.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a phospholipase A1 (EC 3.1.1.32).

Phospholipase A1 catalyses the hydrolysis of the *sn*-1 ester bond of diacylphospholipids.

The enzyme is produced by submerged fermentation of an *Aspergillus niger* microorganism expressing a phospholipase A1 from *Talaromyces leycettanus*.

The phospholipase A1 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 phospholipase A1 preparation is used as a processing aid during degumming of vegetable oils and fats. Phospholipase A1 hydrolyses ester bonds in phospholipids.

Benefits

The benefits of the action of the phospholipase A1 during degumming of vegetable oils and fats 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 phospholipase A1 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 phospholipase A1 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 A/S safety evaluation (confirmed by the above-mentioned bodies), we respectfully request the inclusion of the phospholipase A1 in Schedule 18—Processing aids.