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 serine protease 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 serine protease from *Fusarium oxysporum* produced in a genetically modified strain of *Fusarium venenatum.*

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a serine protease with trypsin specificity (EC 3.4.21.4), which hydrolyses peptide bonds in proteins resulting in smaller proteins and peptides of variable lengths.

The enzyme is produced by submerged fermentation of a *Fusarium venenatum* microorganism expressing a serine protease from *Fusarium oxysporum*.

The commercial enzyme product, TL1 conc BG, is a granulated enzyme preparation and complies with the JECFA recommended purity specifications for food-grade enzymes.

The producing micro-organism, *Fusarium venenatum*, is absent from the commercial enzyme product.

Use of the enzyme

The serine protease is used as processing aid for partial or extensive hydrolysis of animal and vegetable proteins (such as casein, whey, gluten, and proteins from soy, corn, rice, peas, lentils, meat and fish) to be further used as ingredients in a variety of beverage and food products.

The enzyme is added during the food production process, where it performs its function. In the final food product the enzyme protein is denatured by high temperature, which means that the enzyme does not have any action or any function in the final food.

Benefits

Since the 1970s proteases have been increasingly used in various industrial food applications for hydrolysis of proteins. Protein hydrolysates can also be produced by acid and alkaline hydrolysis as well as by heat treatment.

As compared with these alternatives, the benefits of the action of serine protease are:

- Higher yield of soluble proteins and peptides
- Mild process conditions
- Reduced amounts of salts compared to acid hydrolysed protein
- Protein hydrolysate with controlled peptide profile due to specificity of the enzyme
- Increased digestibility of proteins

Safety evaluation

The safety of the strain has been thoroughly assessed:

- The enzyme preparation complies with international specifications ensuring absence of contamination by toxic substances or noxious microorganisms.
- The production organism has a long history of safe use as production strain for food grade enzyme preparations and does not produce any harmful metabolites as demonstrated by analysis.
- The genetic modifications in the production strain are well-characterized and safe and the integrated DNA (enzyme gene) has been shown to be stably maintained.
- Sequence homology assessment to known allergens and toxins shows that oral intake of the serine protease does not pose any food allergenic or toxic concern.
- Two mutagenicity studies show that the food enzyme is unable to damage the genetic material of living organisms.
- Two oral toxicological studies in rodents (a 90-days study and a 25-days study), where groups of animals were given the food enzyme at very high doses, show, that all dose levels were generally well tolerated.

Furthermore, the safety of the serine protease preparation has been confirmed or is under consideration by external expert groups, as follows:

- Denmark: The enzyme preparation has been safety assessed according to the Guidelines for the evaluation of food enzymes (the Scientific Committee for Food, Commission of the European Communities, 1992). This resulted in the authorisation of the enzyme product by the Danish authorities.
- France: The enzyme has been positively evaluated by the French Authorities and has been included in The French order of October 19, 2006 on use of processing aids in the manufacture of certain foodstuff, as amended
- JECFA: The enzyme preparation has been positively evaluated in the 76th meeting of JECFA and has been allocated an Acceptable Daily Intake (ADI) “not specified”.
- Mexico: The enzyme has been positively evaluated by COFEPRIS, however the amendment to the positive list is awaiting the next official update.
- Brazil: The enzyme has been positively evaluated by ANVISA, however the amendment to the positive list is awaiting the next official update, expected in 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.