# Executive summary

This application seeks to amend the Australia New Zealand Food Standards Code (**Food Standards Code**) to permit the use of steviol glycosides (otherwise known as stevia) as a permitted food additive for use in foods for special medical purposes (**FSMPs**) up to a maximum level of 330 mg/kg. This application seeks permission to use stevia in all FSMP products excluding FSMP products for infants under 12 months.

Stevia is a plant-based sweetener extracted from the leaves of Stevia rebaudiana. Stevia is already permitted for use in several food product categories under Standard 1.3.1 and Schedule 15 of the Food Standards Code, and is used widely by the food industry as a high-quality, low-calorie sweetener to partially or completely replace the use of sugar in product formulations.

Stevia can play an important role in FSMPs that have been formulated for consumers that have a medical condition that requires dietary management using products that have been sweetened with a substance other than sugar. The use of stevia in FSMPs would increase palatability and consumer acceptance. Stevia would be added to FSMPs to perform a technological function (as a sweetener), as opposed to a nutritive or health-related function.

The use of stevia in FSMPs is already permitted under *Codex Alimentarius* and is expressly permitted in international jurisdictions including the European Union, Canada, the United States, Turkey, Singapore and Japan. The permission to add stevia to FSMPs in Australia and New Zealand would be consistent with international permissions, therefore giving consumers in Australia and New Zealand greater access to products that have been formulated with stevia for a medical purpose.

FSANZ has reviewed stevia several times, most recently in Application A1222. The safety of the proposed use of stevia in FSMPs can be clearly demonstrated based on previous FSANZ assessments, as well as subsequent scientific literature. Overall, in vitro and in vivo studies have consistently demonstrated that steviol glycosides and its permitted equivalents, are not mutagenic or genotoxic. There is no basis to conclude that the proposed use of stevia in FSMPs poses any risk to any particular segment of the general population, including children.

This application does not seek to introduce new types of stevia or modify or extend the specifications for the different types of stevia that may be used in food in Schedule 3 of the Food Standards Code. It also does not propose any amendment to the mandatory compositional requirement for FSMPs. It seeks to extend the use of an already-permitted additive to the FSMP category. As such, it is not necessary to make any change to the labelling or other requirements for FSMPs.