Application to amend Standard 1.3.1 of the ANZ Food Standards Code to increase the maximum permitted level of Acesulphame Potassium in chewing gum

Application to amend the Australia New Zealand Food Standards Code

Submitted by: Brooke-Taylor & Co Pty Ltd

On behalf of: The Wrigley Company Pty Limited

Date: 31 July 2014

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.

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Part 1 - General Requirements

1.1 Applicant details

[pursuant to section 3.1.2 of the Application Handbook]

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(b)	Company	On behalf of The Wrigley Company Pty Limited
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(d)	Phone contact	ph: 0411 156 773
(e)	Email	email: simon@brooketaylor.com.au
(f)	Information about the applicant	Wm. Wrigley Jr. Company is the world's largest manufacturer of chewing gum and bubble gum. The company has operations in more than 40 countries and distributes its world-famous brands in more than 180 countries. Wrigley is a subsidiary of Mars, Incorporated, one of the world's largest food companies, generating global revenues of $30 billion annually and producing some of the world's leading brands in six segments that include Chocolate, Drinks, Food, Petcare, Symbioscience and Wrigley. The Wrigley Company (Australia) Pty Limited and The Wrigley Company (N.Z.) Limited are wholly owned subsidiaries of Wm. Wrigley Jr Company.
(g)	Other businesses associate with the application	This application has been prepared on behalf of Wm.Wrigley Company by Brooke-Taylor & Co Pty Ltd. Please copy email correspondence in relation to the application to: [redacted] Scientific and Regulatory Affairs Manager The Wrigley Company Pty Limited PO Box: Locked Bag 3355, Hornsby NSW 1630 Address: 48 Michigan Avenue, Asquith 2077 Ph: +61 2 9847 9111 [redacted]

1.2 Purpose of the application

[pursuant to section 3.1.3 of the Application Handbook]

This application 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 from 2000 mg/kg to 5000 mg/kg.

1.3 Justification for the application

[pursuant to section 3.1.4 of the Application Handbook]

1.3.1 The need for the proposed change

The ANZ Food Standards Code Standard 1.3.1 currently permits the following permissions for intense sweeteners in confectionery, including chewing gum:

Sweetener	**Maximum permitted level**
950 Acesulphame potassium	2000 mg/kg
951 Aspartame	10000 mg/kg
955 Sucralose	2500 mg/kg
956 Alitame	300 mg/kg
961 Neotame	300 mg/kg
962 Aspartame-Acesulphame salt	4500 mg/kg

However, Standard 1.3.1 Clause 6 imposes a unity principle qualification on the maximum permitted levels of use such that where two or more additives are used in combination to achieve the same technological function, the sum of the quantities obtained by dividing the amount of each food additive used by the maximum permitted level for that food additive must be no more than 1.

Typical formulas in the United States that meet Wrigley's desired taste profile include about 2200ppm Acesulphame potassium and 6000ppm Aspartame. Most formulas manufactured in the United States use this ratio.

Formulas in Europe, which are similar but not identical in terms of the desired taste profile, use about 1800ppm Ace K. None of these products may be currently sold in Australia or New Zealand. As a consequence, the Wrigley Company are currently prevented from selling products in Australia and New Zealand with organoleptic profiles matching those distributed in the US and other overseas markets.

1.3.2 Alignment with the Codex General Standard for Food Additives (GSFA).

The preferred outcome identified in section 1.2 (above) would align the ANZ Food Standards Code with the Codex General Standard for Food Additives and establishes a maximum level for Acesulphame potassium of 5000 mg/kg in chewing gum.

1.3.3 The advantages of the proposed change over the status quo.

Wrigley manufactures chewing gum and bubble gum products in its plant in Sydney and also sources from a global supply chain which includes factories in China, Europe and the USA. The current regulations mean that product must be formulated especially for the ANZ market. The proposed change will enable Wrigley to more closely align production in and for Australia and New Zealand within its supply chain, thereby maximising production efficiency and reducing unit costs.

The proposed new maximum limit for Ace K will also mean better tasting products for consumers and will align with Codex and promote global harmonization of regulatory limits.

