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Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FINAL ASSESSMENT REPORT

APPLICATION A577

CALCIUM IN CHEWING GUM CONTAINING NO MORE THAN 0.2% RESIDUAL SUGARS

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Regulatory Approach

Food Standards Australia New Zealand (FSANZ) received a paid Application from the Wrigley Company Pty Ltd (the Applicant) on 22 February 2006 seeking to amend the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to chewing gum containing no more than 0.2% residual sugars[1].

Specifically, the Applicant has requested permission to:

- add calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg (25% of the Recommended Dietary Intake[2]) releasable calcium per serve;
- add each of the 14 forms of calcium currently permitted in the Schedule to Standard 1.1.1; and
- base claims on the amount of calcium released from calcium-fortified chewing gum (≤0.2% residual sugars) during 20 minutes of chewing.

The Applicant states the purpose of their request is to provide consumers with an additional source of calcium in their diet. They also consider that chewing calcium-fortified chewing gum (≤0.2% residual sugars) may have benefits for dental health. The respective national dental associations of Australia and New Zealand both promote the use of chewing gum (≤0.2 % residual sugars) for dental health.

At Draft Assessment, FSANZ undertook a robust and extensive assessment of the public health and safety implications of this Application. At Draft Assessment two options were proposed; (1) reject the Application thus maintaining the *status quo*; or (2) prepare a draft Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

Risk Assessment

The risk assessment approach has considered Ministerial policy guidance (*Fortification of Food with Vitamins and Minerals*)[3]. The Application was assessed on the basis of inadequate calcium intakes and whether the proposed addition of calcium to chewing gum (≤0.2% residual sugars) has the potential to assist in addressing calcium inadequacy among consumers of the product. In addition, the Application has been assessed on the ability to deliver a health benefit; in this case, the potential for a dental health benefit arising from a topical application of calcium from chewing gum (≤0.2% residual sugars) with added calcium[4].

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[1] For the purposes of this Report, the term 'chewing gum containing no more than 0.2 % residual sugars' will be abbreviated to 'chewing gum (≤0.2% residual sugars)'.
[2] The current RDI for calcium is 800 mg, as stated in the Schedule to Standard 1.1.1.
[3] http://www.foodstandards.gov.au/_srcfiles/Mandatory_Fortification_June_2006.pdf.
[4] FSANZ notes in the Policy Guideline that 'can deliver a health benefit' is in the context of increased intake of a vitamin or mineral, but has extended the application of the Specific Order Policy Principle in this case to include dental benefit from a topical application of the vitamin or mineral.

Dietary intakes were estimated and were based on the amount of 'releasable calcium' from the chewing gum. The recently endorsed Nutrient Reference Values (NRVs)[5] for calcium (described in Section 2.5) have been used as the basis of assessing inadequate and excess intakes in the population.

At Final Assessment, the key risk assessment findings are:

- the majority of males and females in Australia and New Zealand have inadequate calcium intakes[6];
- calcium-fortified chewing gum (≤0.2% residual sugars) could have a modest impact on reducing the proportion of chewing gum consumers who have inadequate calcium intakes;
- each of the 14 permitted forms of calcium has the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability;
- the calcium content of a food or supplement, the physiological status of an individual, daily calcium intake and presence of other foods are more important to bioavailability than any minor differences in the bioavailability between different forms of calcium;
- there is a small risk that some consumers may replace calcium-rich foods with calcium-fortified chewing gum (≤0.2% residual sugars), but this is unlikely to cause any dietary inadequacies of other nutrients;
- there is no additional risk of excess calcium intake from fortifying chewing gum (≤0.2% residual sugars) with calcium; and
- some evidence exists of a short-term benefit to dental health through increased tooth remineralisation although this has only been shown to date when either calcium lactate, calcium carbonate or some of the more soluble forms of calcium phosphate have been added to chewing gum (≤0.2% residual sugars).

The key risk assessment issues are discussed in Section 7 of this Report. Additional information is provided at Attachment 2 – Hazard Characterisation and Identification of Potential Dental Health Benefits from a Topical Application of Calcium and Attachment 3 – Dietary Intake Assessment Report.

A consumer research study, conducted by Roy Morgan Research (RMR) commissioned by the Applicant, was used extensively to inform the Risk Assessment, primarily the dietary intake assessment. The research looked at current consumption levels of chewing gum (≤0.2% residual sugars) and potential behavioural changes if calcium-fortified chewing gum (≤0.2% residual sugars) was permitted. A report detailing findings from this consumer research study is at Attachment 4.

[5] http://www.nhmrc.gov.au/PUBLICATIONS/synopses/n35syn.htm.

[6] Inadequate calcium intake refers to intakes for the population that are below Estimated Average Requirements (EARs). This differs from calcium deficiency which is a long term inadequate supply of calcium, or a failure in calcium metabolism, which may lead to conditions related to the loss of bone mineral, such as osteoporosis.

Risk Management

This Final Assessment Report also considers, in the context of the findings from the Risk Assessment, a number of issues relevant to permitting the addition of calcium to chewing gum (≤0.2% residual sugars). A key strategy identified to address these issues is the preparation of a stand alone Standard in the Code that:

- recognises the unique nature of chewing gum as a food;
- accommodates unambiguously the concept of *releasable* calcium versus calcium *contained* in the product;
- sets out specific labelling requirements for calcium-fortified chewing gum (≤0.2% residual sugars) to allow for informed choice; and
- provides guidance on available procedures to determine releasable calcium to assist with compliance and enforcement.

Decision

FSANZ approves the inclusion of a Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

Reasons for Decision

FSANZ approves permitting the addition of calcium to chewing gum (≤0.2% residual sugars) as it:

- does not raise any safety concerns for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) or the general population;
- provides consumers with an additional source of calcium in their diet;
- has the potential to assist in addressing inadequate calcium intakes among Australian and New Zealand consumers of calcium fortified chewing gum;
- may provide consumers with a short-term dental benefit arising from topical application of calcium;
- is consistent with FSANZ's statutory objectives including having regard to Ministerial policy guidance on voluntary fortification;
- supports industry innovation;
- provides consumers with adequate labelling information to make an informed choice; and

- the impact analysis concludes that fortification of chewing gum (≤0.2% residual sugars) with calcium provides a net benefit to affected parties.

The approved draft variation to the Code is at Attachment 1.

Consultation

FSANZ received a total of 18 submissions in response to the Draft Assessment Report which was released for public comment from 12 December 2007 to 6 February 2008 (Attachment 5). Seven submissions were received from industry, six from government, three from public health organisations and one each from an academic institution and a consumer group. Overall, twelve submitters (predominately from industry and public health) supported the Application, though seven provided 'in principle' support only, citing concerns regarding minimal nutritional benefit, labelling requirements and the proposed serving size. Those who fully supported the Application considered it would provide a net benefit to consumers and industry, with no public health or safety concerns.

Three of the six Government submitters did not support the Application and a further two, which did not state a preferred option, appeared to also support maintaining the *status quo*. Several Government submitters considered the Application was inconsistent with the Ministerial Council's fortification policy guidance and that it would be difficult to enforce. A number of government submitters believed the Application was more aligned with a therapeutic good than a food due to dosage and chewing instructions to increase bioavailability. In addition, some identified little nutritional benefit, and expressed concern that this Application could set a precedent and be extended to other sugar-free confectionery and beverages.

Issues raised by submitters in response to the Draft Assessment Report have been addressed in this Report. A summary of submissions to the Draft Assessment Report is at Attachment 5.

Implementation and Review

FSANZ will notify the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of the approved draft variations to the Code.

Subject to any request for review by the Ministerial Council of FSANZ's decision, the proposed draft variation permitting the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve is expected to come into effect upon gazettal.

CONTENTS

INTRODUCTION

Food Standards Australia New Zealand (FSANZ) received a paid Application from the Wrigley Company Pty Ltd (the Applicant) on 22 February 2006 seeking to amend the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to chewing gum containing no more than 0.2% residual sugars[7].

This Final Assessment Report discusses issues, including those issues raised following public consultation, regarding the fortification of chewing gum (≤0.2 % residual sugars) with calcium. The approved draft variation to the Code is provided at Attachment 1.

1. Nature of the Application

1.1 Basis of the Application

The Applicant has requested permission to add calcium to chewing gum (≤0.2% residual sugars) to provide consumers with an additional source of calcium in their diet. They also consider that chewing calcium-fortified chewing gum (≤0.2% residual sugars) may have benefits for dental health.

1.2 Scope of the Application

Chewing gum is recognised as a food under paragraph 5(1)(d) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), which states that food includes *chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum*.

The Applicant is seeking permission to add calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg (25% of the Recommended Dietary Intake [RDI][8]) releasable calcium per serve.

The Applicant has requested that all calcium claims relate to the amount of calcium *released* from the chewing gum during 20 minutes of chewing, rather than the amount of calcium *contained* in the product, as some calcium will remain in the chewing gum cud even after 20 minutes of chewing. In this case, the amount of calcium *released* reflects the amount of calcium that is *swallowed* and available for absorption by the body. Therefore, the amount of releasable calcium from chewing gum (≤0.2% residual sugars) is still applicable to the RDI for calcium.

The Applicant is also seeking permission to add all forms of calcium currently permitted in the Schedule to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions.

[7] For the purposes of this Report, the term 'chewing gum containing no more than 0.2% residual sugars' will be abbreviated to 'chewing gum (≤0.2% residual sugars)'.
[8] The current RDI for calcium is 800 mg, as stated in the Schedule to Standard 1.1.1 of the Code.

1.2.1 Use of the term 'chewing gum containing no more than 0.2% residual sugars'

This Application pertains solely to chewing gum products in which the sugar has been replaced by polyols (sugar alcohols) and intense sweeteners, and that contain no more than 0.2% residual sugars. These products are not technically 'sugar-free' (i.e. absolute zero sugars) as the polyols contribute very small amounts of sugars to the final product.

For the purpose of this Application, the term 'chewing gum containing no more than 0.2% residual sugars' is used to describe chewing gum products in which the sugar has been replaced by polyols and intense sweeteners, and that contain no more than 0.2% residual sugars.

Some exceptions for the use of the term 'sugar-free' have been made in this Report, particularly when referring directly to past written documents. For example, some journal articles use the term 'sugar-free' in their titles and text, and accordingly this term is used when referring to these articles.

1.3 Amendments to the original Application and additional information

1.3.1 Amendments to the original Application

The original Application requested permission to add calcium to 'sugar-free' chewing gum at a maximum claim level of 100 mg (12.5% RDI) per reference quantity; based on 'a normal serving'. At Draft Assessment, the Applicant amended their Application to:

- describe the food as chewing gum in which the sugar has been replaced by polyols and intense sweeteners at a maximum level of 0.2 g sugars per 100 g food, which complies with the Code of Practice on Nutrient Claims in Food Labels and in Advertisements (CoPoNC);

- increase the maximum claim to 200 mg (25% RDI), as the original request reflected the current minimum amount of a nutrient required for vitamin and mineral claims;

- permit claims 'per serve' rather than a prescribed reference quantity, which are used in Standard 1.3.2 – Vitamins and Minerals; and

- allow calcium claims to reflect the amount of calcium *released* during 20 minutes of chewing, rather than the amount of calcium *contained* in the product.

1.3.2 Additional information provided by the Applicant

The Applicant, as requested by FSANZ, has provided further information to support the assessment of their Application. Additional information provided by the Applicant and used at Final Assessment includes:

- sales data for chewing gum (≤0.2% residual sugars) compared to total chewing gum sales;

- future market share predictions for chewing gum (≤0.2% residual sugars) and a product containing calcium;

- 'chew-out' tests demonstrating the proportion of calcium that is released into the oral cavity over time from calcium-fortified chewing gum (≤0.2% residual sugars);

- composition of the gum base ingredient used in their chewing gum products;

- the opinion of two dental professionals on the risk of dental calculus from the use of calcium-fortified chewing gum (≤0.2% residual sugars);

- published evidence that 20 minutes represents an average chew time for most chewing gum consumers;

- consumer research study data, collected by Roy Morgan Research (RMR) on behalf of the Applicant (see Attachment 4), relating to consumers':

    - current consumption of chewing gum (≤0.2% residual sugars); and
    - likely response to calcium-fortified chewing gum (≤0.2% residual sugars).

1.4 Regulation as a Therapeutic Good

The request for permission to add calcium to chewing gum (≤0.2 % residual sugars) has been assessed under the FSANZ Act. The reasons for regulating calcium-fortified chewing gum (≤0.2 % residual sugars) as a food rather than as a therapeutic good include:

- the FSANZ Act recognises chewing gum as a food;

- the product will be marketed as a food and sold in food retail outlets;

- the primary benefit of the product is nutritional (in relation to dietary intake) rather than dental (in relation to providing a therapeutic effect); and

- the Australian Therapeutic Goods Administration (TGA) has declared that unmedicated dental chewing gums, with claims restricted to improvements to oral hygiene, are not therapeutic goods[9]. Calcium-fortified chewing gum (≤0.2% residual sugars) could be regulated as a therapeutic good only if therapeutic claims were made in association with the use of the product.

2. Background

2.1 Nutritional role of calcium

Calcium is required for the normal development and maintenance of the skeleton as well as for the proper neuromuscular and cardiac function (NHMRC and NZMoH, 2006). Over 99% of total body calcium is found in bones and teeth where it provides structure and strength. The size of this reserve is dependent upon the balance between calcium intake and absorption, and calcium losses through the skin, kidney and bowel.

[9] Therapeutic Goods (Excluded Goods) Order No. 1 of 2008. www.tga.gov.au/legis/tgeg0801.htm.

Bone mass increases substantially throughout childhood and adolescence and then remains stable in men until about age 50 and until the menopause in women. Thereafter, age-related losses in both men and women average 0.5-1.0% per year. In post-menopausal women this is due in part to a deterioration in the calcium balance arising from reduced calcium absorption and increased calcium excretion (NHMRC and NZMoH, 2006).

Vitamin D (obtained predominantly from exposure to sunlight in Australia and New Zealand) is also essential for the development and maintenance of bone – both for its role in enhancing the ability of the small intestine to absorb calcium and for ensuring the proper renewal and mineralisation of bone tissue (NHMRC and NZMoH, 2006).

2.2 Dietary and supplemental sources of calcium

The primary dietary source of calcium in Australia and New Zealand is dairy foods, with milk contributing 30-45% and cheese contributing about 10% of calcium intake among adults (Russell *et al*., 1999; ABS, 1999). Other sources of calcium in the diet include bony fish, legumes and certain nuts, calcium-fortified breakfast cereals, soy milk, fruit juices, and minor sources such as calcium salts used as food additives.

Dietary supplements may also contribute to total calcium intake, although there are limited data on usage and/or dose in the Australian or New Zealand populations. Nineteen per cent of New Zealanders aged 15 years and over reported using a multivitamin and mineral supplement in the year prior to the 1997 National Nutrition Survey (NNS). Just 2% reported using calcium supplements, although usage was higher among women aged 65-74 years (9%). Dietary supplements contributed <1% to calcium intakes for New Zealanders 15 years and over (Russell *et al*., 1999). Specific details on amounts consumed and the frequency of consumption of individual dietary supplements are not publicly available. Around 5% of New Zealand children reported consuming a dietary supplement for the 24-hour recall from the 2002 New Zealand Children's Nutrition Survey (NZMoH, 2003).

Calcium supplements were not included separately in the 24-hour recall and information on frequency of consumption of dietary supplements was not collected. In the 1995 Australian NNS about 10% of women and 2% of men aged 45 years reported taking a calcium supplement on the day before the survey (ABS, 1997). For the 1995 Australian NNS there were no data collected about dose, however, there was for frequency. The majority of Australians aged 12 years and above (86%) rarely or never consumed calcium supplements in the previous 12 months, whereas 2% consumed them weekly and 5% daily. The 2007 Australian National Children's Nutrition and Physical Activity Survey (CSIRO, 2008) reported approximately 8% of Australian children consuming calcium supplements.

In the Geelong Osteoporosis Study, researchers reported that 6.6% of adult women used calcium supplements (with post menopausal women being the highest users) and a further 4.3% used multivitamins (Pasco *et al*., 2000). As a result of the low supplement usage rate, their contribution to mean daily calcium intake was also low; only 10-20 mg across the different age groups.

There are over 20 forms of calcium listed by the TGA as substances that can be added to supplements for supply in Australia (TGA, 2007). The forms of calcium commonly used in supplements include: calcium carbonate, calcium phosphate, calcium citrate, calcium lactate and calcium gluconate.

