EXECUTIVE SUMMARY

The present application seeks to amend Standard 1.3.3. - Processing Aids of the Australia New Zealand Food Standards Code (the Code) to approve an asparaginase enzyme preparation produced by Novozymes A/S.

Proposed change to Standard 1.3.3 - Processing Aids

The table to clause 17, Permitted enzymes of Microbial Origin, is proposed to be amended to include a genetically modified strain of *Bacillus subtilis* as permitted source for asparaginase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is an asparaginase (EC 3.5.1.1), which catalyze hydrolysis of the amide in asparagine to the corresponding acid, aspartic acid, thereby reducing the risk for acrylamide formation in various food applications during manufacture.

The enzyme is produced by submerged fermentation of a *Bacillus subtilis* microorganism expressing the wildtype, thermotolerant asparaginase from *Pyrococcus furiosus*.

The commercial enzyme product, Acrylaway HighT, is available in a liquid or granulated preparation complying with the JECFA recommended purity specifications for food-grade enzymes.

The producing micro-organism, *Bacillus subtilis*, is absent from the commercial enzyme product.

Use of the enzyme

The asparaginase enzyme preparation is intended to be used as a processing aid during manufacture of various food products. Typical applications include production of breakfast cereals, potato based snacks, sliced potato chips and pre-treatment of green coffee beans.

Benefits

Acrylaway HighT is technologically justified. The enzyme is to be used to reduce potential acrylamide formation in various food applications. Acrylamide is formed as a reaction product in between asparagine and reducing sugars when food products are baked or fried at temperatures above 120°C. Both asparagine and reducing sugars are commonly found in many food raw materials. By using the asparaginase the asparagine content will be reduced, resulting in a reduced acrylamide formation and thereby a reduced acrylamide content in the final product.

Safety evaluation

The safety of the strain 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 recombinant DNA is stably integrated into the production organism and unlikely to pose a safety concern.
- the enzyme preparation complies with international specifications
- there is no evidence of toxicity in the 90-day toxicity study in rats; and
- the enzyme preparation produced no evidence of genotoxic potential in *in vitro* assays.

Furthermore, the safety of the asparaginase preparation was confirmed by external expert groups, as follows:

- Denmark: The enzyme preparation was safety assessed according to the Guidelines for the evaluation of food enzymes (the Scientific Committee for Food, Commission of the European Communities, 1992[1]). This resulted in the authorisation of the enzyme product by the Danish authorities.
- USA: A GRAS determination was done and notified to the US FDA in June 2013 (GRN000476). In the reply letter from FDA dated February 3rd, 2014, the agency has no questions regarding Novozymes' determination that the asparaginase enzyme preparation is GRAS for its intended use.
- Brazil: Dossier was positively evaluated by ANVISA and the enzyme included in the amendment to the positive list, gazetted October 2014.
- Mexico: Dossier was positively evaluated by COFEPRIS and the enzyme included in the amendment to the positive list, gazetted June 2014.

Conclusion

Based on the Novozymes safety evaluation (confirmed by the above-mentioned bodies), we respectfully request the inclusion of this enzyme in the Table to clause 17 of Standard 1.3.3.; Permitted enzymes of Microbial origin.