Imported product containing higher levels of Ace K will be aligned with product made in Australia/New Zealand and not be out of compliance which otherwise requires constant monitoring and expenditure of resources

1.3.4 Regulatory impact information

[pursuant to section 3.1.A of the Application Handbook]

1.3.4.1 Costs and benefits

Consumers

Costs – Wrigley do not envisage any costs for consumers in the proposed amendment.

Benefits – Benefits for consumers are largely organolpetic, in terms of the perceived taste quality and longevity of chewing gum.

Industry and business

Costs – The inclusion of higher levels of Acesulphame potassium in chewing gum will incur setup costs at the point of production. There are no direct costs for manufacturers who do not choose to increase the level of Acesulphame potassium in their products as a result of the proposed amendment.

Benefits – Wrigley is not alone in holding patents relating to the delayed release of Acesulphame potassium from chewing gum and, consequently, all manufacturers of chewing gum will be able to take advantage of the amendment and may take the opportunity to increase the efficiency of their supply chains by aligning formulations between ANZ and overseas products, as discussed in section 1.3.3 (above).

Government

Costs – Acesulphame potassium is already permitted to be added to chewing gum. A change in the maximum permitted level will not alter the role of government agencies in terms of enforcing the Code and will therefore be cost neutral.

Benefits – A change in the maximum permitted level will have the benefit of more closely aligning ANZ standard with those of Codex and overseas trading partners. Otherwise the proposed amendment will be cost neutral to governments. There are potential benefits in relation to population dental health arising from consumers moving from chewing sugar sweetened to sugar free gums as discussed in section 1.4.

1.3.4.2 Impact on international trade

Wrigley manufactures chewing gum and bubble gum products in its plant in Sydney and also sources from a global supply chain which includes factories in China, Europe and the USA. The preferred outcome will allow Wrigley, and other manufactures of chewing gum, to align production processes for products intended for sale in Australia and New Zealand with those for other markets.

The benefits are primarily in production efficiency through reduced downtime for formulation changeovers and longer production runs, reducing overall unit costs. Centralisation of production of specific products in particular factories, including in Sydney, is a possibility, leading to increased movement of product between regions and countries, although, the net effect on chewing gum sales in Australia and New Zealand cannot be predicted.

The requested change will also address a current uneven playing field in relation to domestically produced product compared to the same product introduced as a parallel import. There is an increasing presence in the market of parallel imported Wrigley products, produced overseas to local market preferences, in which Acesulphame potassium levels in the sweetener blends can exceed the maximum levels currently approved in the Australia & New Zealand Food Standard Code. However, as enforcement jurisdictions do not generally allocate a high risk priority to investigating cases that present low health and safety concerns, there is little enforcement action in this area. Consequently, these inconsistencies between fully compliant products manufactured in Australia for the Australian and New Zealand market and products parallel imported by third parties into Australia create an uneven playing field for Australian manufacturers

1.4 Information to support for the application

[pursuant to section 3.1.5 of the Application Handbook]

The oral health benefits of chewing sugarfree gum are well documented and undisputed in over 100 studies published globally, with studies proving that chewing helps to stimulate saliva by 10

per cent[1]. Studies conducted in respected laboratories around the world have confirmed that a large and sustained rise in plaque pH occurs when gum is chewed after consuming sugary foods. The effect of stimulation from chewing is to increase the concentration of bicarbonate in the saliva entering the mouth. This bicarbonate raises the pH of the saliva, and greatly increases its buffering power; the saliva is therefore much more effective in neutralising and buffering food acids and acids arising in plaque from the fermentation of carbohydrates. 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.

It is well recognised in the sweetener industry that none of the available sugar replacement sweeteners deliver a taste profile which precisely matches sugar; therefore it is industry practice to blend sweeteners to achieve an overall sugar-like taste profile.

Acesulphame potassium is a common, safe and suitable intense sweetener. It is approximately 130–100 times sweeter than sucrose, depending on the use level and the food matrix. Information addressing the identity and safety of Acesulphame potassium is included in Part 2 of the application.