There are also natural sources of calcium included in supplements such as oyster shell, dolomite and bonemeal. Each form contains different amounts of elemental calcium. Calcium carbonate (a concentrated form of calcium) supplements typically contain about 600 mg of calcium per tablet whereas other forms usually contain less calcium per tablet.

2.3 Bioavailability of ingested calcium

The bioavailability of ingested calcium refers to the fraction of dietary calcium that can be absorbed by the gut and used for physiological functions, particularly bone mineralisation, or to limit bone loss.

Calcium is absorbed in the small intestine both by passive diffusion and by an active mechanism which requires vitamin D. An inadequate intake of calcium results in a reduced amount of calcium being absorbed, leading to a lower level of blood calcium. In response the body's parathyroid gland releases more parathyroid hormone into the bloodstream which causes calcium to be released from the bone reservoir.

Calcium absorption and intake are inversely related, declining from 45% at intakes of 200 mg/day to 15% at intakes above 2000 mg/day. In women, the ability to absorb calcium in the gut falls with age, declining 2.2% at the time of the onset of menopause and then 0.21% each year thereafter (Heaney *et al.*, 1989). Efficiency of absorption varies throughout the lifespan, being highest in infancy, rising again in early puberty and mid-to late pregnancy, and declining with age (Institute of Medicine, 1997).

The intestinal absorption of calcium (an indicator of the bioavailability) is similar among most foods and supplement sources except in foods high in oxalic acid (spinach, sweet potatoes, rhubarb and beans) and phytic acid (unleavened bread, some raw beans, seeds, nuts and grains, and soy isolates) where it is lower (Institute of Medicine, 1997). Other factors restricting calcium absorption include: caffeine intake, magnesium deficiency, high intakes of phosphorus, and amenorrhoea (Institute of Medicine, 2006).

Bioavailability of ingested calcium when measured from non-food sources such as supplements depends on the presence of a meal and the size of the dose. The Institute of Medicine (1997) reports on several studies that found similar absorption rates for different forms of calcium supplements (calcium citrate malate, calcium carbonate and tricalcium phosphate) and calcium from milk when consumed as part of a breakfast meal. The efficiency of calcium absorption from supplements is greatest when taken in doses of 500 mg or less (Heaney *et al*., 1988).

FSANZ reviewed the bioavailability of calcium as part of Application A424 – Fortification of Foods with Calcium[10]. While different forms show variations in bioavailability under isolated experimental conditions, the variations are not evident in human studies over the long term (based on similar doses of calcium and measures of bone mineral density).

Therefore, the calcium content of a food or supplement, the physiological status of an individual, daily calcium intake and the presence of other foods are more important than differential bioavailability.

[10] The Application A424 Second Review Report is located at http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa424calciuminjuices/index.cfm

2.4 Dietary Guidelines for Australia and New Zealand for calcium

Both the Australian Dietary Guidelines for Adults (NHMRC, 2003a) and those for Children and Adolescents (NHMRC, 2003b) include a guideline that recommends the consumption of reduced fat varieties of 'milks, yoghurts, cheeses and/or alternatives', primarily because of the calcium contained in these foods. The New Zealand Ministry of Health recommends that children, adolescents and adults obtain an adequate calcium intake from milk and milk products and non-dairy sources (NZMoH, 1997; NZMoH, 1998; NZMoH, 2003).

2.5 Nutrient reference values for Australia and New Zealand for calcium

The nutrient reference values (NRVs) recently endorsed by the Australian and New Zealand Governments include two measures of nutritional adequacy: Estimated Average Requirement (EAR) and Recommended Dietary Intake (RDI) (NHMRC and NZMoH, 2006).

The **EAR** is the daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group. The proportion of the population with intakes below the EAR is a good estimator of the prevalence of inadequate intakes within population sub-groups (under certain assumptions).

The **RDI** is the value established to meet the needs of nearly all healthy individuals in a particular life stage and gender group. The RDI is not used to assess inadequate intake in populations. Among individuals, those with intakes above the RDI have a low probability of inadequate intake; the probability of inadequacy rises as intake in individuals falls below the RDI and the probability of inadequacy is greater than 50% if intake is below the EAR.

For some nutrients, such as calcium, an Upper Level of Intake (UL) has also been set. The **UL** is the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

Table 1 below shows the EARs, RDIs and ULs for calcium for various age and gender groups. The higher EAR and RDI for women aged over 50 years compared with men of a similar age, is to account for reduced calcium absorption and additional urinary losses after menopause (NHMRC and NZMoH, 2006). The NRVs are the same for women during pregnancy and lactation.

Table 1: EARs, RDIs and ULs for calcium intake for Australia and New Zealand

Age (years)	EAR (mg/day)	RDI (mg/day)	UL (mg/day)
1-3	360	500	2,500
4-8	520	700	2,500
9-11	800	1,000	2,500
12-13	1,050	1,300	2,500
14-18	1,050	1,300	2.500
19-30	840	1,000	2,500
31-50	840	1,000	2,500
51-70			
Males	840	1,000	2,500
Females	1,100	1,300	2,500
>70	1,100	1,300	2,500

Source: NHMRC and NZMoH, 2006.

3. Current Situation

3.1 Current Domestic Regulations

3.1.1 Australia New Zealand Food Standards Code

The Standards most relevant to this Application are Standard 1.1.1 and Standard 1.3.2.

Standard 1.1.1 contains the Schedule of permitted forms and the reference values of vitamins and minerals that, if permitted elsewhere in the Code, may be added to certain foods. There are 14 forms of calcium currently permitted in Standard 1.1.1[11].

Standard 1.3.2 regulates the addition of vitamins and minerals to foods generally, as well as claims that can be made about the vitamin and mineral *content* of foods. Currently, Standard 1.3.2 permits the voluntary addition of calcium, in addition to other vitamins and minerals, to certain foods such as breakfast cereals, most dairy products, some biscuits, fruit and vegetable juices/drinks, and soups. However, there is no permission for the voluntary addition of calcium to chewing gum (≤0.2% residual sugars) or any similar food in this Standard.

3.1.2 New Zealand Dietary Supplement Regulations 1985

Under the New Zealand *Dietary Supplement Regulations 1985* (the Dietary Supplement Regulations) chewing gum with added calcium is permitted to be manufactured and/or sold in New Zealand. FSANZ is not aware of any fortified chewing gum products currently manufactured in New Zealand as dietary supplements. However, if calcium-fortified chewing gum were to be manufactured in, or imported to, New Zealand, the product could then be exported and sold in Australia by virtue of the Trans-Tasman Mutual Recognition Arrangement.

[11] The fourteen forms of calcium currently permitted in Standard 1.1.1 are: calcium carbonate, calcium chloride, calcium chloride anhydrous, calcium chloride solution, calcium citrate, calcium gluconate, calcium glycerophosphate, calcium lactate, calcium oxide, calcium phosphate dibasic, calcium phosphate monobasic, calcium phosphate tribasic, calcium sodium lactate and calcium sulphate.

The New Zealand Food Safety Authority is currently reviewing the Dietary Supplement Regulations. A discussion document released in July 2008[12] outlined a proposed standard to separate the regulation of food-type dietary supplements (supplemented foods) and therapeutic-type supplements. The intention of the proposed changes is to align supplemented foods more closely with the Code where possible.

3.1.3 Therapeutic goods regulation in Australia

The TGA has declared that oral hygiene products (including unmedicated chewing gum) with no claims other than for oral hygiene are not considered to be therapeutic goods in Australia (Therapeutic Goods (Excluded Goods) Order No. 1 of 2005)[13].

Therefore, a potential avenue for the regulation of calcium-fortified chewing gum (≤0.2% residual sugars) in Australia is as a complementary medicine, only if a therapeutic claim is made in relation to the use of the product. A therapeutic claim is one that makes a reference to a therapeutic action in preventing and/or treating a disease state; for example, calcium fortified chewing gum preventing dental caries. To date, chewing gum (≤0.2% residual sugars) with added calcium has not been listed on the Australian Register of Therapeutic Goods.

3.2 Ministerial Policy Guidance

The Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) approved a Policy Guideline on *Fortification of Foods with Vitamins and Minerals* (the Policy Guideline) in May 2004. Subsequent amendments were made to the Policy Guideline in May 2006[14].

The Policy Guideline provides guidance on the addition of vitamins and minerals to food for both mandatory and voluntary fortification. In considering permissions for voluntary fortification, FSANZ must have regard to this policy guidance. The Policy Guideline provides 'High Order' Policy Principles as well as 'Specific Order' Policy Principles and additional policy guidance for voluntary fortification. The 'High Order' Policy Principles reflect FSANZ's statutory objectives (see Section 5 of this Report) and therefore take precedence over the 'Specific Order' Policy Principles. The 'Specific Order' Policy Principles for voluntary fortification include certain conditions for which the voluntary addition of vitamins and minerals can be permitted.

The 'Specific Order' Policy Principles – Voluntary Fortification most relevant to this Application are:

- *The voluntary addition of vitamins and minerals to food should be permitted only:*

[12] New Zealand Food Safety Authority, Public discussion paper on the proposed standard for supplemented food, July 2008

[13] www.tga.gov.au/legis/tgeg0801.htm.

[14] Policy Guideline on Fortification of Food with Vitamins and Minerals (notified to FSANZ June 2006). Endorsed by the Australia and New Zealand Food Regulation Ministerial Council. Available at: http://www.foodstandards.gov.au/_srcfiles/Mandatory_Fortification_June_2006.pdf

- *where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake; or*
- *where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit.*

- *The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use.*

- *Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand.*

- *Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.*

- *Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.*

- *The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.*

Consideration of this Application in regard to the Policy Guideline is discussed further in Section 10.2.

3.3 Overseas and International Regulations

3.3.1 Codex Alimentarius

The Codex Alimentarius definition of food includes chewing gum. There is no specific Codex Standard for chewing gum, although general principles exist for the addition of essential nutrients to foods[15]. These principles include guidance on the addition of nutrients for the purpose of fortification to prevent or correct a demonstrated deficiency of one or more nutrients in the population or specific population groups.

3.3.2 United States of America

At present, the United States of America (USA) Food and Drug Administration (FDA) does not have regulations permitting the fortification of chewing gum (≤0.2% residual sugars), although a *Fortification Policy* does exist[16]. The *Fortification Policy* provides guidance only, rather than regulates fortification, but must be adhered to if a nutrient content claim is made on a food product.

[15] General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987 (Amended 1989,1991).
[16] U.S. Food and Drug Administration. Code of Federal Regulations. Fortification Policy: Title 21, Chapter 1, Subchapter B, Part 104.20.

In addition, the *Code of Federal Regulations* provides 'reference amounts customarily consumed per eating occasion' for food labelling[17]. The listed reference amount for chewing gum is 3 g.

3.3.3 Canada

Currently, products such as chewing gum are not permitted to be fortified with vitamins or minerals according to the Canadian *Food and Drug Regulations*. Although it is considered a 'food', chewing gum (≤0.2% residual sugars) with added calcium is currently not permitted for sale in Canada.

In 2005, Health Canada released a proposed policy and implementation plan for developing new food fortification regulations[18]. There is no information currently available to indicate that the policy has been adopted. If adopted, the policy on the addition of vitamins and minerals to foods would provide for the voluntary fortification of chewing gum products[19].

Similarly to the USA, Canada also stipulates reference amounts for labelling of foods[20]. The listed reference amount for chewing gum is 3 g.

3.3.4 European Union

In December 2006, the European Parliament and the Council of the European Union adopted Regulation (EC) No 1925/2006[21], on the addition of vitamins and minerals and of certain other substances to foods.

The above Regulation provides for the voluntary addition of vitamins and minerals to foods, for reasons including to account for a deficiency of one or more vitamins and/or minerals in the population or specific population groups. Foods not permitted to be fortified are unprocessed foods (e.g. fruit, vegetables, meat) and beverages containing more than 1.2% alcohol. Therefore, the Regulation currently allows the voluntary addition of calcium to chewing gum (≤0.2% residual sugars), provided all necessary criteria are met[22].
Council Directive 90/496/EEC regulates nutrition labelling for foodstuffs[23]. The Directive prescribes nutrition labelling requirements, and provides for minimum and maximum amounts of addition to be set. Under the Directive, the addition of a vitamin or a mineral to food must result in the presence of that vitamin or mineral in the food in at least a 'significant amount'. A 'significant amount' is defined, as a rule, as 15% of the recommended daily allowance per 100 g or 100 mL. This Directive is currently under review.

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[17] U.S. Food and Drug Administration. Code of Federal Regulations. Food Labelling: Title 21, Volume 2, Part 101.12.
[18] Health Canada. Addition of Vitamins and Minerals to Foods: Proposed policy and implementation plans (2005).
[19] Personal communication. Nutrition Evaluation Division, Health Canada (September 2006).
[20] Health Canada. Food and Drug Regulations. Reference amounts: Part D, Schedule M.
[21] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. *Official Journal,* L 404:26-38.
[22] Personal communication. Nutrition Division, United Kingdom Food Standards Agency (October 2006).
[23] Council Directive 90/496/EEC of the Council of the European Communities of 24 September 1990 on nutrition labelling for foodstuffs. *Official Journal,* L 276:40-44.

3.4 Current Market

3.4.1 Australia and New Zealand

The Wrigley Company is the leading chewing gum manufacturer in Australia and New Zealand, with approximately 97% market share[24,25]. Growth in the chewing gum market in Australia is coming from 'innovative' products such as Wrigley's Extra Professional and Extra White[26], and latterly, some new packaging variants.

Chewing gum can be widely purchased in grocery stores, convenience stores and other retail outlets. Total annual chewing gum sales are worth approximately $AUD223 million in Australia and $NZ53 million in New Zealand[27]. Total sales for chewing gum (≤0.2% residual sugars) account for approximately 74% of units sold in Australia and New Zealand[28].

The consumer research study findings revealed that approximately 40% of Australians and 35% of New Zealanders aged 14 years and above consume chewing gum (≤0.2% residual sugars)[29]. The proportion of consumers across age groups varies, with the highest in the 14-19 years age group (71% in Australia and 66% in New Zealand); and the lowest in the 50 years and above age group (21% in Australia and 18% in New Zealand). Across the various age groups, a higher proportion of females tend to consume chewing gum (≤0.2% residual sugars) compared to males in both Australia and New Zealand. See Attachment 4 – Consumer Research Report.

FSANZ is not aware of chewing gum (≤0.2% residual sugars) with added calcium being sold over the counter in Australia or New Zealand for the purpose of contributing towards calcium intake. However, some chewing gums (sweetened by polyols and intense sweeteners) that contain calcium that aim to improve dental health are available in Australia and New Zealand over the internet and in Australia through some dentists.

For example, Recaldent™, which contains calcium phosphopeptide-amorphous calcium phosphate (CPP-ACP), is manufactured from milk protein and provides bioavailable minerals to tooth enamel to help prevent decay[30]. Recaldent™ (CPP-ACP) has been incorporated into a chewing gum (sweetened by polyols and intense sweeteners). Recaldent™ chewing gum is also included in every ration pack issued to New Zealand Defence Force personnel, for the purpose of healing early-stage cavities[31].

The amount of calcium (as CPP-ACP) in Recaldent™ is 1.2 mg per 1.4 g piece of gum.

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[24] Synovate AZTEC data: moving annual total for Australia as at 8 June 2008 - 96.6% market share by value in Australia.
[25] Synovate AZTEC data: moving annual total for New Zealand as at 15 June 2008 – 95.1% market share by value in New Zealand.
[26] Retail World's Australasian Grocery Guide (2006).
[27] Wrigley internal estimate based on Synovate AZTEC data: moving annual total for Australia (as at 6 June 2008 and for New Zealand (as at 15 June 2008).
[28] Synovate AZTEC data: moving annual total for Australia (as at 6 June 2008) and for New Zealand (as at 16 June 2008).
[29] Consumers of chewing gum (≤0.2 % residual sugars) were all respondents that reported they consumed chewing gum, from less than weekly to daily or more.
[30] Biotimes (November 2006). Available at: http://www.novozymes.com/en/MainStructure/PressAndPublications/BioTimes/Articles/2006/4.+December/Recaldent™+-+made+from+milk+to+protect+teeth.htm. Accessed 20 August 2007.
[31] New Zealand Defence Update, Issue 49, June/July 2007.

