Application to Amend Standard 1.3.3 of the Australia New Zealand Food Standards Code to Include AMP deaminase from *Streptomyces murinus* as a Processing Aid

Executive Summary

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Amano Enzyme Inc. (Amano Enzyme) wishes to request an amendment to Schedule 18 of Standard 1.3.3 Processing Aids of the Food Standards Code to include AMP deaminase derived from *Streptomyces murinus* as a processing aid.

AMP deaminase is an enzyme that catalyzes the deamination of adenosine monophosphate (AMP) and converts it into inosine monophosphate (IMP). It is used as a processing aid intended for use in the manufacture of yeast extracts, as well as the manufacture of food products that are used as seasonings (*e.g.*, soups, bouillons, dressings, savory snacks). Yeast extract has been widely used as food material and seasoning in recent years because it has a strong taste (Umami).

The AMP deaminase is an enzyme derived from non-genetically modified strain of *Streptomyces murinus*. The production process of the AMP deaminase enzyme comprises a cultivation step with *Streptomyces murinus*, followed by several filtration and purification steps to result in AMP deaminase concentrate.

All of the raw materials used in the manufacture of the AMP deaminase are safe and suitable for use. The enzyme is produced according to Good Manufacturing Practices (GMP) and the FSSC22000 quality control system. Production controls are in place to monitor the strain during the fermentation and ensure the avoidance of genetic drift. Furthermore, the product specifications along with extensive batch analysis of AMP deaminase demonstrate the purity of the enzyme preparation, including the absence of microbiological and heavy metal contaminants, as well as the lack of antibiotic activity.

AMP deaminase is stable at least 18 months from the manufacturing date under sealed conditions. The optimum pH of AMP deaminase is 6.0 and the optimum temperature is 65℃. AMP deaminase is inactivated when exposed to temperature greater than 75°C. Also, as far as Amano Enzyme is aware, Amano Enzyme's AMP deaminase described in this dossier does not have any enzymatic side activities which might cause adverse effects.

The safety of AMP deaminase derived from *Streptomyces murinus* is supported by its history of use and toxicity studies. Several countries have approved of the AMP deaminase. The European Food Safety Authority (EFSA) and JECFA evaluated the enzyme and concluded that its use in yeast processing would not significantly affect the human body.

As for the toxicity studies, the food enzyme has been subjected to a standard package of toxicological tests, with the following results:

- No mutagenic or clastogenic activity under the given test conditions were observed
- The 13-week Oral Toxicity Study in Rats showed a No Observed Adverse Effect Level (NOAEL) of at least 2000 mg TOS/kg body weight/day (274 mgTOS/Kg-bw/day)

AMP deaminase derived from *Streptomyces murinus* also does not pose any allergenicity concerns, given the long history of use of the enzyme. Additionally, the amino acid sequence of AMP deaminase does not indicate that AMP deaminase has a potency of any allergenicity concerns.

Theoretical Maximum Daily Intake was calculated using the Budget Method. Based on this method, the Total TMDI of AMP deaminase was calculated as 0.0105 mg TOS/kg body weight/day. As described above, NOAEL of the enzyme is 274 mgTOS/kg/day. Consequently, the safety margin of AMP deaminase is 26,100 (274/0.0105).

As such, no safety concerns are anticipated with the proposed use of AMP deaminase from *Streptomyces murinus* as a processing aid in Australia/New Zealand.