Acesulphame potassium is characterised by a fast sweetness onset and short duration (Haber et al 2006[2]). Consequently, it is rarely used in isolation as a sole sweetener, but is more commonly blended with other sweeteners, such as Aspartame, Sucralose, and Neotame, which have slower onset but longer flavour duration.

The actual ratios in the blend will vary based on a number of factors including the sweeteners in the blend, the food matrix, pH and the desired level of sweetness.

It is also common practice for sweeteners in chewing gum and bubble gum to be encapsulated such that they provide a progressive release of sweetness as the gum is chewed, whilst avoiding a high initial sweetness spike. Consequently the maximum levels of the various sweeteners permitted to be added to chewing gum are generally significantly greater than that which would be predicted from a calculation based on the replacement of a level of sweetness equivalent to that obtainable from sugar.

Processes for encapsulation of a blend of Aspartame and Acesulphame potassium in chewing gum were first described by Mohammad and et al in 1997[3]. Such gums have a longer chew period and greater consumer acceptance than gums containing unencapsulated sweeteners.

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1 Dawes C, Macpherson LM (1992). "Effects of nine different chewing gums and lozenges on salivary flow rates and pH." Caries Res 26: 176-182.

2 Haber B, von Rymon Lipinski G-W and Rathjen S. 2006. Acesulphame K in Sweeteners and Sugar Alternatives in Food Technology. Ed. Helen Mitchell. Blackwell Publishing Ltd.

3 Muhammad J, Yatka RJ, McGrew GN, Record DW, Broderick KB, Song, JH (1997) Chewing gum containing encapsulated Aspartame/acesulfame K. Trends in Food Science & Technology 8: 197.

Encapsulation of the two sweeteners independently for inclusion in chewing gum and also the encapsulation of mixtures of sweeteners for inclusion in other foods had been described previously. Subsequently, other authors have described further methods of encapsulation of a variety of sweetener blends for use in gum.

However, to illustrate the current regulatory problem when using blends of sweeteners, if a mix of 6000 ppm Aspartame (73%) to 2200ppm Acesulphame potassium (27%) , is taken to be a representative of a desirable blend, the unity principle in Standard 1.3.1 Clause 6 currently prevents this blend from being used as it limits the amount of Acesulphame potassium which may be added to the blend to 800 mg/kg:

- Aspartame 10,000 x 0.6 = 6000 mg/kg
- Acesulphame potassium 2000 x 0.4 = 800mg/kg

In spite of this, the Code apparently recognises the problem inherent in the application of the unity principle, and effectively relaxes the requirement for use of the Acesulphame potassium-Aspartame salt in confectionery. This product is a salt which, on a molecular basis, contains equal quantities of Acesulphame potassium and Aspartame. The maximum level (4500 mg/kg) is set to correspond to the current maximum permitted level for the Ace K (2000 mg/kg), but also provides 2500 mg/kg Aspartame, a profile which could not be achieved my blending Aspartame and Acesulphame potassium.

Due to the steady release of flavour as the product is chewed, a 3g stick of gum containing Aspartame-Acesulphame potassium in the ratio as described above (Aspartame (73%) : Acesulphame potassium (27%) could theoretically yield a sweetness equivalent to about 4g sugar during its usable life.

In contrast, a similar product manufactured with 100% Aspartame, sucralose or neotame at the maximum permitted levels, or a combination of these sweeteners, could yield total theoretical sweetness equivalent in excess of 5.5g sugar per stick, although the taste profile might be less sugar-like and therefore less optimal.

Wrigley manufactures chewing gum and bubble gum products in its plant in Sydney and also sources from a global supply chain which includes factories in China, Europe and the USA. Adoption of the requested amendment, would allow relevant products for the ANZ markets to be reformulated to modify the levels of Acesulphame potassium and other sweeteners to be consistent with the Wrigley Company's international product standards.

1.5 Assessment procedure

[pursuant to section 3.1.6 of the Application Handbook]

The application seeks a minor extension of use of this additive in one food category.

Acesulphame potassium is a well-established food additive permitted in a large number of food categories that has been shown by recent surveys in Australia and New Zealand to be consumed well within the ADI.