Another product available over the internet is B-Fresh® Gum (sweetened by 100% xylitol) which contains two forms of calcium: calcium hydroxide and calcium gluconate[32], which raise the pH level in the saliva. Product information claims that bacteria that cause tooth decay cannot survive in the altered pH environment[33]. There is approximately 0.5 mg of calcium per piece (unknown quantity) of chewing gum. The Applicant's current formulation provides 21 mg calcium per gram of gum.

3.4.2 International market

The Wrigley Company is the world's largest manufacturer and marketer of chewing gum, with global sales of more than $US4 billion annually and its brands marketed in more than 180 countries[34].

Only one calcium-fortified chewing gum (sweetened by polyols and intense sweeteners) was identified in the international market that aims to contribute to calcium intake. In 2004, Ford Gum & Machine Company introduced 'Cow Power Calcium Chewing Gum' onto the market promoting it as an 'easy and delicious' way for consumers to meet their daily requirement of calcium. Each piece of the chewing gum contains 250 mg of calcium, plus vitamin D to aid in the absorption of calcium. While this is the amount of calcium in the chewing gum, no information is provided on the amount of calcium available for absorption.

The Adams confectionery business was the first company to use Recaldent™ (CPP-ACP) in chewing gum (sweetened by polyols and intense sweeteners) that was marketed in the USA, Japan and four European countries. Recaldent™ chewing gum has been well received in Japan, where it has been sold over the counter and through dental surgeries since 2000. Recaldent™ (CPP-ACP) is also used in Trident White Gum, a leading whitening gum in the USA[35].

3.4.3 Future market share predictions

The Applicant predicts that a calcium-fortified chewing gum (≤0.2% residual sugars) in Australia and New Zealand would achieve a 12% market share in the first year, and generate a 5% growth in the chewing gum market. This would include a 1% growth in units of chewing gum (≤0.2% residual sugars) in Australia. Similarly in New Zealand, an increase of approximately 2% in market share sales of chewing gum (≤0.2% residual sugars) is predicted. In the absence of a calcium-fortified chewing gum (≤0.2% residual sugars), the Applicant predicts the market share of sugared chewing gum verses chewing gum (≤0.2% residual sugars) and the overall size of the gum market would remain stable.

The consumer research study also included a component on consumer interest in purchasing calcium-fortified chewing gum (≤0.2% residual sugars). Thirty-three percent of Australians and 38% of New Zealanders aged 14 years and above stated they would be either 'somewhat' or 'very' interested. In both Australia and New Zealand, females were generally more interested and the level of interest decreased with age.

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[32] Calcium gluconate is listed as a permitted form of calcium in the Schedule to Standard 1.1.1, however calcium hydroxide is not.

[33] www.xylitolnow.com/B-fresh.html Accessed 21 August 2007.

[34] www.wrigley.com. Accessed 28 July 2008.

[35] Biotimes (November 2006). Available at: http://www.novozymes.com/en/MainStructure/PressAndPublications/BioTimes/Articles/2006/4.+December/Recaldent™+-+made+from+milk+to+protect+teeth.htm. Accessed 20 August 2007.

Of those who stated they would be interested in purchasing calcium-fortified chewing gum (≤0.2% residual sugars), 51% of Australians and 50% of New Zealanders stated they would consume this chewing gum in *addition* to other chewing gum products or food already consumed. Conversely, 40% of Australians and 38% of New Zealanders reported they would consume this chewing gum as a *replacement* for other chewing gum products or other foods in their diet.

The Applicant states the primary target group for calcium-fortified chewing gum (≤0.2% residual sugars) is women over 35 years of age, and that the product has been specifically designed to meet the needs of this group. The potential target groups for calcium-fortified chewing gum (≤0.2% residual sugars) is discussed further in Section 10.1.2.

4. The Issue

The Applicant is seeking permission for the voluntary addition of calcium to chewing gum (≤0.2% residual sugars). The Applicant states the purpose of their request is to provide consumers with an additional source of calcium. Calcium has a beneficial role in bone health and dental health, and data available for Australia and New Zealand indicates low levels of intake of calcium across the population.

Currently, the Code permits the voluntary addition of calcium, in addition to other vitamins and minerals, to certain foods; however, there is no permission for the voluntary addition of calcium to chewing gum (≤0.2% residual sugars).

The issue is whether the addition of calcium to chewing gum (≤0.2% residual sugars), at the requested level, is safe and provides a benefit to calcium intakes and/or dental health for the Australian and New Zealand population.

5. Objectives

The specific objectives for the assessment of this Application are to:

- protect the public health and safety of consumers of chewing gum (≤0.2% residual sugars); and
- ensure adequate information is provided to enable consumers to make informed choices.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

6. Key Assessment Questions

6.1 Prevalence of calcium inadequacy

- What is the evidence for inadequate calcium intake in the Australian and New Zealand populations?

6.2 Potential nutritional benefits and risks from ingested calcium

- What is the bioavailability of the proposed forms of calcium to be used in calcium-fortified chewing gum (≤0.2% residual sugars)?
- What is the estimated calcium intake from calcium-fortified chewing gum (≤0.2% residual sugars)? Will this level of intake assist in addressing inadequate calcium intakes in the population?
- Is there a risk of excess calcium intake?
- What is the likelihood that calcium-fortified chewing gum (≤0.2% residual sugars) will be used to substitute other sources of calcium in the diet?

6.3 Potential dental health benefits and risks

- What are the potential benefits to dental health from calcium-fortified chewing gum (≤0.2% residual sugars)?
- What form(s) of calcium provide(s) this potential dental health benefit?
- If a dental benefit exists, how much calcium is required to achieve this beneficial effect?
- Are there risks to dental health from calcium-fortified chewing gum (≤0.2% residual sugars)?

6.4 Technical issues

- What forms of calcium are technically able to be added to chewing gum (≤0.2% residual sugars)?

- Is calcium used as an ingredient of gum base? If so, does this contribute to the potential nutritional and/or health benefits of calcium-fortified chewing gum (≤0.2% residual sugars)?

- In the case of polyols, what amount constitutes 'excessive consumption' and may have a laxative effect?

RISK ASSESSMENT

7. Approach to the Risk Assessment

In accordance with the Ministerial Policy Guideline on the fortification of foods with vitamins and minerals (see Section 3.2), FSANZ has assessed this Application on whether there is a need to increase the intake of calcium in one or more population groups due to inadequate intakes[36], whether the addition of calcium to chewing gum (≤0.2 % residual sugars) has the potential to address the deficit in the population that consumes the chewing gum and the safety of adding calcium to the chewing gum in terms of the potential to result in detrimental excess or imbalance of calcium. Dietary intakes were estimated and were based on the amount of 'releasable calcium' from the chewing gum. The recently endorsed NRVs for calcium (described in Section 2.5) have been used as the basis of assessing inadequate and excess intakes in the population.

As chewing gum promoted as 'sugar free' is already used for its potential dental health benefit, the addition of calcium to chewing gum (≤0.2 % residual sugars) and its effect on dental health has also been considered.

FSANZ has enhanced the rigour of the risk assessment in two ways. Firstly, FSANZ obtained advice from experts in the area of dental health. Secondly, recent consumer research data on consumption patterns of chewing gum were obtained (see Attachment 4). The dietary intake assessment used consumption data for chewing gum from this consumer research study, and not a specified serve size, in order to better approximate actual gum chewing behaviour.

Responses to the issues on the risk assessment raised by submitters at Draft Assessment have also been considered and addressed where required.

Information contributing to the risk assessment can be found in Attachment 2 and Attachment 3 – Dietary Intake Assessment.

[36] Inadequate calcium intake refers to intakes for the population that are below Estimated Average Requirements (EARs). This differs from calcium deficiency which is a long term inadequate supply of calcium, or a failure in calcium metabolism, which may lead to conditions related to the loss of bone mineral, such as osteoporosis.

8. Risk Assessment

8.1 Prevalence of inadequate calcium intake

8.1.1 What is the evidence for inadequate calcium intake in the Australian and New Zealand populations?

The estimates of calcium intakes included natural sources of calcium and the current market uptake of other calcium fortified foods but excluded supplements. There are already several calcium-fortified foods on the market in Australia and New Zealand including: orange juice, low-fat milk, breakfast cereal, soy milk, formulated beverages and one dairy blend spread. Therefore, consumers can choose to consume these products to boost their calcium intakes.

In determining the prevalence of inadequate intakes, the following assumptions were made:

- dietary calcium intakes (excluding supplements) in the Australian and New Zealand populations are normally distributed. As a result, the proportion of the population with intakes currently below the EAR has been used to estimate inadequate calcium intake in the population and within various sub-groups of the population (Table 2)[37]; and

- only populations with more than 3% calcium intakes below the EAR are considered to have inadequate intakes because smaller percentages may reflect inherent uncertainties in population nutrient intakes.

Table 2 below shows the estimated mean dietary calcium intakes for each age group and the proportion of the population with intakes below the EAR. These estimates have been determined by FSANZ taking into account inherent limitations in the dietary intake assessments using the Australian and New Zealand NNSs[38].

Table 2: Estimated current mean calcium intakes[1] and proportion below the EAR[2], Australia and New Zealand, by age and sex

Age (years)	Males		Females	
	Mean intake	% < EAR	Mean intake	% < EAR
Australia				
2-3	932	0	807	0
4-8	901	4	759	10
9-13	1,018	45	802	65
14-18	1,180	45	789	80
19-29	1,136	30	797	65
30-49	952	45	744	70
50-69	861	55	721	90
> 70	779	90	679	95

[37] When certain conditions are met, the proportion of the population group with intakes below the EAR can be used to estimate the prevalence of inadequacy (Health Canada, 2006).

[38] Dietary intake data collected using 24 hour recall methods such as are used in the NNSs, are only an estimate of an individual's actual food intake. Hence statistical adjustments are made to the data to address limitations.

Age (years)	Males		Females	
	Mean intake	% < EAR	Mean intake	% < EAR
New Zealand				
15-18	966	70	770	85
19-29	962	50	766	70
30-49	888	55	712	75
50-69	798	40	667	95
>70	737	90	642	95

Source: FSANZ analysis of the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey.

1. Current mean intakes are based on a market share model. Mean calcium intakes are determined by weighting the concentration of calcium in foods according to the proportion of a food group that is fortified. The estimates for both Australia and New Zealand have been adjusted based on a second day's intake.
2. Percentages above 10% have been rounded to the nearest 5%.

Mean intakes are higher in each comparable age group among males and females in Australia than in New Zealand, although particularly among young males.

Conversely, the proportion with calcium intakes below the EAR is lower in Australia than in New Zealand, although adolescent girls (80-85%), women of all ages (65-95%) and older men (90%) in both countries are particularly at risk of inadequate intakes. See Attachment 3 – Dietary Intake Assessment for further details on results by gender.

The differences between Australia and New Zealand may be due to several factors including: differences in the foods that were assumed to be fortified; differences in the way foods were reported in the 1995 Australian NNS and the 1997 New Zealand NNS; and potential differences in food consumption patterns.

Due to the age of the NNS data and the small number of chewing gum consumers in the consumer research study, the differences in calcium intakes between chewing gum consumers and others in the population cannot be determined. Some other population sub-groups, which FSANZ is not able to investigate through its dietary intake assessment, may be at further risk of deficiency. For example, as milk and dairy products are the main sources of calcium in the Australian diet (ABS, 1998), Asian communities whose rates of lactose intolerance are high (80-90%) may be at greater risk of inadequate calcium intake (NHMRC, 2003a) because they avoid, or are not high consumers of, dairy foods.

Aboriginal adults may also have high rates of lactose intolerance (NHMRC, 2003a). Data from the 1995 Australian NNS indicate that mean daily calcium intakes for people born in East Asia were much lower (709 mg) than for people born in Australia (855 mg) (ABS, 1998). Comparable data are not available for Indigenous Australians. In general, a greater proportion of New Zealand Māori have inadequate calcium intakes than the general New Zealand population, particularly older women. Among New Zealand women aged 45 years and over, the mean intake is about 700 mg per day compared with less than 600 mg per day among Māori women of a similar age (Russell *et al*., 1999).

Other at-risk populations include young women with amenorrhoea resulting from anorexia nervosa or women with exercise-induced amenorrhoea who have reduced calcium retention and lower bone mass (Institute of Medicine, 1997). Those on vegetarian diets may also be at risk of deficiency because a relatively high oxalate and phytate content reduces calcium bioavailability (Institute of Medicine, 1997).

8.1.2 What is the bioavailability of the proposed forms of calcium to be used in calcium-fortified chewing gum (≤0.2% residual sugars)?

The Applicant is seeking permission for each of the 14 forms of calcium currently permitted in the Schedule to Standard 1.1.1 to be added to chewing gum (≤0.2% residual sugars).

The bioavailability of calcium was described in the previous FSANZ Applications: Application A424 – Fortification of Foods with Calcium which permitted the voluntary addition of each of the 14 forms of calcium to be added to fruit and vegetable juices, biscuits and soups; and Application A470 – Formulated Beverages which permitted the voluntary addition of each of the 14 forms of calcium to be added to formulated beverages.

A comparison of the bioavailability of different forms of calcium is best made on the basis of physiological outcomes, such as bone mineral density, rather than assessments under isolated, experimental conditions.

Although high doses of different supplemental calcium forms (such as calcium carbonate, calcium citrate-malate, and calcium lactate-gluconate) have been shown on occasions to differ in their impact on bone mineral density, the overall difference in impact between these forms is not clinically significant (Dawson-Hughes *et al*., 1990; Chevalley *et al*., 1994; Ruegsegger *et al*., 1995; Prince *et al*., 1995). More importantly, comparisons between similar doses of supplemental and dairy-based sources of calcium indicate that their impact on bone mineral density is approximately the same (Reid, 2005).

In general, the absorption of calcium from supplements, especially those which are less soluble, is substantially better if they are taken with a meal. This may be because the meal stimulates gastric secretion and delays emptying, so that the calcium sources are better dispersed and dissolved.

The calcium content of a food or supplement, the physiological status of an individual, daily calcium intake and presence of other foods are more important to bioavailability than any minor differences in the bioavailability between different forms of calcium.

8.2 Potential health benefits and risks from ingested calcium

8.2.1 What is the estimated calcium intake from calcium-fortified chewing gum (≤0.2 % residual sugars)? Will this level of intake assist in addressing inadequate calcium intakes in the population?

8.2.1.1 Chewing gum (≤0.2 % residual sugars) consumption patterns

The consumer research study findings showed very similar chewing gum (≤0.2% residual sugars) consumption patterns in Australia and New Zealand. About one in three people aged 14 years and over reported consuming chewing gum (≤0.2% residual sugars) with 14-19 year olds being much higher consumers (about 2 in 3) than respondents aged 50 years and over (less than 1 in 5)[39]. Slightly more women than men in the study reported consuming chewing gum (≤0.2% residual sugars).

[39] Chewing gum consumption patterns are based on frequency of consumption per week.

Of those who reported consuming chewing gum (≤0.2% residual sugars), either pellets or tabs, the majority reported consuming it less than once a day; when they do consume it, over 85% reported consuming either one to two pellets or one tab on any one occasion.

Respondents of the study were also asked about their interest in buying chewing gum (≤0.2% residual sugars) with added calcium. The results reflected similar trends between Australia and New Zealand although there was generally more interest in New Zealand than in Australia. About one in three were 'very' or 'somewhat' interested in Australia (more than 30%) compared with more than 35% in New Zealand. Younger people aged 14-19 years were more interested (48% in Australia and 58% in New Zealand) than respondents aged 50 years and over (21% in Australia and 27% in New Zealand) and more women (40% in Australia and 44% in New Zealand) than men (25% in Australia and 31% in New Zealand) were interested. See Attachment 4 - Consumer Research Report.

8.2.1.2 Scenarios used in the dietary intake assessment

The dietary intake assessment investigated a number of scenarios to reflect both current intakes of calcium and intakes following the permission to fortify chewing gum (≤0.2% residual sugars) with calcium:

- 'Baseline' – calcium intakes from food and beverages in the current regulatory environment, based on both naturally occurring calcium in the food supply and the current uptake of voluntary calcium fortification permissions by industry, other than chewing gum;

- 'Scenario 1 – Current technology' – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in 21.3 mg releasable calcium per gram of chewing gum. This level represents the amount of calcium that can be delivered using current technology.

- 'Scenario 2 – Anticipated future technology' – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in 41.7 mg releasable calcium per gram of chewing gum. This level represents the amount of releasable calcium that may be possible in the future.

