EXECUTIVE SUMMARY

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

The present application by DSM Food Specialties intends to amend Schedule 18—Processing aids of the Australia New Zealand Food Standards Code to include a phospholipase A_1 produced by a non-genetically modified strain of *Fusarium commune* (strain LFC).

The application is submitted for assessment under the General Procedure (Level 1).

Description of the food enzyme preparation

The enzyme is a phospholipase A_1 (EC 3.1.1.32), which hydrolyses the fatty acyl ester bond at the sn-1 position of the glycerol moiety of phospholipids, resulting in the formation of 2-acyl-1-lysophospholipid and free fatty acid.

The food enzyme subject of this dossier will be sold as a formulated enzyme preparation (granulate) under the dsm-firmenich's Panamore® line of products.

The finished products are subjected to extensive quality control testing to ensure that they comply with internal purity specifications established by dsm-firmenich, which consider those of JECFA for chemical and microbiological purity of food enzymes and the USP Food Chemicals Codex, 12th edition monograph for Enzyme Preparations.

The production microorganism, *Fusarium commune*, is absent from commercial enzyme preparation.

Intended use of the enzyme

The enzyme may be used in the processing of the following food categories at levels that do not exceed the amounts reasonably required to accomplish its intended effect on foods and in accordance with current Good Manufacturing Practices (cGMP):

- Production of industrial and artisanal grain-derived (organic) bakery products such as, but not limited to, bread, steamed bread, rolls, pastries, cakes, tortillas, waffles and wafers, biscuits, pancakes, and baking specialties.
- Production of cereal products and flour products (including noodles and pasta) such as, but not limited to, pasta, noodles, etc.

Beneficial effects

Depending on the application, the conversion of phospholipids with the help of phospholipase A_1 in production of bread and bakery products can result in the following benefits:

- Improved dough handling and dough stability that results in processing tolerance.
- More standardized and controlled processing of the dough.
- Improved volume and shock stability of the proofed dough leading to an increased volume and oven spring.
- Regulate batter viscosity, which is beneficial in the production process for waffles, pancakes, and biscuits.

Depending on the application, the conversion of phospholipids with the help of phospholipase A_1 in production of cereal products and flour products (including noodles and pasta) can result in the following benefits:

- Facilitate handling of the dough.
- Reduce checking (i.e., cracks in pasta).
- Improve dough properties (e.g., smoothness).

Safety evaluation

The safety of the non-genetically modified *Fusarium commune* strain LFC is well documented and the safety of the phospholipase A_1 has been established in a complete toxicology program:

- The production strain, *Fusarium commune* strain LFC, is non-pathogenic and non-toxigenic, belonging to *Fusarium* species which have a long-standing history of use in food applications.
- Based on literature and genome sequencing and analysis, the strain LFC may have the genetic potential to possibly produce the relevant mycotoxins Beauvericin, Fusaric acid, and Moniliformin. Analyses of these mycotoxins revealed that no toxicologically relevant levels were produced during controlled submerged fermentation (below Limit of Detection) in the food enzyme. This ensures that no toxicologically relevant levels of mycotoxins are present in the food enzyme preparation. The toxicity studies performed with the food enzyme confirmed that no toxicological relevant levels

of secondary metabolites are present in the food enzyme. Strain LFC is considered non-toxigenic under standard industrial fermentation conditions.

- The food enzyme was tested in several toxicity studies (an Ames test, an *in vitro* micronucleus test, an *in vivo* Comet assay, and a sub-chronic 90-day oral toxicity study in rats) based on which the following conclusions can be drawn:
    - The Ames test gave an equivocal outcome, but based on the in vivo Comet assay it can be concluded that the test item is not mutagenic;
    - No clastogenic or aneugenic activity was observed under the given test conditions;
    - The sub-chronic oral toxicity study showed a No Observed Adverse Effect Level (NOAEL) of at least 1124 mg TOS/kg body weight/day.
- The safety margin for human consumption can be calculated by dividing the NOAEL derived from the 90-day oral toxicity study in rats, 1,124 mg TOS/kg bw/day, by the anticipated consumer intake of maximally 0.29 mg TOS/kg bw/day.
  Consequently, the safety margin is 1,124 / 0.29 = 3,876.
  Given the high safety margin, there are no safety concerns under the intended conditions of use of the enzyme.
- The food enzyme has no relevant matches with known (food) allergens and toxins. Therefore, it is not likely to produce an allergenic or sensitization response or toxic concerns upon oral consumption.

The safety of the food enzyme has been further evaluated and confirmed by the Danish, French and Mexican regulatory authorities.

Conclusion

Taking into consideration the above-mentioned points, we respectfully request the inclusion of phospholipase A_1 produced by a non-genetically modified strain of *Fusarium commune* (strain LFC) in Schedule 18—Processing aids.