Accordingly, Wm. Wrigley Jr. Company considers that the General Procedure (under 350hr) is the appropriate assessment procedure for this application. It is not the applicant's intention to pay fees for immediate assessment in advance of the FSANZ Workplan.

1.6 Confidential commercial information (CCI)

[pursuant to section 3.1.7 of the Application Handbook]

The current draft contains no confidential commercial information.

1.7 Exclusive capturable commercial benefit (ECCB)

[pursuant to section 3.1.8 of the Application Handbook]

Wrigley does not have exclusive rights to the use of Acesulphame potassium in chewing gum nor to the encapsulation technology that allows its use at higher levels.

The increased level of use, if approved would be available to all chewing gum manufacturers. For example a number of patents are held by Warner -Lambert, now owned by Mondaleze, . Accordingly, Wrigley does not have an Exclusive Capturable Commercial Benefit.

1.8 International and other national standards

[pursuant to section 3.1.9 of the Application Handbook]

A. International Standards

Codex General Standard for Food Additives
(extract from Table 1)

Acesulfame potassium INS: 950

Function: flavour enhancer, sweetener

FoodCatNo	FoodCategory	MaxLevel	Notes	Year Adopted
05.3	Chewing gum	5000 mg/kg	161 & 188	2007

Note 161 Subject to national legislation of the importing country aimed, in particular, at consistency with Section 3.2 of the Preamble.

Note 188 Not to exceed the maximum use level for acesulphame potassium (INS 950) singly or in combination with aspartame- acesulphame salt (INS 962).

B. Other National Standards or Regulations

USA

21 CFR 172.800 – Acesulphame potassium, may be safely used as a general-purpose sweetener and flavour enhancer in foods generally, except in meat and poultry, in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended technical effect in foods for which standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act* do not preclude such use (*fresh or dried fruits, fresh or dried vegetables, or butter). There is no unity principle in the USA.

Canada

The Canadian Food and Drug Regulations permit acesulphame potassium to be added to Chewing gum at up to 0.5% (5000mg/kg). There is no unity principle in the Canadian food additive regualtions and the maximum permitted level applies irrespective of whether other sweeteners are also added to the same food.

European Union

Directive 94/35/EC

EC No	Name	Foodstuffs	Maximum usable dose
E 950	Acesulphame K	Chewing gum with no added sugar	2000 mg/kg

There is no unity principle in the EU for chewing gum (<0.5% residual sugars).The maximum permitted levels in Directive 94/35/EC apply irrespective of whether other sweeteners are also added to the same food.

Japan

The Food Sanitation Act permits the addition of acesulphame potassium to chewing gum to a maximum level of "Not more than 5.0 g/kg".

South Korea

The South Korean Food Additives Code permits the use of acesulphame potassium up to 5000mg/kg in chewing gum

The Philippines

The Philippines allows acesulphame potassium in chewing gum up to 5000mg/kg

None of the Asian countries mentioned above have a unity principle for sweeteners in their food additive regualtions.

Part 2. Technical information about Acesulphame potassium

[pursuant to section 3.3.1 of the Application Handbook]

2.1 Nature and technological function of Acesulphame potassium

(a) Acesulphame potassium functions as an intense sweetener and a flavour enhancer

(b) Acesulphame potassium is recognised within the food industry as having an early taste onset. For this reason it is an important component in sweeteners blends, with slower taste onset sweeteners, such as Aspartame, sucralose and neotame, to provide an overall sugar-like taste.

2.2 Identification of the Acesulphame potassium

IUPAC name: potassium 6-methyl-2,2-dioxo-oxathiazin-4-olate

Other names: Acesulphame potassium, Ace K

CAS number 55589-62-3

Molecular formula: $C_4H_4KNO_4S$

Molecular weight: 201.24

INS Number: 950

Standard 1.3.4 establishes the following primary sources for specification monographs for food additives:

- Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005) as superseded by specifications published in FAO JECFA Monographs 3 (2006) and FAO JECFA Monographs 4 (2007) and FAO JECFA Monographs 5 (2008) and FAO JECFA Monographs 7 (2009), FAO JECFA Monographs 10 (2010) and FAO JECFA Monographs 11 (2011), Food and Agriculture Organisation of the United Nations. Rome; or

- *Food Chemicals Codex* (8th Edition) published by United States Pharmacopoeia (2012).