8.2.1.3 Additional calcium from fortified chewing gum (≤0.2% residual sugars) at a population level in various population sub-groups

FSANZ estimated additional dietary calcium intakes taking into account chewing gum consumption amounts for specific age and gender sub-groups derived from the results of the consumer research study (see Section 8.2.1.1). At the population level, the additional dietary calcium was estimated by applying the average daily amount of chewing gum (≤0.2 % residual sugars) consumed by consumers for each age and sex sub-group to the proportion in each age and sex sub-group who indicated that they were interested in purchasing calcium-fortified chewing gum (≤0.2 % residual sugars). It was assumed that there is no difference in dietary patterns among the consumers and non-consumers of this product. FSANZ used this approach as the NNSs did not contain adequate data on current chewing gum consumption patterns of individuals.

At the population level, the results indicate that in Australia and New Zealand calcium-fortified chewing gum (≤0.2 % residual sugars), regardless of the level of fortification, has very little impact on reducing the proportion in various age and sex population sub-groups with inadequate calcium intakes (maximum of 5% reduction).

8.2.1.4 Additional calcium among consumers of chewing gum (≤0.2% residual sugars)

FSANZ also estimated the additional dietary calcium intakes among consumers of chewing gum (≤0.2 % residual sugars), based on results from the consumer research study.

The 1995 Australian and 1997 New Zealand NNSs reported very low numbers of chewing gum consumers (<1% of the population). However, results from the consumer research study indicated that approximately 40% of Australians and 35% of New Zealanders aged 14 years and over are consumers of chewing gum (≤0.2% residual sugars).

These data, specifically the frequency of chewing gum consumption and the number of pieces of gum consumed at any one time, were combined with the NNS dietary calcium intake data to estimate the impact on calcium intakes for groups of individuals (by age and sex) who consume calcium-fortified chewing gum on a daily basis (≤0.2% residual sugars) (Table 3).

Table 3: Estimated proportion of calcium-fortified chewing gum (≤0.2% residual sugars) consumers with inadequate calcium intakes, Australia and New Zealand, by age and sex

	Males (%<EAR)			Females (%<EAR)		
Age* (years)	**Baseline**	**Scenario 1**	**Scenario 2**	**Baseline**	**Scenario 1**	**Scenario 2**
Australia						
14-18	45	40	35	80	80	75
19-29	30	25	20	65	60	55
30-49	45	45	40	70	65	60
50-69	55	50	45	90	90	85
> 70	90	85	85	95	95	90
New Zealand						
15-18	70	65	60	85	80	80
19-29	50	45	35	70	65	60
30-49	55	50	45	75	70	65
50-69	40	40	35	95	90	90
>70	90	90	85	95	95	95

Source: FSANZ analysis of the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey combined with consumer research study data.
* Chewing gum consumption patterns were not collected for children less than 14 years in the consumer research study conducted by RMR.

The results indicate that in Australia and New Zealand chewing calcium-fortified chewing gum (≤0.2% residual sugars) could have a modest impact on reducing the proportion of chewing gum consumers who have inadequate calcium intakes. At the highest level of fortification there is a 5% reduction in the proportion of teenage girls and women aged 51-70 years below the EAR but greater reductions (up to 15%) among other age and sex groups.

8.3 Is there a risk of excess calcium intake?

The NHMRC and NZMoH (2006) has set an upper level of intake (UL[40]) for calcium of 2,500 mg/day for the population aged one year and above including pregnant and lactating women. The UL has been set on the basis of the toxic effects of hypercalcaemia with renal calcification and renal failure observed when calcium is given in high doses as an antacid in a carbonate form. This is the only circumstance where calcium toxicity has been observed. A Lowest Observed Adverse Effect Level (LOAEL) of about 5,000 mg was identified in studies and an uncertainty factor of two used to determine the UL (2,500 mg).

The uncertainty factor takes into account the potential for increased risk of high calcium intake, given the relatively common occurrence of kidney stones in Australia and New Zealand and concern that excess calcium will interfere with absorption of other minerals such as zinc and iron in vulnerable populations (NHMRC and NZMoH, 2006). Too much calcium may also cause gastrointestinal upsets, such as bloating and constipation.

The proportion of calcium-fortified chewing gum (≤0.2 % residual sugars) consumers likely to exceed the UL at baseline and for each fortification scenario has been estimated (Table 4). All estimates take into account calcium-fortified foods that are already available for sale but do not account for intakes from calcium supplements.

Table 4: Estimated proportion of calcium-fortified chewing gum (≤0.2 % residual sugars) consumers above the UL at baseline and following the introduction of calcium-fortified chewing gum (≤0.2% residual sugars), Australia and New Zealand, by age and sex

	Males (%>UL)			Females (%>UL)		
Age* (years)	Baseline	Scenario 1	Scenario 2	Baseline	Scenario 1	Scenario 2
Australia						
2-3	0	0	0	0	0	0
4-8	0	0	0	0	0	0
9-13	1	1	1	0	0	0
14-18	3	3	3	<1	<1	<1
19-29	2	2	3	<1	<1	<1
30-49	<1	<1	<1	<1	<1	<1
55-69	<1	<1	<1	<1	<1	<1
> 70	0	0	0	0	0	0
New Zealand						
15-18	2	2	2	0	0	0
19-29	2	2	2	<1	<1	<1
30-49	<1	<1	<1	<1	<1	<1
50-69	0	0	<1	0	0	0
>70	0	0	0	0	0	0

Source: FSANZ analysis of the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey combined with consumer research study data.

* The proportion of young children likely to exceed the UL in Australia has been estimated by applying the chewing gum (≤0.2 % residual sugars) consumption patterns among 14-18 year olds to the younger age group. This would be an overestimate of consumption but has been used to ensure that young children are not exceeding the calcium UL for their age.

[40] The Upper Level of Intake (UL) is the highest intake, including potential intakes from supplements, likely to pose no adverse health risk for almost all individuals in the specified life stage group (NHMRC and NZMoH, 2006). The UL is not a recommended level of intake; individuals who exceed the UL increase their risk of adverse health effects.

The results indicate that the addition of calcium to chewing gum (≤0.2% residual sugars) will have minimal effect on exceedances of the calcium UL in the Australian and New Zealand populations compared with the situation at baseline.

8.4 What is the likelihood that calcium-fortified chewing gum (≤0.2% residual sugars) will be used to substitute other sources of calcium in the diet?

As with any fortified product, there is a potential risk that consumers might substitute a product naturally high in a vitamin or mineral with one that is fortified; this potentially changes their intake of other nutrients.

In this case, consumers could replace a proportion of their consumption of nutrient-dense milk and dairy products (the major source of calcium in the Australian and New Zealand diet) with calcium-fortified chewing gum (≤0.2% residual sugars). However, research commissioned by FSANZ in 2005 indicates that this is unlikely to occur[41].

Additionally, dairy foods and chewing gum are not similar foods or consumed in the same way, therefore reducing the likelihood of substitution. Dairy foods would continue to be used where such foods are normally used, such as milk with breakfast cereal, in hot beverages and as an ingredient in baked products, sauces and custards. Milk and dairy products are also consumed for reasons other than their calcium content such as taste.

The consumer research study canvassed responses on foods that might be displaced by calcium-fortified chewing gum (≤0.2% residual sugars). Overall, 40% of Australian respondents and 38% of New Zealand respondents indicated they would replace a food in their diet with this chewing gum. However, only 2-3% of gum consumers in either country would substitute calcium-rich foods in the diet, such as milk, cheese or yoghurt, with a calcium-fortified 'sugar-free' chewing. These data are based on self-reported intention; hence they may not result in actual behavioural change.

As consumption of chewing gum (≤0.2% residual sugars) is highest among 14-19 year olds (nearly 2 in 3), adolescent girls and young women, particularly those who are weight conscious, may be at greatest risk from substituting dairy foods with calcium-fortified chewing gum (≤0.2% residual sugars). In an earlier survey commissioned by the Applicant[42], when respondents snacked 'to avoid eating something more fattening' chewing gum was used on 49% of eating occasions. Female respondents were nearly twice as likely as male respondents to use chewing gum for this reason. However, chewing gum was more likely to be used by respondents because it was 'good for my teeth' (85% of eating occasions).

Any effects of substitution behaviours on nutrient intakes resulting from new fortified products coming onto the market would be identified in future monitoring activities and would cover both foods that are a natural source of the nutrient and those that have been fortified.

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[41] TNS Social Research Report on Analysis of Fortification of Foods with Calcium Research. Prepared for FSANZ, August 2005. Available at: http://www.foodstandards.gov.au/_srcfiles/SSR%20A424%20Calcium%20fortification%20SRR%20FINAL.doc#_Toc115508695

[42] Added Value (2004) Wrigley Market Mapping.

8.4.1 Risk of nutrient deficits or imbalances resulting from milk substitution

Due to the nutrition profile of calcium-fortified chewing gum (≤0.2% residual sugars), additional consumption of this product is unlikely to make any difference to the nutrient intake of consumers apart from the added calcium. It contains very small amounts of energy per serve (approximately 27 kJ in two pellets) and so will have negligible effect on overall energy intakes.

In Application A424, FSANZ undertook a worst case dietary modelling scenario by assuming a 50% reduction in milk consumption due to substitution with calcium-fortified beverages. The results showed a small decrease in riboflavin and zinc intakes – micronutrients that are abundant in milk. Similarly, vitamin B_{12} and protein intakes would decrease slightly but still remain above the current RDI for all population subgroups. While reduced iron absorption is also recognised as a risk among vulnerable populations with high calcium intakes, this is unlikely to be of significance given the small expected increases in calcium intake from fortified chewing gum (≤0.2% residual sugars).

8.5 What are the potential benefits to dental health from calcium-fortified chewing gum (≤0.2 % residual sugars)?

The Australian Dental Association (ADA) recommends the use of chewing gum (≤0.2% residual sugars) to promote the clearance of food from the mouth and to dilute plaque acids following food consumption but not in place of regular daily tooth brushing[43]. The Applicant provided a sample of research to support this recommendation in their Application to FSANZ (see Attachment 2). FSANZ has not investigated the basis of this recommendation further as it is outside the scope of the risk assessment.

There is some evidence of a short term benefit to dental health arising from the topical application of calcium from chewing gum (≤0.2% residual sugars) with added calcium. The evidence, however, is based on a limited number of small but well-controlled studies investigating the immediate effects of chewing gum, fortified with predominantly soluble forms of calcium, consistently report a short-term dental health benefit. This is supported by increased salivary and plaque fluid calcium concentrations and remineralisation of enamel sub-surface lesions.

There is insufficient evidence to date that calcium-fortified chewing gum (≤0.2% residual sugars) prevents dental caries in the long term.

8.6 What form(s) of calcium provide(s) this potential dental health benefit?

Chewing gums containing casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) (<1-3%) may be more effective at both remineralising sub-surface lesions as well as improving their resistance to subsequent acid challenges, even at lower concentrations of total calcium than chewing gums (≤0.2% residual sugars) containing other forms of calcium.

However, other forms of calcium that may provide a dental health benefit include:

- calcium lactate (permitted form of calcium);

[43] ADA Policy Statement 1.2.3: Oral Hygiene. November 21/22, 2002.

- calcium carbonate (permitted form of calcium);
- tetracalcium phosphate/dicalcium phosphate (equivalent to the permitted form calcium phosphate dibasic);
- monocalcium phosphate monohydrate (equivalent to the permitted form calcium phosphate monobasic); and
- α-tricalcium phosphate (equivalent to the permitted form calcium phosphate tribasic).

The Applicant is initially proposing to add calcium lactate or calcium carbonate to chewing gum (≤0.2% residual sugars). They are, however, also seeking permission for each of the 14 forms permitted in the Schedule to Standard 1.1.1 to allow for product innovation in the future. The evidence for a dental health benefit from the addition of calcium in the forms described above is limited. Hence, FSANZ cannot draw a conclusion regarding the potential dental health benefits of all 14 permitted forms of calcium in Standard 1.1.1.
However, the potential to provide a dental health benefit does appear to depend on the solubility of the form of calcium in water; and not all 14 permitted forms are water-soluble.

8.7 If a dental benefit exists, how much calcium is required to achieve this beneficial effect?

Short-term dental health benefits (such as those described in Section 8.5) were reported for chewing gums containing between <1-5% of the forms of calcium listed in Section 8.6. CPP-ACP containing gums may be more effective at remineralising subsurface lesions at lower doses of calcium than other calcium-fortified chewing gums (see Attachment 2). The amount of elemental calcium in these studies was not reported. The Applicant is requesting to add calcium at a maximum claim level of 200 mg per serve which equates to about 7% calcium for a 3 g serve. This proportion of elemental calcium is higher than the proportion of the forms of calcium described above as having an effect. Therefore, the amount requested by the Applicant may have a similar effect; assuming the form is one of those described above (see Section 8.6).

8.8 Are there risks to dental health from calcium-fortified chewing gum (≤0.2% residual sugars)?

An issue raised in a submission to the Initial Assessment Report from an expert in dental health, which was not raised again at Draft Assessment, was the concern that increased salivary calcium from unstabilised calcium in chewing gum (≤0.2% residual sugars) may increase the risk of developing dental calculus (tartar) and subsequent periodontal disease. The potential increased risk of dental calculus related only to calcium phosphate but not other permitted forms of calcium in the Code.

FSANZ could find no reference in the literature of a dental risk to humans from chewing calcium-fortified chewing gum (≤0.2% residual sugars). As a result, FSANZ sought expert advice[44] on the issues raised in the submission.

[44] FSANZ commissioned Dr Peter Shellis, from the University of Bristol Dental School, to provide advice on the potential dental benefits and risks from calcium-fortified chewing gum (≤0.2% residual sugars).

This advice indicated that addition of calcium to chewing gum (≤0.2% residual sugars), if it were to promote calculus at all, would only stimulate supra-gingival calculus because saliva is the source of calcium for this form of calculus. Furthermore, in populations where regular hygiene is practised and where professional dental care is widely available, supra-gingival calculus formation has little impact on oral health.

The Applicant also sought further advice on this issue from two international dental experts who both concluded that a risk to dental health from calcium-fortified chewing gum (≤0.2% residual sugars) was unlikely and that the concern was based mainly on theoretical grounds and was not supported by scientific evidence.

8.9 What forms of calcium are technically able to be added to chewing gum (≤0.2% residual sugars)?

The Applicant has requested that each of the 14 forms of calcium included in the Schedule to Standard 1.1.1 be permitted to be added to chewing gum (≤0.2% residual sugars).

While it is technically possible to add any of these forms to chewing gum (≤0.2% residual sugars), lower molecular weight forms are likely to be the most suitable for delivering the desired quantity of calcium due to the limited size of a chewing gum pellet or tab.

In addition, 19 forms of calcium are permitted to be added to chewing gum for a technological purpose (Schedule 2 to Standard 1.3.1 – Food Additives). This list includes calcium lactate and the calcium phosphates.

8.10 Is calcium used as an ingredient of gum base? If so, does this contribute to the potential nutritional and/or health benefits of calcium-fortified chewing gum (≤0.2% residual sugars)?

The Applicant has indicated that calcium carbonate is added to the base of their chewing gum to maintain softness. The calcium in the gum base is not available because it is bound into the latex gum base and is not released on chewing. However, the releasable calcium added for a nutritional purpose would be added to the chewing gum at the same stage as other ingredients that are released upon chewing, such as artificial sweeteners and polyols. For example, it can be demonstrated that approximately 30% is released from a product containing calcium carbonate during 20 minutes of chewing, using current technology[45].

8.11 In the case of polyols, what amount constitutes 'excessive consumption' and may have a laxative effect?

Polyols is a term used to describe a number of sugar alcohols including sorbitol, mannitol, maltitol, xylitol, lactitol, isomalt and erythritol. Polyols are generally less sweet or equally as sweet as sucrose or sugar, but are incompletely absorbed and metabolised in humans, which results in them having a lower energy value than sucrose. For this reason they can be used as lower energy sweetening agents to replace part or all sugar in a food product. Polyols may also be added to foods for other technological purposes, including use as bulking agents and humectants.

[45] Based on 'chew-out' test data provided by the Applicant for chewing gum products with added calcium carbonate.

Foods containing polyols at certain levels are required in Australia and New Zealand to carry a label advisory statement to the effect that excess consumption of the food may have a laxative effect (clause 5 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations). The label advisory statement is triggered by the proportion of polyols in a food product rather than the total quantity present.

Sorbitol, erythritol and isomalt are required to include the laxative advisory statement on the label of a food that contains 25 g or greater per 100 g of those polyols. Lactitol, maltitol and maltitol syrup are also required to include the laxative advisory statement on the label of a food that contains 10 g or greater per 100 g of those polyols.

