Executive summary
[pursuant to section 3.1.1B of the Application Handbook]

This application, submitted by the Wm. Wrigley Jr. Company, seeks to amend Standard 1.3.1 – Food Additives: Schedule 1 food category 5 Confectionery, to increase the permitted maximum level of Acesulphame potassium (Ace-K) in chewing gum to 5000 mg/kg.

The purpose is to enable The Wrigley Company to standardise formulations, thereby maintaining a standardised optimum flavour profile across the company's products and operations and advance product innovations in promoting the salivary and oral health benefits of chewing sugarfree gum as part of a good oral care routine.

This proposed amendment seeks to align the relevant provision for chewing gum with the Codex General Standard for Food Additives (Provisions for Food Category 05.3).

There are recognised oral health benefits from chewing sugarfree gum including stimulating the production and increasing the pH of saliva. The Australian New Zealand Food Standards Code, Schedule 3 Standard 1.2.7 Section 4 recognises food-health effect relationships and permits general level health claims relating to dental health, maintenance of tooth mineralisation, neutralisation of plaque acids and the reduction of oral dryness associated with chewing gum.

Wrigley uses Acesulfame-potassium as a sweetener in many of its sugar-free brands and in combination with traditional sugars to add and extend the flavour of its sugar-sweetened brands across the World. Acesulfame-potassium is approved for use in food in more than 90 countries worldwide.

In order to produce a product that meets both flavour and format preferences, it is necessary for Wrigley to use a blend of sweeteners. These sweeteners have different organoleptic profiles and by blending them, Wrigley can create an optimal sweetness profile for the product that offers longevity of both sweetness and flavour.

The current maximum permitted level for Acesulphame potassium in confectionery under Australian New Zealand Food Standards is comparatively low compared to other sweeteners, and significantly lower than maximum permitted levels of Ace-k in regulations in other markets, including USA, Canada, Japan, Korea and The Philippines. Consequently, The Wrigley Company is unable to sell chewing gum products in Australia and New Zealand with sweetness profiles matching the company's desired optimum profile, as implemented in products distributed in other overseas markets.

This issue is compounded by the increasing presence of non-compliant parallel imported Wrigley products in which additive levels in the formulas exceed approved Australian & New Zealand food standard levels. Furthermore, enforcement jurisdictions do not generally allocate a high priority to investigating cases that present low health and safety concerns.

These inconsistencies in standards between food products manufactured in Australia for the Australian and New Zealand market and that fully comply with the Code, and those parallel products imported by third parties into Australia create an uneven playing field for Australian manufacturers.

Acesulphame potassium has a long history of safe use in foods in Australia, New Zealand and internationally.

The current JECFA ADI of 0-15 mg/kg body weight was established at the 37th meeting in 1990. Australia and New Zealand have historically accepted this ADI. Toxicity studies undertaken since 1990 by the US NTP do not affect the ADI.

The maximum level in chewing gum to 5000 mg/kg is permitted in the Codex General Standard for Food Additives. This maximum level is not subject to a unity principle reduction when Acesulphame potassium is used in combination with other sweeteners.

The 2004 FSANZ report on the consumption of intense sweeteners in Australia and New Zealand reported that Australia and New Zealand consumers did not differ significantly in their daily exposure to Acesulphame potassium. Expressed as a percentage of ADI, consumption was 3% and 7% for mean and 95th percentile consumers respectively. The highest reported mean and 95th percentile consumption was reported by 25-39 year old consumers at 5% and 13% of the ADI, respectively for Australia and 3% and 11% for New Zealand. Confectionery accounted for 7% and 10% of Acesulphame potassium consumption in Australia and New Zealand, respectively.

A survey commissioned by The Wrigley Company Pty Ltd and undertaken by Roy Morgan Research Pty Ltd (RMR) to provide consumption data in support of application A577, and previously discussed in the Final Assessment of that application, reported the mean daily consumption of chewing gum (≤0.2% residual sugars) for self-reported consumers was 1.83 g in Australia and 2.19 g in New Zealand.

Two estimates of exposure at the requested higher maximum level have been made using data from these surveys. Both models indicate that total exposure to Acesulphame potassium will not be significantly increased by an increase in the maximum permitted level for Acesulphame potassium in chewing gum as requested in this application.

There are no costs for consumers, industry or governments arising from the proposed amendment.
The cost and benefits accrue primarily to businesses increasing Acesulphame potassium levels in their products, in terms of costs of setup to implement the change and potential benefits in improved efficiency of production from standardised product formulations between markets.

Wrigley is not alone in holding patents relating to the delayed release of Acesulphame potassium from chewing gum and, consequently, the application would not confer an exclusive capturable commercial benefit.

The applicant considers that the General Procedure (under 350hr) is the appropriate assessment procedure for this application. This dossier contains no information for which commercial confidential information status has been requested.

The application does not contain Confidential Commercial Information.