A specification for Acesulphame potassium was prepared at the 57th JECFA (2001), originally published in FNP 52 Add 9 (2001) and republished in the Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005).

The Food Chemical Codex (8th Edition) also contains a specification for Acesulphame potassium.

2.3 Information related to the safety of Acesulphame potassium

2.3.1 Toxicological evaluation

JECFA

Acesulphame potassium has been evaluated by JECFA on 3 occasions, at the 25th, 27th and 37th meetings (1981, 1983 and 1990). A toxicological monograph was prepared and published on each occasion. The current JECFA ADI of 0-15 mg/kg body weight was established at the 37th meeting.

The JECFA ADI for Acesulphame potassium has been consistently accepted by FSANZ, and its predecessors (NFA and ANZFA), most notably in exposure modelling during the development of Standard 1.3.1 and in the FSANZ report on the Consumption of intense sweeteners in Australia and New Zealand published March 2004.

A literature search of the PubMed MEDLINE and TOXLINE databases has identified 2 relevant studies undertaken, by the US National Toxicology Program (NTP), since 1990, the date of the last JECFA evaluation.

NTP

National Toxicology Program (NTP) studies on the toxicity of Acesulphame Potassium, October 2005. NTP GMM 2, NIH Publication No. 06-4460.

In parallel studies, male and female Tg.AC hemizygous and p53 haploinsufficient mice were exposed to Acesulphame potassium (at least 99% pure) in feed for 9 months. The two mouse strains have been genetically altered with either a loss of heterozygosity in a critical cancer gene (Trp53) or a gain of oncogene function (Ha-ras) to provide mouse models that are susceptible to the rapid development of cancer.

9-Month study in Tg.AC hemizygous mice

Groups of 15 male and 15 female Tg.AC hemizygous mice were fed diets containing 0%, 0.3%, 1%, or 3% Acesulphame potassium (equivalent to average daily doses of approximately 420, 1,400, or 4,500 mg Acesulphame potassium/kg body weight to males and 520, 1,700, or 5,400 mg/kg to females) for 40 weeks. Exposure to Acesulphame potassium had no effect on survival nor mean body weights. Feed consumption by the exposed groups was similar to that by the control groups throughout the study. There was no evidence of the development of neoplasms nor nonneoplastic lesions attributable to exposure to Acesulphame potassium. The survival and rate of tumour development in both males and females was comparable with historical data for the strain and there was no evidence of a dose related variation.

Acesulfame potassium did not increase the frequency of micronucleated normochromatic erythrocytes in peripheral blood of male or female Tg.AC hemizygous mice at any dose. Furthermore, there was no significant alteration in the percentage of polychromatic erythrocytes.

9-Month study in p53 haploinsufficient mice

Groups of 15 male and 15 female p53 haploinsufficient mice were fed diets containing 0%, 0.3%, 1%, or 3% Acesulphame potassium (equivalent to average daily doses of approximately 475, 1,500, or 4,700 mg/kg to males and 570, 1,800, or 5,700 mg/kg to females) for 40 weeks. Exposure to Acesulphame potassium had no effect on survival or mean body weights. Feed consumption by the exposed groups was similar to that by the control groups throughout the study. There were no neoplasms or nonneoplastic lesions that were attributed to exposure to Acesulphame potassium.

A small but statistically significant exposure-related increase in the frequency of micronucleated normochromatic erythrocytes was noted in males but not females.

There was no significant alteration in the percentage of polychromatic erythrocytes.

Conclusions

The NTP concluded that, in the absence of any increase in tumour frequency and having regard to the pre-existing database, the increase in the frequency of micronucleated normochromatic erythrocytes in p53 haploinsufficient exposed to Acesulphame potassium in males but not in females would classify as a weak response and, therefore, of uncertain biological significance. The studies demonstrate that Acesulphame potassium is not carcinogenic following dietary administration at levels between 0.3-3% for 9 months in male or female Tg.AC hemizygous or p53 haploinsufficient mice.