The polyols used in chewing gum (≤0.2% residual sugars) may have a laxative effect for some individuals at high levels of consumption. However, the intake of polyols from chewing gum (≤0.2% residual sugars) is likely to be much less than the daily threshold levels for such laxative effects. For example, quantities greater than 50 g daily of sorbitol are indicated to be laxative (WHO/FAO, 1974).

A pellet of chewing gum (≤0.2% residual sugars)[46] contains 0.4 g of sorbitol. Assuming a regular consumer of chewing gum (≤0.2% residual sugars) consumed four pellets daily, their daily intake of sorbitol from chewing gum would only be 1.6 g.

9. Summary of risk assessment

FSANZ has undertaken a robust and extensive assessment of the public health and safety implications of this Application and the risk has been characterised accordingly.

9.1 Evidence of inadequate calcium intakes

The majority of males and females in Australia and New Zealand, most notably adolescent girls (80-85%) and older men and women (90-95%), have daily calcium intakes below the EAR.

9.2 Evidence that voluntary fortification of chewing gum (≤0.2% residual sugars) with calcium will address inadequate intakes or deliver a health benefit

At a population level, the addition of calcium to chewing gum (≤0.2% residual sugars) in Australia and New Zealand is likely to have very little impact on reducing the proportion of the population with inadequate calcium intakes (maximum of 5% reduction).

However, for chewing gum (≤0.2% residual sugars) consumers, the reduction in the proportion below the EAR may be up to 15% among some age and sex groups.

Each of the 14 permitted forms of calcium have the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability based on an assessment of physiological outcomes, such as bone mineral density. Lower molecular weight forms of calcium are likely to be the most suitable for delivering the desired quantity of calcium in a small volume such as chewing gum.

[46] Based on a current pellet of Wrigley's chewing gum (≤0.2 % residual sugars), which weighs 1.4 g.

There is some evidence of a short-term benefit to dental health through increased tooth remineralisation as a result of chewing calcium-fortified chewing gum (≤0.2% residual sugars) containing soluble forms of calcium, but long-term dental health benefits remain uncertain. Both calcium lactate and calcium carbonate, the forms the Applicant is proposing to add initially, are two of the forms identified as potentially providing a short-term dental health benefit. This conclusion cannot be extended to all 14 permitted forms of calcium in the Code.

9.3 Evidence that voluntary fortification of chewing gum (≤0.2% residual sugars) will not cause excess calcium intakes or imbalances in vitamin and mineral intakes

Small proportions of the population already exceed the calcium UL for their age group (e.g. up to 3% of young males in Australia and New Zealand). There is no additional risk of excess calcium intake from fortifying chewing gum (≤0.2% residual sugars) with calcium.

There is a small risk that some segments of the population may replace calcium-rich foods with calcium-fortified chewing gum (≤0.2% residual sugars) but this is unlikely to cause any dietary inadequacies of other nutrients.

Although increased dental calculus was raised as a potential risk to dental health from consuming chewing gum (≤0.2% residual sugars) with added calcium phosphate, FSANZ's review of the evidence indicated this is unlikely.

RISK MANAGEMENT

10. Risk Management Issues

On the basis of FSANZ's risk assessment the following sections discuss approaches to managing any identified public health and safety risks, other broader issues relevant to the regulation of calcium-fortified chewing gum (≤0.2 % residual sugars), and responds to issues raised in submissions.

10.1 Patterns of consumption

10.1.1 Nature of chewing gum as a food

Chewing gum is recognised as a food under paragraph 5(1)(d) of the FSANZ Act. However, chewing gum is considered a unique food, compared with other foods, as it:

- is only partially ingested, as the chewing gum cud is discarded after chewing;
- is not consumed as a meal or part of a meal, rather it is marketed to be consumed immediately after meals;
- may be consumed on multiple occasions per day;
- has little or no nutritional value; and

- is consumed in small quantities per eating occasion (i.e. gram weight).

The unique nature of chewing gum as a food has been considered in the assessment of this Application, as detailed in the sections below.

10.1.2 Target group

The Applicant states the primary target group for calcium-fortified chewing gum (≤0.2% residual sugars) is women over 35 years of age and that the product has been specifically designed to meet the needs of this group. In addition, they consider the benefits of increased calcium intake could be accrued more widely, as chewing gum is consumed broadly across the population.

Some submitters to the Initial Assessment Report commented on the likely target group(s) for the proposed product. Potential target groups were considered to be: teenagers and young adults, current consumers of chewing gum who are concerned with dental health, and those who believe they are not consuming sufficient calcium. Post-menopausal women were not considered a likely target group as they would be unlikely to consume chewing gum at a level that would convey any benefit.

The consumer research study findings showed approximately 40% of Australians and 35% of New Zealanders are consumers of chewing gum (≤0.2% residual sugars)[47]. Those aged 14-19 years represent the largest proportion of consumers of these products and there is a decline in consumption with increasing age. Those aged 50 years and over represent the smallest proportion of consumers of these chewing gum products. Overall, more females consume chewing gum (≤0.2% residual sugars) than males.

The consumer research study also considered consumer interest in purchasing calcium-fortified chewing gum (≤0.2% residual sugars). Females and those aged 14-29 years showed greatest interest in purchasing the proposed product. Interest in purchasing the fortified product declined with increasing age.

Therefore, based on current chewing gum consumption patterns, the most likely group to consume calcium-fortified chewing gum (≤0.2% residual sugars) is females aged 14-29 years. However, other factors may influence purchase behaviour including marketing of the product, information on the product label and price. See Attachment 4 – Consumer Research Report.

10.1.3 Amount consumed per eating occasion

The Applicant considers a serving size of chewing gum of 3 g, which equates to approximately 2 pellets, 1.5 tabs or 1 stick of chewing gum, is appropriate. This amount is consistent with food labelling regulations in both the USA and Canada, which both list the reference amount for chewing gum as 3 g.

In addition, the consumer research study gathered data on the number of pellets and tabs of chewing gum (≤0.2% residual sugars) consumed per eating occasion.

[47] Consumers of chewing gum (≤0.2 % residual sugars) were all respondents that reported they consumed chewing gum, from less than weekly to daily or more.

The data showed that the majority of people consume one or two pellets per eating occasion (average of around one and a half pellets), or one tab per eating occasion (average of just under one and a half tabs). The gram weight of current Wrigley chewing gum products is 1.4 g per pellet and 1.93 g per tab.

Some submitters to the Draft Assessment Report noted the difference between the Applicant's stated serve size (i.e. 3 g) and the serve size found by the consumer research study (i.e. approximately 2.1 g for pellet and 2.8 g for tab chewing gum respectively). Of note is that the Dietary Intake Assessment used chewing gum consumption amounts for specific age and sex sub-groups derived from the results of the consumer research study, and not a 3 g serve size, to estimate additional dietary calcium intake from calcium-fortified chewing gum (≤0.2 % residual sugars).

10.2 Consistency with the Policy Guideline

The Ministerial Policy Guideline provides guidance on the voluntary addition of vitamins and minerals to food. In submissions to the Draft Assessment Report, some government submitters stated that they believe the proposed fortification of chewing gum (≤0.2 % residual sugars) with calcium is inconsistent with and contrary to the intent and spirit of the Policy Guideline.

This section outlines FSANZ's consideration of the request to permit the addition of calcium to chewing gum (≤0.2% residual sugars) in regard to the Ministerial policy guidance.

10.2.1 Potential benefits

10.2.1.1 Evidence of inadequate calcium intakes in Australia and New Zealand

As reported in the risk assessment, the majority of males and females in Australia and New Zealand, most notably adolescent girls and older men and women, have inadequate calcium intakes.

The Policy Guideline outlines specific criteria for permitting voluntary fortification. This includes:

> *where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake.*

The evidence of inadequate calcium intakes in Australia and New Zealand across a number of population groups meets the above condition to permit the fortification of foods with calcium, if all other relevant policy principles are met.

10.2.1.2 Evidence that calcium-fortified chewing gum (≤0.2% residual sugars) has the potential to address inadequate calcium intakes

The Policy Guideline states that:

> *The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use.*

Specifically, this policy principle relates to the potential of the permitted fortification to address the deficit in *a population group that consumes the fortified food*. In this case, consumers of chewing gum (≤0.2 % residual sugars).

Some submitters to the Draft Assessment Report commented that the contribution of calcium-fortified chewing gum (≤0.2 % residual sugars) to calcium intake would be negligible at a population level. As confirmed by the risk assessment, at a population level the proposed fortification will have very little impact on reducing the proportion of the population with inadequate calcium intakes (maximum of 5% reduction).

However, for consumers of chewing gum (≤0.2 % residual sugars), who will be the population group that consumes the fortified food, the risk assessment found that chewing calcium-fortified chewing gum (≤0.2% residual sugars) will have a modest impact on reducing the proportion of these consumers who have inadequate calcium intakes. At the highest level of fortification, there is a 5% reduction in the proportion of teenage girls and women aged 51-70 years below the EAR, and greater reductions (up to 15%) among other age and sex groups.

In addition, the risk assessment noted that each of the 14 permitted forms of calcium have the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability.

Assuming a consumption pattern of chewing gum similar to current reported levels, calcium-fortified chewing gum (≤0.2% residual sugars) will provide a nutritional benefit for its consumers as it has the potential to assist in addressing inadequate calcium intakes among Australian and New Zealand consumers of the calcium fortified chewing gum.

10.2.1.3 Evidence that calcium-fortified chewing gum (≤0.2% residual sugars) has the potential to deliver a health benefit

In addition to providing consumers with an additional source of calcium in their diet, the Applicant identified potential benefits for dental health as reasons for requesting permission to add calcium to chewing gum (≤0.2 % residual sugars). A number of submitters to the Draft Assessment Report agreed that there was some evidence to support a dental benefit.

The risk assessment identified a potential short-term dental benefit from increased tooth remineralisation from chewing calcium-fortified chewing gum (≤0.2 % residual sugars). Specifically, from calcium-fortified chewing gum (≤0.2 % residual sugars) that contained a soluble form of calcium such as calcium lactate. Therefore, chewing calcium-fortified chewing gum (≤0.2 % residual sugars), depending on the form, may provide a short term dental health benefit to consumers of the fortified food, in addition to the nutritional benefit.

10.2.2 Potential risks

10.2.2.1 Potential risk of excess calcium intake

The Policy Guideline requires that a permission to fortify will not have the potential to result in detrimental excesses or imbalances of the vitamin or mineral in the context of total intake across the general population.

The risk assessment concluded that there is no additional risk of excess calcium intake from fortifying chewing gum (≤0.2% residual sugars) with calcium.

10.2.2.2 Potential risk to dental health

A submitter to the Initial Assessment Report identified increased dental calculus as a potential risk from consuming chewing gum (≤0.2% residual sugars) with added calcium phosphate. FSANZ's review of the evidence and comments from dental experts indicated this risk is unlikely.

10.2.3 Appropriateness of the food vehicle

It is important to consider the appropriateness of chewing gum (≤0.2% residual sugars) as a food vehicle for voluntary fortification. The Policy Guideline states that voluntary permission to fortify *should not promote increased consumption of foods high in salt, sugar or fat* and *should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand.*

Several submitters considered that the proposed fortification has the potential to 'promote consumption patterns inconsistent with nutrition policies and guidelines' and that although the product is low in fat, salt and sugar, chewing gum (≤0.2 % residual sugars) remains an inappropriate food vehicle for fortification. Concerns included that chewing gum (≤0.2% residual sugars) is a confectionery product, it provides little nutrition and that it may be perceived as a nutritious food.

The introduction of a newly fortified food or food category into the market can result in four possible scenarios[48]. In this case for example, calcium-fortified chewing gum (≤0.2% residual sugars) may:

- substitute for a non-fortified chewing gum or similar product(s) (substitution);
- displace other food or beverage product(s) including those that are traditional sources of calcium (displacement);
- be consumed in addition to usual food and beverage intake (addition); and/or
- not be consumed (avoidance).

Consumer research commissioned by the Applicant[49] suggests that other chewing gum and confectionery products would be substituted with calcium-fortified chewing gum (≤0.2% residual sugars). Their research indicated that the substituted products would be: other gums (58%), mints and lollies (25%) and other foods (7%), with the remaining 10% coming from uptake by new consumers.

Findings from the consumer research study (at Attachment 4) investigated the likelihood of consumers substituting other foods with calcium-fortified chewing gum (≤0.2% residual sugars).

[48] FSANZ (2005). *Fortification Implementation Framework, June 2005.*
[49] Ipsos (March 2006) Concept Screening: evaluation of confectionery concepts.

These data show that approximately 40% *of people interested in buying calcium-fortified chewing gum* (≤0.2% residual sugars) would *substitute* some foods in their diet with the proposed product. The majority claimed they would substitute other chewing gum products or confectionery while few (2-3%) reported that they would replace calcium-rich foods such as milk, cheese or yoghurt. In addition, as dairy foods and chewing gum are not similar foods or consumed in the same way, this reduces the likelihood of substitution.

Therefore, the above data support the risk assessment conclusion that it is unlikely that a permission to fortify chewing gum (≤0.2% residual sugars) with calcium will cause any dietary inadequacies of other nutrients. Additionally, the likely consumption patterns identified in relation to substitution should not adversely affect consumption patterns inconsistent with national nutrition policies or guidelines.

FSANZ is intending to include calcium-fortified food items in its proposed monitoring program for voluntary fortification permissions. Also, future national nutrition surveys in Australia and New Zealand are likely to record consumption of calcium containing foods and foods fortified with calcium and other nutrients. Other monitoring activities likely to detect changes to the food supply include future food composition activities where the levels of nutrients in foods and beverages are assessed, including non-fortified and fortified foods.

Also, the respective national dental associations of Australia and New Zealand both promote the use of chewing gum (≤0.2 % residual sugars) for dental health. The Australian Dental Association says using sugarless chewing gum may help protect teeth from decay by stimulating extra saliva[50] and 'Wrigley Extra Sugar Free Chewing Gum' is a New Zealand Dental Association approved product[51].

10.2.4 Potential to mislead consumers

The Policy Guideline's principles for voluntary fortification include that *the fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.*

A number of submitters to the Initial and Draft Assessment Reports considered there is potential for consumers to be misled as to the nutritional quality of calcium-fortified chewing gum (≤0.2% residual sugars). Submitter concerns related to uncertainty as to the bioavailability of calcium in the chewing gum and that a large serving size may be required to obtain a reasonable amount of calcium. In addition, several submitters were concerned that consumers would substitute foods naturally high in calcium for the fortified product, however, the majority of submitters considered this unlikely.

10.2.4.1 Nutritional quality of calcium-fortified chewing gum (≤0.2% residual sugars)

FSANZ considers that the potential for consumers to be misled as to the nutritional quality of calcium-fortified chewing gum (≤0.2% residual sugars) is small. Data presented in Section 10.2.3 shows that few consumers would intentionally substitute calcium-fortified chewing gum (≤0.2% residual sugars) for foods naturally rich in calcium, such as milk, cheese or yoghurt.

[50] Australian Dental Association – www.ada.org.au
[51] New Zealand Dental Association – www.nzda.org.nz

Instead, most consumers will purchase the proposed product for use in addition to their normal diet or as a substitute for other chewing gum products, lollies or mints. Therefore, it could be safely assumed that the majority of consumers understand the appropriate use of calcium-fortified chewing gum (≤0.2% residual sugars) in the context of their overall diet.

The Applicant has clarified that some calcium *contained* in the proposed product will not be *released* on chewing. In this case, there is potential for consumers to be misled about the amount of calcium they will obtain from the food and therefore the nutritional benefit achieved. This potential risk would be realised if the product label claimed the amount of calcium contained in the product rather than the amount of calcium released during chewing and subsequently swallowed. The Applicant has requested that calcium claims for the proposed product relate to the amount of calcium released during 20 minutes of chewing. The appropriate risk management strategy to address this issue, incorporating the Applicant's request, is discussed in Section 10.3.1.

As noted in the risk assessment, there is no appreciable difference in bioavailability between the 14 permitted forms of calcium and the level of bioavailability is comparable to calcium from dairy-based sources. Subsequently, the calcium released from calcium-fortified chewing gum (≤0.2% residual sugars) will be available for absorption and use by the body in comparable amounts as calcium from other foods, both naturally occurring and added.

