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 beta-galactosidase enzyme preparation produced by Novozymes A/S.

Proposed change to Australia New Zealand Food Standards Code – Schedule 18 – Processing aids

The table in S18—4, Permitted enzymes (section 1.3.3—6)—Enzymes of microbial origin, is proposed to be amended to include a genetically modified strain of *Bacillus licheniformis* as permitted source for beta-galactosidase.

The application is applied for assessment by the general procedure.

Description of enzyme preparation

The enzyme is a beta-galactosidase (EC 3.2.1.23), commonly known as lactase.

Beta-galactosidases catalyze the hydrolysis of terminal non-reducing beta-D-galactose residues in beta-D-galactosides. The most common and well-known reaction is the hydrolysis of D-lactose into D-glucose and D-galactose.

The enzyme is produced by submerged fermentation of a *Bacillus licheniformis* microorganism expressing a beta-galactosidase from *Bifidobacterium bifidum*.

The commercial enzyme product, Saphera, is available in two product strengths as liquid preparations complying 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 lactase preparation is used as a processing aid during the manufacture of milk and other lactose containing products. Lactase converts lactose to glucose and galactose helping to produce lactose free or lactose reduced milk/dairy products.

The enzyme is used during milk production in either of two methods to produce low-lactose milk. In the classical, low-lactose process, milk is pasteurized and then cooled. At this point the lactase is added and allowed to react with the milk. The milk is then heat treated again to preserve the milk and to stop the action of the lactase enzyme.

In the low-lactose UHT process, milk is UHT treated and cooled to ambient temperature, at which time sterile filtered lactase is added and the product sterile packed. The lactase is allowed to react with lactose in the milk over several days, and the action of the lactase stops when there is no more lactose present. In the final dairy product the substrate is depleted,

which means that any remaining low level of food enzyme does not have any action or any function, and is thus, like any other protein, inert.

Benefits

The benefits of the action of the food enzyme in milk/dairy processing are:

- Lactose-reduced products are easier and safer to digest for lactose-intolerant individuals
- Sweeter dairy products due to glucose and galactose formation
- Less sugar addition needed to obtain the wanted product sweetness – thus, reduced caloric value
- Reduced sandiness in ice cream because no lactose crystals are formed
- Softer scoop of ice cream due to lower freezing point

Safety evaluation

The safety of the strain 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 strain are well-characterized 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 beta-galactosidase 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 beta-galactosidase preparation was confirmed by external expert groups, as follows:

- Denmark: The enzyme preparation was safety assessed resulting in the authorization of the enzyme product by the Danish authorities.
- USA: A GRAS determination was done and notified to the US FDA in March 2015 (GRN000572). In the reply letter from FDA dated August 28th, 2015, the agency has no questions regarding Novozymes' determination that the beta-galactosidase enzyme preparation is GRAS for its intended use.
- Mexico: Based on a dossier submitted by Novozymes, the Mexican food authorities, COFEPRIS, has approved the enzyme in February 2016.

Conclusion

Based on the Novozymes safety evaluation (confirmed by the above-mentioned bodies), we respectfully request the inclusion of this enzyme in the table in S18—4, Permitted enzymes (section 1.3.3—6)—Enzymes of microbial origin.