The NTP study does not affect the JECFA ADI of 0-15 mg/kg bw/day.

2.3.2 Information related to the dietary exposure to Acesulphame potassium

Proposed changes: Currently Standard 1.3.1 Schedule 1 Food Category 5.0 Confectionery establishes a maximum permitted level of Acesulphame potassium in all confectionery products of 2000 mg/kg. The proposed change would increase the maximum level to 5000mg/kg for chewing gum.

The 2004 FSANZ report on the consumption of intense sweeteners in Australia and New Zealand reported that the mean daily exposure to Acesulphame potassium across both Australia and New Zealand was 31 mg for all respondents and at 35 mg amongst consumers. Australia and New Zealand consumers did not differ significantly in their daily exposure. Consumption of confectionery contributed 7% and 10% to total Acesulphame potassium consumption in Australia and New Zealand respectively. When expressed in terms of bodyweight, the mean daily exposure to Acesulphame potassium across both Australia and New Zealand was 0.44 mg/kg bw for all respondents, and at 0.51 mg/kg bw for consumers.

Expressed as a percentage of the 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.

In 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 to permit the addition of calcium to chewing gum (≤0.2% residual sugars), data was collected about the consumption of chewing gum with ≤0.2% residual sugars in Australia and New Zealand. The results of this study have previously been discussed by FSANZ in the Final Assessment report to Application A577. This study reported that 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 have been made using data from these surveys.

Exposure estimate METHOD 1

The method applies an adjustment factor to the levels of consumption of Acesulphame potassium, for different groups, as reported in the 2004 FSANZ. This factor assumes that:

- consumers eat 1.83g gum/day containing intense sweeteners in Australia and 2.19 g/day in New Zealand, as reported in the RMR survey,
- all gum with ≤0.2% residual sugars currently contains Acesulphame potassium at the maximum permitted level, and
- the proposed amendment will result in the level of Acesulphame potassium in all relevant gum products being increased 2.5 fold from 2000mg/kg to 5000mg/kg.

Adjustment factor for Australia:

1.82 * (5000-2000)/1000 = +5.5 mg Acesulphame potassium per day

Adjustment factor for New Zealand:

2.19 * (5000-2000)/1000 = +6.6 mg Acesulphame potassium per day

This method over-estimates the effect of the proposed amendment as:

- it assumes that all gum with ≤0.2% residual sugars contains Acesulphame potassium at the maximum permitted level, and
- the assumed contribution of gums with ≤0.2% residual sugars (from the RMR survey) to total Acesulphame potassium consumption is higher than the contribution of all confectionery in the 2004 survey in either Australia or New Zealand

METHOD 1 – estimated consumption of Acesulphame potassium from all foods with the proposed increased maximum level in gum products

Group		% of ADI	
all consumers		Australia	New Zealand
	mean	4%	3%
	90th percentile	7%	7%
	95th percentile	10%	11%
25-39 yr olds			
	mean	6%	6%
	90th percentile	8%	9%
	95th percentile	13%	14%

RESULTS: Method 1 predicts that, the revised level of exposure to Ace K from all foods, would result in exposure to Acesulphame potassium from all foods that is less that 4% and 11% of the

ADI for mean and 95th percentile consumers and less than 6% and 14% of the ADI for mean and 95th percentile 25-39 year olds, the highest consuming age group in the 2004 FSANZ survey.

Exposure estimate METHOD 2

The method applies an adjustment factor to the levels of consumption of Acesulphame potassium, for different groups, reported in the 2004 FSANZ survey. This factor for each group is calculated based on the following assumptions:

- the mean contribution of confectionery to total Acesulphame potassium consumption, 7% for Australia and 10% for New Zealand, is uniform across all groups of consumers in the FSANZ 2004 survey,
- the proposed amendment will result in a 2.5 fold increase in exposure to Acesulphame potassium for all confectionery products.

This method over estimates the effect of the proposed amendment as:

- it assumes that the level of Acesulphame potassium will increase in all confectionery, irrespective of technological justification, not just in gum products.