The risk assessment also reported that the bioavailability of calcium from food is enhanced when consumed in the presence of other foods. The Applicant proposes to market calcium-fortified chewing gum (≤0.2% residual sugars) with the recommendation that the chewing gum be consumed immediately after ingestion of food. If calcium-fortified chewing gum (≤0.2 % residual sugars) is consumed following these directions, the absorption of calcium from the chewing gum that reaches the gut may be improved.

10.2.4.2 Serving size

The Applicant has requested that claims are based on the amount of releasable calcium *per serve*. Several submitters expressed concern that this may provide incentive for manufacturers to manipulate the serving size in order to meet claim conditions, and there was a preference for the serving size to be prescribed.

There is potential for consumers to be misled if the serve size used by the manufacturer is larger than the amount of chewing gum normally consumed in one eating occasion. In this case, consumers may be misled as to the nutritional contribution of calcium-fortified chewing gum (≤0.2% residual sugars) to their calcium intakes if their perceived serve size is smaller than the serve size used as the basis for calcium claims on the product label. However, consumers will not be misled if a realistic serving size is chosen. Use of *per serve* for the basis of labelling and nutrition claims is discussed further in Section 10.4.

10.2.5 Summary

As demonstrated above, the request to permit the addition of calcium to chewing gum (≤0.2% residual sugars) meets FSANZ's objectives including having regard to the Ministerial policy guidance on voluntary fortification. Furthermore, the proposed fortification has the potential to assist in addressing inadequate calcium intakes among consumers of the food and does not pose any risk to public health and safety.

10.3 Addition of calcium

10.3.1 Releasable calcium

Unlike other foods, chewing gum is not consumed whole and consequently some ingredients remain in the chewed cud that is discarded. In the case of calcium-fortified chewing gum (≤0.2% residual sugars) some calcium *contained* in the food will not be *released* on chewing, and therefore will not be swallowed and available for use by the body.

The amount of calcium released from the chewing gum will vary depending on the form of calcium used. For example, approximately 30% is released from a product containing calcium carbonate during 20 minutes of chewing, using current technology[52]. A greater release rate will be achieved for soluble forms of calcium compared to insoluble forms.

Consequently, flexibility as to the amount of calcium that chewing gum (≤0.2% residual sugars) can *contain* is required. For example, if a relatively insoluble form of calcium is used, rather than a more soluble form, the chewing gum will need to *contain* a greater amount of calcium to achieve the same *releasable* amount of calcium. Therefore, it is appropriate to require calcium claims for calcium-fortified chewing gum (≤0.2% residual sugars) to relate to the amount of calcium *released* during chewing, rather than the amount of calcium *contained* in the food.

Another factor influencing the amount of calcium *released* is the amount of time a consumer chews the chewing gum product. The Applicant reflected this factor in their request for calcium claims to be based on the amount of calcium released during 20 minutes of chewing. The Applicant provided to FSANZ published evidence that 20 minutes represents an average chew time for most chewing gum consumers.

The above approach is a new concept in relation to the fortification of foods. The concept of *contains* is used throughout Standard 1.3.2. For other fortified foods, the level of addition and the associated claims are based on the nutrient *content* of the edible portion of the food, as the whole of the edible portion is consumed. However, chewing gum is a unique food as it is not consumed whole.

For this reason, it is proposed that a draft stand-alone Standard for chewing gum is prepared in Part 2.10 of the Code, rather than incorporating a permission to add calcium to chewing gum (≤0.2% residual sugars) into Standard 1.3.2.

Some submitters commented that the concept of 'releasable calcium' needed to be articulated. To address this issue, FSANZ has developed both a definition for 'releasable calcium' and a formula for how releasable calcium should be calculated as part of the draft variation. Use of a stand-alone standard will allow the concept of *releasable* calcium to be unambiguously incorporated into the Code. Enforceability of the concept of *releasable* is considered in Section 10.5.

[52] Based on 'chew-out' test data provided by the Applicant for chewing gum products with added calcium carbonate.

10.3.2 Permitted forms

The Applicant has requested permission to use all 14 forms of calcium currently permitted in the Schedule to Standard 1.1.1, however calcium lactate or calcium carbonate are proposed to be used initially. As noted in Section 8.9, it is technically possible to add any of these 14 permitted forms of calcium to chewing gum. However, lower molecular weight forms are likely to be more suitable to achieve the required amount of calcium, due to the limited size of a chewing gum pellet or tab.

Submitters questioned why the Applicant wanted permission to use all 14 permitted forms of calcium when they only want to use two forms initially and there is only evidence for releasable calcium provided for these two permitted forms from the chewout tests. Submitters also suggested that only the soluble forms should be permitted as they are the ones that provide dental health benefits.

The permitted forms have both nutrition and dental health benefits. As concluded in the risk assessment, each of the 14 permitted forms of calcium have the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability based on an assessment of physiological outcomes, such as bone mineral density. There is some evidence for a dental health benefit from some of the more soluble permitted forms. A claim related to dental health benefit and calcium will only be able to be made if it can be substantiated.

Permitting all forms of calcium listed in Standard 1.1.1 to be added to calcium-fortified chewing gum (≤0.2% residual sugars) is consistent with other voluntary permissions for calcium and allows for product innovation in the future.

10.3.3 Level of addition

The Applicant's current formulation for calcium-fortified chewing gum (≤0.2% residual sugars) provides approximately 21 mg releasable calcium per gram of chewing gum. It is anticipated that future technology may achieve up to 42 mg releasable calcium per gram of chewing gum.

The risk assessment did not identify any safety concerns associated with addition of calcium to chewing gum (≤0.2% residual sugars) at these concentrations, based on current consumption levels of chewing gum (≤0.2% residual sugars).

As there are no identifiable safety concerns, an absolute maximum level of calcium that can be added to chewing gum (≤0.2% residual sugars) will not be prescribed. However, a maximum claim for releasable calcium will be prescribed, which is likely to indirectly limit the amount of calcium added.

The Applicant has requested a maximum claim level of 200 mg releasable calcium per serve of calcium-fortified chewing gum (≤0.2% residual sugars). A maximum claim of 25% of the RDI is consistent with other voluntary fortification permissions for calcium.

To discourage insignificant amounts of calcium being added to chewing gum (≤0.2% residual sugars), it is appropriate to prescribe a minimum amount of releasable calcium per serve that is required before a calcium claim can be made. This is discussed in Section 10.4.1.

10.4 Labelling and claims

Generic labelling provisions are provided in the Code to achieve three main objectives: to protect public health through the management of risk; to provide adequate information to consumers to facilitate informed choice; and to prevent misleading conduct.

The majority of the generic labelling Standards in the Code are considered to be appropriate as they currently stand and will apply to the labelling of calcium-fortified chewing gum (≤0.2% residual sugars), for example:

- the name of the food (Standard 1.2.2);
- mandatory advisory statements and declarations (Standard 1.2.3); and
- listing of ingredients (Standard 1.2.4).

However, some of the current labelling requirements of Standard 1.2.8 – Nutrition Information Requirements and Standard 1.3.2 – Vitamins and Minerals are not considered appropriate. In these cases, specific labelling provisions are recommended, as outlined in the following sections and are provided in the draft Standard (see Attachment 1). Other provisions in these Standards still apply where appropriate.

10.4.1 Criteria for making claims

A nutrition claim about a vitamin or mineral is currently permitted under Standard 1.3.2, if the food is a 'claimable food' and contains at least 10% of the RDI for that vitamin or mineral in a 'reference quantity' of the food. Permission for claims about calcium on chewing gum (≤0.2% residual sugars) and associated criteria will be provided in the stand-alone Standard; hence these conditions in Standard 1.3.2 will not apply to claims about calcium on chewing gum (≤0.2% residual sugars).

At Draft Assessment, it was proposed that the conditions for a calcium claim on chewing gum (≤0.2% residual sugars) are based on per serve rather than per reference quantity, and that the manufacturer would determine the most appropriate serve size. Some submitters expressed concern that this may provide incentive for manufacturers to manipulate the serving size in order to meet claim conditions, and there was a preference from submitters for the serving size to be prescribed. However, at Final Assessment FSANZ recommends that the proposed approach is retained.

The per serve basis is consistent with the approach recommended under Proposal P293 – Nutrition, Health & Related Claims[53], for vitamin and mineral content claims. Although this approach leaves it somewhat open for industry to manipulate (i.e. increase) serving sizes in order to meet the qualifying criteria, the serving size is required to be declared on the label and according to fair trading legislation it should not be misleading.

[53] FSANZ is currently drafting Standard 1.2.7 – Nutrition, Health & Related Claims under Proposal P293 – Nutrition, Health and Related Claims. Draft Standard 1.2.7 is currently undergoing a First Review as requested by the Ministerial Council. It is not possible to anticipate at this point in time the ultimate gazettal date for Standard 1.2.7.

FSANZ also notes that Australian Food and Grocery Council (AFGC) member food businesses have agreed to adhere to certain principles governing serving size, one of which is that *serve sizes will not be used inappropriately to manipulate energy or nutrient content per serve*. The Wrigley Company is listed as a member of AFGC.

Under Standard 1.3.2, in order to make a claim about the presence of a vitamin or mineral the food must contain at least 10% of the RDI for the nutrient and the claimed amount of the vitamin or mineral must not exceed any prescribed maximum claim level. For calcium, 10% of the RDI equates to 80 mg of calcium[54]. These same conditions will apply to claims about calcium in chewing gum (≤0.2% residual sugars) except that at least 80 mg of calcium must be *released* from one serve of the product during 20 minutes of chewing rather than *contained* in the product, and the claimed amount of releasable calcium should not exceed 200 mg (25% of the RDI) per serve. Providing the above criteria are met, a claim such as 'with calcium' or 'source of calcium' would be permitted on the label of calcium-fortified chewing gum (≤0.2% residual sugars). The use of a maximum claimable amount is consistent with the conditions in Standard 1.3.2 for fortified foods. The Applicant requested a maximum claim level for releasable calcium equivalent to 25% of the RDI for calcium.

Despite the fact that Standard 1.3.2 currently allows a claim to the effect that a food is a good source of a vitamin or mineral to be made if a reference quantity of the food contains no less than 25% of the RDI for that nutrient, it is recommended that claims such as 'good source' of calcium or releasable calcium are not permitted on calcium-fortified chewing gum (≤0.2% residual sugars). The draft Standard provides an explicit prohibition of such claims. This approach was proposed at Draft Assessment, there was no opposition to this approach by submitters and some specifically stated their support.

The drafting has been amended at Final Assessment to reflect the intent that no more than 200 mg of releasable calcium per serve can be claimed rather than prohibiting all claims if the chewing gum contained more than 200 mg of releasable calcium per serve (see paragraph 3(1)(c) of Attachment 1).

Paragraph 4(b) of Standard 1.3.2, which prohibits claims that compare the vitamin or mineral content of a food with that of any other food, will apply to calcium-fortified chewing gum (≤0.2% residual sugars).

10.4.2 Nutrition information panels and wording conditions for claims

Standard 1.2.8 requires a nutrition information panel (NIP) on the label of most packaged foods. The NIP must declare the amounts of certain nutrients contained in a serve and in 100 g or 100 mL of the food. The same requirement is considered appropriate for calcium-fortified chewing gum (≤0.2% residual sugars). However, it is recommended that when a calcium claim on calcium-fortified chewing gum (≤0.2% residual sugars) is made, the amount of calcium declared in the NIP must relate to the amount *released* during 20 minutes of chewing, rather than the amount of calcium *contained* in the product. This reflects the basis for the criteria for nutrition claims about calcium in chewing gum (≤0.2% residual sugars), which relate to releasable calcium.

[54] The current RDI for calcium is 800 mg, as stated in the Schedule to Standard 1.1.1.

In addition, it was considered to be potentially misleading and of no value to consumers if the amount of calcium contained in the chewing gum was declared in the NIP, given that the calcium remaining in the cud would not contribute to their dietary intake. Therefore, consumers must be made aware that the amount of calcium claimed relates to the amount released from the chewing gum during 20 minutes of chewing. To ensure that consumers are provided with this information, the draft Standard requires the NIP to include a statement indicating that the claimed amount of calcium *is released during 20 minutes of chewing.* This statement is intended to provide clarification to consumers that the claim relates only to the amount of calcium *released* from the chewing gum rather than *contained* in the chewing gum, and that this amount will only be released after a certain period of chewing. This statement must be located within the NIP and must be linked to the calcium declaration, for example by the use of an asterix (i.e. *).

One submitter recommended including an advisory statement on the label to inform consumers to chew immediately after the ingestion of food to increase the bioavailability of calcium. However, FSANZ does not propose to require an advisory statement, which is used when the general public or a sub-population group is exposed to a significant, but not life-threatening potential risk to health, or when guidance about the potential use is needed to protect public health and safety. Also, bioavailability is not taken into account in the conditions for other similar nutrition claims. FSANZ considers the inclusion of a statement in the NIP indicating the amount of calcium released during 20 minutes of chewing provides sufficient information for consumers to make an informed choice. Industry may however provide additional information on increasing calcium bioavailability on a voluntary basis, noting any such information needs to be consistent with fair trading regulations.

In response to the Draft Assessment Report, there was support for the use of the statement about the required chewing time to achieve the stated amount of calcium, although some submitters considered that it should also be placed on the front of the pack. However, FSANZ considers it to be overly prescriptive to require this information to be located in two different positions on the label and its location within the NIP is consistent with the normal use of an NIP to support a nutrition claim. Although one submitter requested the exact wording of the statement be prescribed for enforcement purposes, the wording will not be prescribed. The recommended draft Standard requires 'a statement to the effect that the average quantity of calcium is released during 20 minutes of chewing'. This provides flexibility for industry to incorporate the required information into NIPs and is consistent with the provisions for similar labelling requirements in the Code, such as advisory statements, where the actual wording is not prescribed.

In addition, Standard 1.3.2 requires that the proportion of the RDI of the claimed vitamin or mineral contributed by one serving of the food be declared on the label. This requirement will also apply to calcium-fortified chewing gum (≤0.2% residual sugars), and will be prescribed in the stand-alone Standard. The percentage of the RDI for calcium, released from one serve of chewing gum during 20 minutes of chewing, will be required to be declared in the NIP.

10.4.2.1 Considerations for small packages

If a nutrition claim is made on a small package, the average quantity of the claimed nutrient must be declared. Currently in the Code, paragraph 8(1)(a) of Standard 1.2.8 requires small packages to refer to the calcium content per 100 g.

FSANZ considers that for the declaration of calcium on chewing gum where the small package contains a number of servings that weigh much less than 100 g, this information would be more useful to consumers if presented on a per serve basis. Therefore, the draft Standard includes the requirement that when nutrition claims about calcium are made on a small package, the average quantity of calcium per serve (not per 100 g) and the serve size must be declared.

In the Draft Assessment Report it was proposed that the declaration of energy, carbohydrate, sugar and dietary fibre (required on a small package when a claim about sugar is made) would also be required on a per serve basis rather than per 100 g or 100 mL. This has now been revised to retain the approach currently required under Standard 1.2.8 which requires these substances to be declared on a per unit quantity basis (e.g. per 100 g). This is to ensure that consumers can easily compare these values with those declared on other non-calcium-fortified chewing gum products, which are required to declare the energy, carbohydrate, sugars and dietary fibre on a per 100 g basis. The declarations of certain nutrients required when other nutrition claims are made on calcium-fortified chewing gum (≤0.2% residual sugars) will also be required on a per unit basis, as currently required under clause 8 of Standard 1.2.8. This will provide consistency of nutrient declarations across all chewing gum products contained in small packages.

The declaration of the average quantity of calcium on a small package must also be based on the amount of calcium *released* during 20 minutes of chewing. In addition, the statement indicating that the claimed amount of calcium *is released during 20 minutes of chewing,* as outlined previously, must also be made in association with this declaration.

On small packages, the proportion of the RDI of calcium, released from one serve of chewing gum during 20 minutes of chewing, must be declared in association with the average quantity of calcium.

Where they differ to current requirements in Standard 1.2.8 and Standard 1.3.2, the requirements outlined above, for both normal and small packages, will apply only to calcium-fortified chewing gum (≤0.2% residual sugars) that carries a calcium claim, but not to other chewing gum products and as such are drafted into Standard 2.10.3.

10.4.3 Health claims

Health claims are currently regulated in Standard 1.1A.2 – Transitional Standard for Health Claims. This transitional Standard specifically prohibits certain claims, such as claims of a therapeutic or a prophylactic nature and those that make reference to a disease or physiological condition. Draft Standard 1.2.7 – Nutrition, Health and Related Claims, currently being drafted under Proposal P293, will permit a wider range of claims in the future.

