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 a xylanase 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 licheniformis* as permitted source for endo-1,4-β-xylanase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a xylanase (EC 3.2.1.8), which hydrolyses xylosidic linkages in the arabinoxylan backbone resulting in a depolymerisation of the arabinoxylans into smaller oligosaccharides.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing a xylanase variant from *Bacillus licheniformis*.

The commercial enzyme product, Panzea, is a granulated enzyme preparation and complies with the JECFA recommended purity specifications for food-grade enzymes.

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

Use of the enzyme

The enzyme preparation is to be used in the baking industry as a processing aid. The active enzyme is a xylanase (EC 3.2.1.8) which catalyzes the endo-hydrolysis of 1,4-β-D-xylosidic linkages in xylans. The xylanase preparation is used to modify the arabinoxylans in cereals such as wheat, barley, and oats, thereby improving the dough handling and characteristics of the final bread.

Benefits

The xylanase preparation is technologically justified. The enzyme adds value to the bread manufacturing process by facilitating the dough handling and improving the characteristics of the final bread.

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 in the production organism is considered to be stable 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 xylanase preparation was confirmed or is under consideration 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 May 2013 (GRN000472). In the reply letter from FDA dated January 10th, 2014, the agency has no questions regarding Novozymes' determination that the xylanase enzyme preparation is GRAS for its intended use.
- Brazil: Dossier was submitted in March 2013 and positively evaluated by ANVISA, however the amendment to the positive list is awaiting the next official update, expected beginning of 2014.
- Canada: Dossier was submitted in May 2013 and is currently being reviewed by Health Canada.

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.