Executive Summary

Meiji Food Materia Co., Ltd., wish to update the current microbial source name, for the enzyme β-fructofuranosidase, listed in subsection S18—4(5) of Schedule 18 in the Australia New Zealand Food Standards Code (the Code), from *Aspergillus niger* to include and add the more recently identified name of *Aspergillus fijiensis*. The Code was amended in 2013 by FSANZ following the submission of Application A1055 to permit the addition of short chain fructo-oligosaccharides $(FOS)_{sucrose}$ to infant formula products, foods for infants and supplementary formulated foods for young children. As part of this evaluation FSANZ indicated that these substances would not be regarded as nutritive substances, thus also permitting the addition of short chain $FOS_{sucrose}$ to general purpose foods. At that time, the Code was also amended to permit the enzyme β-fructofuranosidase from *A. niger* as a processing aid. While the request is to update the Code to add the name change, it should be noted that both the enzyme and the microbial source are considered identical to that which was part of application A1055. The only difference from the original approval back in 2013 being that the microbial source name has been updated while the ATCC number (20611™) has remained the same, signifying the fact that they are identical in nature.

In comparison to the information provided in Application A1055, the β-fructofuranosidase food enzyme is produced by fermentation using a non-genetically modified *Aspergillus* whose name has been updated from *niger through japonicus to fijiensis with the identical* ATCC® 20611™. The manufacturing process is conducted in accordance with HACCP principles and the final product specification for the final enzyme preparation complies with current purity and microbial limits for microbially-derived enzyme preparations established by JECFA (JECFA, 2006). Furthermore, as outlined in the Application A1055, the enzyme is analysed for potential impurities and contaminants associated with the source organism (*i.e.*, mycotoxins) and the enzyme activity has been fully characterised, considering both the primary fructose-transferring activity and secondary activities (present at negligible levels).

This enzyme has a long safe history of use in Australia and New Zealand, with an acceptance for general food use as well as infant formula products, foods for infants and supplementary formulated foods for young children dating back to 2013 (Application A1055). The enzyme has been assessed by a number of other international regulatory bodies and deemed to be safe for use in the production of FOS. In addition, the Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail (ANSES) within France and Health Canada have both recently updated their regulations to take in to account the name change of the microbial source to include *Aspergillus fijiensis*.

A series of inactivation and filtration stages are incorporated into the FOS production process to ensure complete inactivation and removal of the enzyme from the final material. As outlined in

the FSANZ approval report, FOS is intended for use as an ingredient in a range of general foods and formulae for infants and young children. The intakes of FOS were calculated based on all proposed uses in foods with exposure to the food enzyme subsequently calculated based on the maximum amount of β-fructofuranosidase which may theoretically be present during the manufacture of FOS. The Theoretical Maximum Daily Intake (TMDI) for adults was calculated to be 0.52 mg TOS/kg body weight/day based on Budget method assumptions. The highest potential intake by young children considering budget method assumptions were calculated to be 0.02 mg TOS/kg body weight/day.

A set of toxicological studies on the food enzyme have been conducted subsequently to Application A1055. The toxicological tests consisted of 2 *in vitro* genotoxicity tests and a 90-day toxicity study conducted in rats. The food enzyme was demonstrated not to be mutagenic or genotoxic and a no-observed-adverse-effect level (NOAEL) of 1,000 mg/kg body weight/day (the highest dose tested) equivalent to 920 mg/kg body weight/day when expressed as TOS was determined. When compared to the maximum exposure to the food enzyme based on the conservative assumptions considered in the dietary Budget method exposure assessment, the margin of exposure was determined to be extremely high (1,769 to 30,667). Furthermore, based on the outcome of the homology searches conducted, no evidence exists that would indicate that β-fructofuranosidase from *A. fijiensis* ATCC® 20611™ would cross-react with known allergens. Furthermore, as a number of steps are included in the manufacture of FOS which removes the enzyme from the ingredient, the potential for an allergenic reaction is thereby further reduced. A pathogenicity study was also conducted with *A. fijiensis* ATCC® 20611™ in mice.

Overall, the long history of use of this enzyme in the food supply in Australia/New Zealand and worldwide and the lack of any safety issues, indicates a lack of concern for updating the listing within subsection S18—4(5) of Schedule 18 of the Code to add the more recently identified name of *Aspergillus fijiensis*.