One submitter sought clarification on whether chewing gum (≤0.2% residual sugars) fortified with calcium to a level of 10% of the RDI would be eligible to make a general level health claim under the proposed Standard 1.2.7. The regulation of health claims is not within the scope of this Application and specific conditions have therefore not been included in the new Standard for chewing gum. As the Ministerial Council has recently requested FSANZ review draft Standard 1.2.7, the exact conditions that would apply to general level health claims are not finalised.

FSANZ can therefore not provide clarification at this stage on whether calcium-fortified chewing gum (≤0.2% residual sugars) would be eligible to carry a general level health claim under Standard 1.2.7 when gazetted.

10.4.4 Other labelling issues

One submitter considered that the chemical source of calcium should be clearly labelled on calcium-fortified chewing gum (≤0.2% residual sugars). However, this is not currently included in the general labelling requirements in Standard 1.2.4 which requires that ingredients are declared using the common name or a name that describes the true nature of the ingredient. Therefore, declaration of 'calcium' rather than the permitted form of calcium would be sufficient to meet this condition. However, as small packages are exempt from this requirement, the presence of calcium may not be identified unless a claim is made. This is consistent with current labelling provisions in the Code, whereby, if no public health and safety concerns have been identified with a specific ingredient, then general labelling provisions, including exemptions, apply. However, manufacturers may choose to voluntarily declare the chemical source of calcium on the label.

10.5 Enforcement

In responding to the Draft Assessment Report, jurisdictions raised a number of issues in relation to the difficulties associated with compliance and enforcement.

Specifically, comments highlighted the need to ensure a procedure was available to determine the amount of releasable calcium that should in turn be used by manufacturers to generate records to validate releasable calcium claims. This would ensure consistency in the procedures used and would facilitate inspection and assessment by compliance agencies.

The Applicant initially requested referencing the use of their proprietary method for determining releasable calcium. This method has not been validated, peer reviewed or published to date. FSANZ is not aware of when this validation may occur. FSANZ has identified that the *British Pharmacopoeia* and the *European Pharmacopoeia* include procedures for determining the releasable amount of an active ingredient from medicated chewing gums. These procedures provide an objective means of determining releasable calcium that could be used by manufacturers to generate records. These pharmacopoeial references are already used in the Code for other purposes and so they are considered to be of sufficient standing to be further referenced for determining releasable calcium from chewing gum.

Internationally, the procedures for determining releasable constituents from chewing gum are currently under review. While a procedure is currently included in the *British Pharmacopoeia* and the *European Pharmacopoeia*, this procedure is in the process of being supplemented with an alternate procedure.

In addition, the *United States Pharmacopeia* does not currently include a procedure for determining releasable constituents in chewing gum. However, the procedures under consideration in Europe are also under consideration for inclusion in the *United States Pharmacopeia*. FSANZ is not aware of when these pharmacopoeial revisions may be finalised.

On this basis, FSANZ considers that the best approach would be to not prescribe a particular procedure for determining releasable calcium in the proposed standard. FSANZ considers that it would be appropriate to include an editorial note to provide information to guide manufacturers as to procedures that are currently available in the *British Pharmacopoeia* and *European Pharmacopoeia* and those that are under development in Europe and the United States. The following editorial note is therefore proposed to be included in the draft variation:

'As a guide, procedures and apparatus for determining releasable constituents from chewing gum are published in the *British Pharmacopoeia* and the *European Pharmacopoeia*, and are under consideration for inclusion in the *United States Pharmacopeia*.'

The editorial note could be revised upon approval of the revisions in the *United States Pharmacopeia*.

FSANZ recognises that compliance agencies would need to inspect records to satisfy themselves that manufacturers' representations about releasable calcium can be substantiated. For this reason, the requirement for this information to be provided to compliance agencies remains a requirement in the draft variation.

10.6 Other issues raised in submissions

10.6.1 Regulation as a therapeutic good

A number of submitters to both the Initial and Draft Assessment Reports commented that calcium-fortified chewing gum (≤0.2% residual sugars) should be regulated as a therapeutic good. Supporting rationale provided by submitters included that chewing gum (≤0.2% residual sugars) is a non-nutritional substance, it is not appropriate that FSANZ considers the tooth remineralisation properties of the food, and chewing gum is a vehicle for some complementary medicines.

A number of reasons exist for not regulating calcium-fortified chewing gum (≤0.2% residual sugars) as a therapeutic good. These were discussed above in Section 1.4. Accordingly, permission to add calcium to chewing gum (≤0.2% residual sugars) will continue to be assessed under the FSANZ Act.

10.6.2 Use of the term 'sugar-free'

Several submitters to the Initial Assessment Report and one submitter to the Draft Assessment Report commented on the use of the term 'sugar-free'. These submitters recommended that a quantified definition of 'sugar-free' be included in the Code, with the same limits as those currently outlined in the CoPoNC – less than 0.2% sugars. Submitters considered that trace amounts of sugars are nutritionally, physiologically and clinically insignificant at this level. Also, it was considered that such as definition would aid in interpretation and consumer understanding, and in preventing false and misleading information. It was noted by submitters that the issue of 'sugar-free' is integral to the future of marketing of any calcium-fortified chewing gum (≤0.2 % residual sugars), should the Application be approved. Although the Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC) have stated that in the absence of any consumer complaints, claims may continue to be made under the CoPoNC criteria, this does not provide business confidence.

The Australian *Trade Practices Act 1974* and the New Zealand *Fair Trading Act 1986* prohibit conduct that is false, misleading or deceptive with respect to the supply of food in trade and commerce. The ACCC and the NZCC, which administer the respective Acts, both interpret 'free' claims as meaning that none of the substance should be present in the food, irrespective of food regulations and codes of practice. This creates potential inconsistency between fair trading legislation and the CoPoNC. If conditions for 'sugar-free' claims (for example, the food must contain less than 0.2% sugars) were included in the Code, this would create potential inconsistency between fair trading legislation and the Code. The Trade Practices and Fair Trading Acts would effectively override conditions in the Code to the extent of the inconsistency between the two.

FSANZ has met with the ACCC and the NZCC on several occasions in relation to the issue of 'free' claims. The agreed position was to not stipulate specific criteria for 'free' in the Code; that is, to remain silent in relation to what is required for unqualified 'free' claims. Claims would therefore be regulated through fair trading laws and manufacturers would be able to use 'free' claims provided they are consistent with these requirements.

It has been suggested that manufacturers can use alternative claims to 'free' including '99.5% sugar-free' or 'contains less than 1% sugar'. The rationale is that the ACCC and NZCC's interpretation of 'free' is that the term means 'zero'. Consistency with fair trading laws will therefore be assured.

10.6.3 Draft Standard 2.10.3

Submitter comments questioned the rationale for a stand-alone standard rather than using Standards 1.3.2 and 1.2.8. Claims in Standard 1.3.2 relate to how much of a vitamin and/or mineral a food 'contains', whereas this Application relates to the amount of calcium 'released' from the food. A stand-alone standard minimises confusion with respect to claims for this unique fortified food. At Final Assessment, FSANZ has retained the proposed stand-alone standard for chewing gum. Other relevant provisions in other standards, including Standards 1.3.2 and 1.2.8, still apply to calcium-fortified chewing gum (≤0.2% residual sugars).

Also, one submitter commented on the use of the term 'supplier' in the drafting at DAR, as this captures vendors and packers as well as manufacturers and importers under Standard 1.1.1. The drafting has been revised to include a definition of *supplier making the claim* for the purpose of calcium fortified chewing gum in Standard 2.10.3.

11. Options

At Final Assessment, FSANZ is considering two options for addressing this Application:

- Option 1 – rejecting the Application, thus maintaining the *status quo* by not amending the Code to permit the voluntary addition of calcium to chewing gum (≤0.2 % residual sugars); and

- Option 2 – prepare a draft Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

12. Impact Analysis

12.1 Affected Parties

The parties likely to be affected by this Application include:

- **consumers** of chewing gum;
- Australian and New Zealand manufacturers and importers of chewing gum **(industry)**; and
- **Government,** including the enforcement agencies of Australia States/Territories and New Zealand.

12.2 Benefit Cost Analysis

- The Benefit Cost Analysis assesses the immediate and potential impacts of each regulatory option on the affected parties.

12.2.1 Option 1 – Rejecting the Application

Under this Option, the *status quo* would be maintained and the Code would not be amended to allow the addition of calcium to chewing gum (≤0.2% residual sugars).

12.2.1.1 Benefits and Costs

It is unlikely that maintaining the *status quo* will greatly impact the identified parties. As chewing gum will continue to be produced and consumed in the current environment, there will be no additional benefits or costs to consumers, industry and government.

12.2.2 Option 2 – Prepare a draft Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

12.2.2.1 Benefits

Industry

Permitting the addition of calcium to chewing gum (≤0.2% residual sugars) would increase the scope for product innovation in the chewing gum market. The Applicant anticipates that calcium-fortified chewing gum (≤0.2% residual sugars) would generate 5% growth in the total chewing gum market, which equates to approximately $8.6 million for Australia and $1.9 million for New Zealand.

The consumer research study showed that currently there are about 6.8 million consumers of chewing gum (≤0.2% residual sugars) in Australia and 1.2 million consumers of chewing gum (≤0.2% residual sugars) in New Zealand[55].

[55] Numbers reported here are weighted quantities. Consumer research data was post-weighted (in thousands) from 1311 Australian participants and 1084 New Zealand participants to accurately represent the general population (14 years and over) of each country.

A further 1.7 million people in Australia and about 0.5 million in New Zealand could be interested in buying calcium-fortified chewing gum (≤0.2% residual sugars). This translates to a possible 25% market growth in Australia and 40% for New Zealand.

In this case, the Applicant's prediction of 5% market growth is achievable in the short-term. If only one consumer out of every five of interested people who do not currently consume chewing gum were to buy the new product, it is likely that the Applicant's market growth projection would materialise.

Consumers

The consumer research study showed that approximately 33% of Australians and 38% of New Zealanders would be interested in buying calcium-fortified chewing gum (≤0.2% residual sugars). Generally, consumers will benefit in terms of increased choice of chewing gum products.

Option 2 would provide consumers with an additional source of calcium in their diet. An additional source of calcium may be particularly beneficial for those consumers who have inadequate intakes of calcium – greater than 30% of Australians and 50% of New Zealanders aged 14 years and over respectively[56]. Consumers of calcium-fortified chewing gum (≤0.2% residual sugars) will increase their calcium intake. The additional calcium has the potential to reduce the proportion of consumers with inadequate calcium intakes by up to 15%. However, the increase in calcium intake may be limited by the small amount of calcium that can be added to a serve of chewing gum (≤0.2% residual sugars).

Chewing calcium-fortified chewing gum (≤0.2% residual sugars) may also provide consumers with a short-term dental benefit.

Government

The impact on health care expenditure of government is likely to be negligible, due to the minimal increase in calcium intake across the population, and the potential dental benefit is generally limited to specific forms of calcium.

12.2.2.2 Costs

Industry

As the addition of calcium to chewing gum (≤0.2% residual sugars) would be a voluntary permission, no additional costs would be imposed on industry.

A manufacturer will incur costs if they choose to fortify chewing gum (≤0.2% residual sugars) with calcium, however FSANZ expects this cost will either be passed on to consumers at the point of sale or recovered by improved sales margins.

[56] FSANZ analysis of the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey - see section 7.1.1 table 2.

Consumers

A potential cost to consumers may arise if they are misled to believe that the fortified product would make a significant contribution to their daily calcium requirements and therefore substitute it for other calcium-rich foods such as milk. However, the consumer research study showed that very few consumers interested in purchasing the fortified product would substitute calcium-fortified chewing gum (≤0.2% residual sugars) for other calcium-rich foods. The risk assessment also showed the impact on nutrient intakes would be minimal. Additionally, information provided on the product label would also assist in minimising consumers being mislead. Therefore, the risks and costs of misleading consumers are considered minimal.

Government

Government enforcement agencies would need to monitor for compliance with the composition and labelling requirements for calcium-fortified chewing gum (≤0.2% residual sugars). Aspects of the fortified product that would need to be monitored include: correct use of claims, substantiation of claims about the amount of releasable calcium and serving size. However, the resource cost is expected to be small.

12.3 Comparison of Options

Both Option 1 and Option 2 would continue to protect the health and safety of consumers of chewing gum (≤0.2% residual sugars). Evidence shows that the addition of calcium to chewing gum (≤0.2% residual sugars) at the levels proposed (Option 2) is safe and will provide a nutritional benefit and a potential short-term dental benefit for consumers.

Option 2 would promote industry innovation and has the potential to generate growth in the total chewing gum market. Option 2 also potentially increases opportunities for international trade through potential importation and export of chewing gum (≤0.2% residual sugars) with added calcium. As Option 2 is a voluntary permission, no additional regulatory requirements will be imposed on manufacturers that do not use the permission.
Overall, a comparison of the options at Final Assessment suggests Option 2 provides greater net benefit to the affected parties.

COMMUNICATION AND CONSULTATION STRATEGY

13. Consultation

13.1 Public Consultation

13.1.1 Initial Assessment

The Initial Assessment Report for Application A577 was released for public comment from 4 October to 15 November 2006. A total of 17 submissions were received, with nine submissions from industry, five from government, and one each from a consumer group, an academic institution and a public health association.

Overall, five of the 17 submitters did not specify their preferred option, including four of the five government submitters. These submitters did not object to the consideration of this Application, however, recommended further assessment of the benefits and safety of the proposed product and the consistency with the Ministerial Council's fortification policy guidance.

Of those who did specify a preferred option, submitters were evenly divided in their support for and against the voluntary fortification of chewing gum (≤0.2% residual sugars).

13.1.2 Draft Assessment

FSANZ received a total of 18 submissions in response to the Draft Assessment Report which was released for public comment from 12 December 2007 to 6 February 2008. Seven submissions were received from industry, six from government, three from public health organisations and one each from an academic institution and a consumer group. Overall, twelve submitters (predominately from industry and public health) supported the Application, though seven provided 'in principle' support only, citing concerns regarding minimal nutritional benefit, labelling requirements and the proposed serving size. Those who fully supported the Application considered it would provide a net benefit to consumers and industry, with no public health or safety concerns.

Three of the six government submitters did not support the Application and a further two, which did not state a preferred option, appeared to also support maintaining the *status quo*. Several submitters considered the Application was inconsistent with the Ministerial Council's fortification policy guidance and that it would be difficult to enforce. A number of government submitters believed the Application was more aligned with a therapeutic good than a food due to dosage and chewing instructions to increase bioavailability. In addition, some identified little nutritional benefit, and expressed concern that this Application could set a precedent and be extended to other sugar-free confectionery and beverages.

Issues raised by submitters are addressed in relevant sections of the Report.

A summary of these submissions is at Attachment 5.

13.2 Targeted Consultation

At Draft Assessment, additional targeted consultation was undertaken with dental professionals and jurisdictions on specific issues relevant to this Application.

FSANZ commissioned Dr Peter Shellis, from the University of Bristol Dental School, to provide advice on the potential dental benefits and risks from calcium-fortified chewing gum (≤0.2% residual sugars). Specifically, he advised on the potential risk to dental health that was raised in a submission by an Australian professor of dental science. The Applicant also sought further advice on this potential risk from two international dental experts.

In addition, the findings from the consumer research study were discussed with jurisdictional representatives. These results were used extensively to inform the assessment of this Application. Also, additional targeted consultation was undertaken with the jurisdictions on specific issues relevant to this Application.

13.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to allow the addition of calcium to chewing gum (≤0.2% residual sugars) is unlikely to have a significant effect on international trade as the proposed permission will be voluntary and similar products are marketed internationally.

Therefore, amending the Code to permit the voluntary addition of calcium to chewing gum (≤0.2 % residual sugars) is unlikely to have a significant effect on trade. As such, WTO member nations were not notified of the proposed new standard for chewing gum, under either the Technical Barriers to Trade or the Sanitary and Phytosanitary Agreements.

14. Communication

At Final Assessment, FSANZ does not intend to undertake specific communication strategies. Feedback via submissions indicated general support from public health professionals and the food industry for the proposed fortification. Any concerns raised by stakeholders have been assessed and risk management strategies identified, as required.

CONCLUSION

15. Conclusion and Decision

Decision

FSANZ approves the inclusion of a Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve (Option 2).