METHOD 2 – estimated consumption of Acesulphame potassium from all foods with the proposed increased maximum level in gum products

Group		%of ADI	
all consumers		Australia	New Zealand
	mean	4%	3%
	90th percentile	7%	7%
	95th percentile	10%	12%
25-29 yr olds			
	mean	6%	6%
	90th percentile	9%	9%
	95th percentile	14%	15%

RESULTS: Method 2 predicts that, the revised level of exposure to Ace K from all foods would result in exposure to Acesulphame potassium from all foods that is less than 4% and 12% of the ADI for mean and 95th percentile consumers and less than 6% and 15% of the ADI for mean and 95th percentile 25-39 year olds, the highest consuming age group in the 2004 FSANZ survey.

Both of the methodologies used to estimate the effect of an increase in the maximum permitted level of Acesulphame potassium in chewing gum indicate that dietary exposure will remain substantially below the ADI for average and high level consumers.

Part 3 – Statutory declaration
[pursuant to section 3.1.30 of the Application handbook]

See Appendix 6

3.5 Checklist

General Requirements (3.1)	
☑ Form of application	☑ Assessment procedure
☑ Applicant details	☑ Confidential Commercial Information
☑ Purpose of the application	☑ Exclusive Capturable Commercial Benefit
☑ Justification for the application	☑ International standards
☑ Information to support the application	☑ Statutory Declaration

Food Additives (3.3.1)	
☑ Support for the application	NA Analytical detection method
☑ Nature and technological function information	☑ Toxicokinetics and metabolism information
☑ Identification information	☑ Toxicity information
☑ Chemical and physical properties	☑ Safety assessments from international agencies
NA Impurity profile	☑ List of foods likely to contain the food additive
NA Manufacturing process	☑ Proposed levels in foods
☑ Specifications	☑ Percentage of food group to contain the food additive
NA Food labelling	☑ Use in other countries (if applicable)

NA- Since the application relates to the extension of use of an already permitted food additive, information relating to the items the items marked "NA" has not been included in the current application on the basis that the information has not changed since the additive was originally permitted and/or its inclusion in the Joint ANZ Food Standards Code and is not affected by this application.

Appendices

Appendix 1 - Dawes C, Macpherson LM (1992). "Effects of nine different chewing gums and lozenges on salivary flow rates and pH." Caries Res 26: 176-182.

Appendix 2 - Haber B, von Rymon Lipinski G-W and Rathjen S. 2006. Acesulphame potassium in "Sweeteners and Sugar Alternatives in Food Technology". Ed. Helen Mitchell. Blackwell Publishing Ltd.

Appendix 3 - Muhammad J, Yatka RJ, McGrew GN, Record DW, Broderick KB, Song, JH (1997) Chewing gum containing encapsulated Aspartame/Acesulphame potassium. Trends in Food Science & Technology 8: 197.

Appendix 4 – National Toxicology Program (NTP) studies on the toxicity of Acesulfame Potassium, October 2005. NTP GMM 2, NIH Publication No. 06-4460.

Appendix 5 – Warner-Lambert patents relating to encapsulation of sweeteners in chewing gum.

- Wong LL, Faust SM and Cherukuri SR. An Acesulphame-K containing composition exhibiting enhanced sweetness comprises one or more food grade acids, Acesulphame-K and potassium chloride.US Patent 5,106,632, Warner-Lambert Company (Morris Plains, NJ),Filed: January 23, 1990.
- Cherukuri SR, Faust SM and Mansukhani G. Chewing gums having longer lasting sweetness. US Patent 5,110,608, Warner-Lambert Company (Morris Plains, NJ), Filed: March 9, 1990.
- Cherukuri S R, Chau T L., Raman K P and Orama A M. Multiple encapsulated flavor delivery system and method of preparation. US Patent 5,004,595, Warner-Lambert Company (Morris Plains, NJ). March 30, 1990.

Appendix 6 – Statutory Declaration Pursuant to Part 3 made by [redacted] Scientific and Regulatory Affairs Manager, The Wrigley Company Pty Limited.