15.1 Reasons for Decision

FSANZ approves permitting the addition of calcium to chewing gum (≤0.2% residual sugars) as it:

- does not raise any safety concerns for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) or the general population;
- provides consumers with an additional source of calcium in their diet;
- has the potential to assist in addressing inadequate calcium intakes among Australian and New Zealand consumers of calcium fortified chewing gum;
- may provide consumers with a short-term dental benefit arising from topical application of calcium;

- is consistent with FSANZ's statutory objectives including having regard to Ministerial policy guidance on voluntary fortification;

- supports industry innovation;

- provides consumers with adequate labelling information to make an informed choice; and

- the impact analysis concludes that fortification of chewing gum (≤0.2% residual sugars) with calcium provides a net benefit to affected parties.

The approved draft variations to the Code are at Attachment 1.

16. Implementation and Review

The FSANZ Board's decision will be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

Subject to any request for review by the Ministerial Council of FSANZ's decision, the proposed draft variation permitting the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve will come into effect upon gazettal.

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ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Hazard Characterisation and Identification of Potential Health Benefits from a Topical Application of Calcium
3. Dietary Intake Assessment
4. Consumer Research Report
5. Summary of Submissions to the Draft Assessment Report

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunsetting.

To commence: on gazettal

[1] *The Australia New Zealand Food Standards Code is varied by inserting –*

STANDARD 2.10.3

CHEWING GUM

Purpose

This Standard regulates the addition of calcium to chewing gum containing no more than 0.2% residual sugars; the calcium claims which can be made in relation to chewing gum containing no more than 0.2% residual sugars and certain other labelling requirements.

Table of Provisions

Clauses

1 Interpretation

In this Standard –

calcium claim means a claim about the presence of calcium in chewing gum.

chewing gum suitable for added calcium means chewing gum containing no more than 0.2% residual sugars.

releasable calcium means the amount of calcium released into the mouth during 20 minutes of chewing calculated using the following formula –

$$Ca_R = \frac{(Ca_O \times W_O) - (Ca_C \times W_C)}{W_O}$$

Where –

Ca_R is the releasable calcium (mg/g of chewing gum)

Ca_O is the original calcium concentration in the chewing gum (mg/g)

W_O is the weight of the original chewing gum (g)

Ca_C is the residual calcium in gum that has been chewed for 20 minutes (mg/g)

W_C is the weight of the chewed gum (g).

Editorial note:

As a guide, procedures and apparatus for determining releasable constituents from chewing gum are published in the *British Pharmacopoeia* and the *European Pharmacopoeia*, and are under consideration for inclusion in the *United States Pharmacopeia*.

supplier making the claim means the supplier who makes or includes on a label or in an advertisement a calcium claim.

2 Permitted addition of calcium

Chewing gum suitable for added calcium may contain added calcium provided that the calcium is in a permitted form specified in the Schedule to Standard 1.1.1.

3 Calcium claims

(1) A calcium claim may be made only if –

(a) the chewing gum to which the claim relates is chewing gum suitable for added calcium; and
(b) the chewing gum contains no less than 80 mg (10% of the RDI) of releasable calcium per serve; and
(c) the maximum quantity claimed is no more than 200 mg (25% of the RDI) of releasable calcium per serve; and
(d) the supplier making the claim has records that substantiate the matters listed in paragraphs (b) and (c); and
(e) the supplier making the claim makes the records available to the relevant authority upon request.

(2) To avoid doubt, a claim to the effect that chewing gum is a good source of calcium or releasable calcium must not be made.

4 Labelling requirements

(1) Where a calcium claim is made in relation to chewing gum suitable for added calcium, the nutrition information panel must also include –

(a) the average quantity of releasable calcium per serve; and
(b) the average quantity of releasable calcium per 100 g; and
(c) the proportion of the RDI (for calcium) of releasable calcium per serve; and
(d) a statement to the effect that the average quantity of calcium is released during 20 minutes of chewing.

(2) Subclause (1) does not apply to chewing gum suitable for added calcium in a small package.

Editorial note:

EXAMPLE

NUTRITION INFORMATION Servings per package: 10 Serving size: 3 g		
	Average quantity per serve	Average quantity per 100 g
Energy	25 kJ	833 kJ
Protein	0 g	0 g
Fat, total	0 g	0 g
– saturated	0 g	0 g
Carbohydrate	Less than 1 g	Less than 1 g
– sugars	Less than 1 g	Less than 1 g
Dietary fibre	0 g	0g
Sodium	0 mg	0 mg
Calcium*	80 mg (10% RDI**)	2670 mg
*average quantity of calcium released during 20 minutes of chewing **Recommended Dietary Intake		

Standard 1.1.1 defines a 'nutrition information panel or panel' as a panel which complies with the requirements of Division 2 of Standard 1.2.8.

5 Small packages

(1) Where a calcium claim is made in relation to chewing gum suitable for added calcium contained in a small package, the label must include the following calcium declaration –

(a) the average quantity of releasable calcium per serve; and
(b) the serving size; and
(c) the proportion of the RDI (for calcium) of releasable calcium per serve; and
(d) a statement to the effect that the average quantity of calcium is released during 20 minutes of chewing.

(2) To avoid doubt, the declaration requirement in paragraph 8(1)(a) of Standard 1.2.8 does not apply to the calcium declaration in subclause (1).

(3) The declaration required in subclause (1) need not be set out in the prescribed panel format.

Editorial note:

For the purposes of labelling, Standard 1.2.1 defines a 'small package' as a package with a surface area of less than 100 cm^2.

See clause 8 of Standard 1.2.8 for labelling requirements where nutrition claims, other than calcium claims, are made on small packages of chewing gum suitable for added calcium.

Attachment 2

Hazard Characterisation and Identification of Potential Dental Health Benefits from a Topical Application of Calcium

Summary

Calcium in the body is primarily stored in bone where it provides structure and strength. Thus, an inadequate calcium intake increases the risk of calcium resorption from bone to maintain circulating calcium levels which are essential for the proper functioning of neuromuscular and cardiac function.

There is also the potential risk of excess calcium intake although this has only been observed from therapeutic doses, not from dietary sources. In response, however, the NHMRC and New Zealand MoH (2006) have set an upper level of intake (UL) for calcium intake for males and females aged one year and above of 2 500 mg/day.

There is the potential risk that good sources of calcium-rich foods will be substituted with calcium-fortified foods thus reducing the intake of other essential nutrients. However, FSANZ's assessment of an earlier Application to add calcium to a range of foods (Application A424) indicated that this was unlikely to cause inadequacy of other nutrients as a result of nutrient interactions.

A potential increased risk of dental calculus was raised in a submission to the Initial Assessment Report. To date, however, this is not supported by any evidence nor is it likely on theoretical grounds.

There is some evidence of a short term benefit to dental health arising from the topical application of calcium from chewing gum (≤0.2% residual sugars) with added calcium. The evidence, however, is based on a limited number of small studies and applies only to calcium lactate, calcium carbonate and more water-soluble forms of calcium phosphate. There is insufficient evidence to date that chewing gum (≤0.2% residual sugars) with added calcium prevents dental caries in the long term.

1. Introduction

Calcium is an essential nutrient. It is required for the normal development and maintenance of the skeleton as well as for the proper functioning of neuromuscular and cardiac function (NHMRC and MoH, 2006). As such, the hazard characterisation has considered the potential risks from both inadequate as well as excess dietary intake of calcium. In addition, because the food vehicle is chewing gum (≤0.2% residual sugars) any potential risks to dental health associated with the addition of calcium to chewing gum (≤0.2% residual sugars) are also considered.

Potential dental health benefits arising from a topical application of calcium from chewing gum (≤0.2% residual sugars) with added calcium are also discussed.

2. Potential risks

2.1 Potential risks from inadequate calcium intake

When there is insufficient calcium absorbed from the diet, calcium is drawn from the bone to maintain critical circulating concentrations necessary for vascular contraction and dilation, muscle contraction, nerve transmission and glandular secretion. Although calcium absorption increases when intakes are low, there is a limit to which this can offset skeletal calcium loss, particularly in the long term. This adaptive response to low calcium intakes (i.e. increased calcium absorption) is less efficient among older people. This predisposes them to increased calcium resorption from bone to maintain circulating calcium levels; and thus weaker bone strength (Institute of Medicine, 1997).

2.2 Potential risks from excess calcium intake

The NHMRC and NZMoH (2006) has set an upper level of intake (UL[57]) for calcium of 2,500 mg/day for the population aged one year and above including pregnant and lactating women. The UL has been set on the basis of the toxic effects of hypercalcaemia with renal calcification and renal failure observed when calcium is given in high doses as an antacid in a carbonate form. This is the only circumstance where calcium toxicity has been observed. A Lowest Observed Adverse Effect Level (LOAEL) of about 5,000 mg was identified in studies and an uncertainty factor of two used to determine the UL (2,500 mg). The uncertainty factor takes into account the potential for increased risk of high calcium intake, given the relatively common occurrence of kidney stones in Australia and New Zealand and concern that excess calcium will interfere with absorption of other minerals such as zinc and iron in vulnerable populations (NHMRC and NZMoH, 2006). Too much calcium may also cause gastrointestinal upsets, such as bloating and constipation.

2.3 Potential risks from significantly reduced milk consumption due to substitution with calcium-fortified foods

FSANZ previously assessed the substitution of foods naturally rich in calcium with calcium-fortified foods in Application A424 – Fortification of Foods with Calcium. The results of this assessment are described below.

Additional dietary modelling was undertaken at Final Assessment of Application A424 in response to concerns that calcium-fortified foods would reduce milk consumption which could lead to compromised zinc and riboflavin intakes. The modelling was based on a worst-case scenario – a 50% reduction in milk consumption. The results indicated a small decrease in riboflavin intakes and a modest decrease in average zinc intakes. The population group most at risk following a 50% decline in milk consumption were girls aged 12-15 years. The population group at least risk of zinc and riboflavin deficiency as a result of halving their milk intake were children aged 6-12 years.

[57] The Upper Level of Intake (UL) is the highest intake, including potential intakes from supplements, likely to pose no adverse health risk for almost all individuals in the specified life stage group (NHMRC and NZMoH, 2006). The UL is not a recommended level of intake; individuals who exceed the UL increase their risk of adverse health effects.

It was noted that the modelled scenario is theoretical and very unlikely; thus in reality there would be minimal adverse effects on the micronutrient intake of the Australian and New Zealand populations from calcium fortification of various foods.

Further dietary modelling was undertaken for the Second Review of Application A424 to assess the impact on vitamin B_{12} and protein intakes assuming the entire milk content of the diet was substituted for a product not high in these nutrients. The results indicated that all population sub-group mean intakes would be above the 2006 RDIs for vitamin B_{12} and protein.

2.4 Potential dental health risks from calcium-fortified chewing gum (≤0.2 % residual sugars)

An issue raised in submissions to the Initial Assessment Report, which was not raised again at Draft Assessment, was the potential risk associated with increased salivary levels of free calcium that may occur from chewing gum fortified with unstable calcium phosphate. Increased salivary calcium may result in the precipitation of calcium phosphate within the oral cavity, placing the consumer at risk of developing dental calculus (tartar) and subsequent periodontal disease[58]. Vogel *et al*. (1998) refer to animal studies suggesting that diets high in calcium and phosphorus could promote calculus formation.

The potential risk arises from an increase in the concentration of calcium ions in saliva triggering a precipitation of calcium phosphate and for those in a fluoridated environment a precipitation of calcium fluoride phosphate (e.g. fluoroapatite). The submitter stated that this risk is high in individuals with poorly stabilised calcium phosphate in their saliva and dental plaque and relates only to gum fortified with calcium phosphate – not to other forms of calcium.

Dental plaque can be a site for build up of calcium phosphate to form a mineralised dental plaque referred to as dental calculus or tartar. Iijima *et al*. (2004) state that casein phosphopeptides prevent this transformation and deliver calcium ions to the tooth surface to promote remineralisation with structured, acid resistant mineral.

While the submitter stated that the risk is theoretical only, there are no studies to confirm or refute the potential risk. Furthermore, although dental calculus can be treated effectively with regular visits to a dentist, it is not a trivial condition, particularly among older people, because it increases the risk of periodontal disease.

FSANZ could find no reference in the literature of a dental risk to humans from chewing calcium-fortified chewing gum (≤0.2% residual sugars). As a result, FSANZ requested additional advice from Dr Peter Shellis[59] on the issues raised in the submission and to review FSANZ's assessment of the potential dental health benefits and risks from calcium-fortified chewing gum (≤0.2% residual sugars).

[58] Periodontal disease has been associated with several detrimental health outcomes including preterm low birth weight and cardiovascular disease (Fowler *et al*., 2001).
[59] Division of Restorative Dentistry, University of Bristol Dental School, Bristol, United Kingdom and Editor of *Dental Caries*.

Dr Shellis provided a comprehensive response to this request. In particular, he noted that addition of calcium to chewing gum (≤0.2% residual sugars), if it were to promote calculus at all, would only stimulate supra-gingival calculus because saliva is the source of calcium for this form of calculus. He acknowledges that in populations where regular hygiene is practised and where professional dental care is widely available, supra-gingival calculus formation has little impact on oral health. Furthermore, in his expert opinion, the risk of promoting calculus formation is small compared with the caries-preventive effect of using chewing gum (≤0.2% residual sugars).

In the absence of literature based on *in situ* models assessing calculus risk, Dr Shellis assessed the risk of calculus formation based on his knowledge of calcium phosphate chemistry. Specifically, dicalcium phosphate dihydrate (a form of calcium phosphate) is one of the first solids to precipitate out of plaque fluid supersaturated with calcium into the precursor solids. These solids, in turn, recrystallise to hydroxyapatite, the principal form of calcium phosphate in dental calculus, and the greater the saturation of dicalcium phosphate dihydrate, the more likely it is to precipitate into these precursor solids.

He then compared his knowledge of the chemistry with the results from a paper by Vogel *et al*. (2000). The findings showed that the plaque fluid saturation of dicalcium phosphate dihydrate following 15 minutes of chewing 'sugar-free' gum containing 2.5% w/w α-tricalcium phosphate resulted in only a small increase in the mean degree of dicalcium phosphate dihydrate saturation (from 1.55 to 1.71 compared with 1.58 to 1.69 among the control group). From these results, Dr Shellis concluded that chewing gum fortified with calcium phosphate was unlikely to increase the risk of calculus formation.

The Applicant also sought further advice on this potential risk from two international dental experts – Emeritus Professor Colin Dawes[60] and Professor Domenick T. Zero[61,62] – who both concluded that a risk to dental health from calcium-fortified chewing gum (≤0.2 % residual sugars) was unlikely and that the concern was based mainly on theoretical grounds and was not supported by scientific evidence.

Professor Zero also stated that the role of calculus in the initiation and progression of periodontal disease is unclear. There was no distinction made regarding the form of calcium and potential risk.

3. Potential dental health benefits from a topical application of calcium

The Australian Dental Association (ADA) recommends the use of chewing gum (≤0.2% residual sugars) to promote the clearance of food from the mouth and to dilute plaque acids following food consumption but not in place of regular daily tooth brushing[63].

The Applicant provided a sample of research to support this recommendation in their Application to FSANZ (Leach *et al*., 1989; Park *et al*., 1990; Dawes and Macpherson, 1992; Manning and Edgar, 1993; Szoke *et al*., 2001).

[60] Department of Oral Biology, Faculty of Dentistry, The University of Manitoba, Canada.
[61] Oral Health Research Institute, Indiana University School of Dentistry, United States.
[62] Both of these experts have undertaken consultancy work for The Wrigley Co.
[63] ADA Policy Statement 1.2.3: Oral Hygiene. November 21/22, 2002.

FSANZ has not investigated the basis of this recommendation further as it is outside the scope of the risk assessment. However, the underlying physiology of the effect of chewing gum (≤0.2% residual sugars) on dental health is summarised below.

When carbohydrate is consumed the oral plaque microflora ferment the carbohydrate to produce organic acids. These acids can dissolve tooth enamel when pH falls below about 5.5-5.7. Chewing gum substantially increases saliva flow (by up to 10 times) and is effective in raising pH because the stimulated saliva contains the same types of calcium, phosphate and hydroxyl ions that occur naturally in teeth. This flood of salivary ions remineralises early lesions on the tooth surface – the precursors to dental decay. Fluoride (from water or fluoridated toothpaste) further encourages the remineralisation process by replacing the hydroxyl ions in the natural calcium phosphate compounds that make up the tooth (hydroxyapatite) and replacing it with the more acid-resistant fluoroapatite.

Dental caries (or tooth decay) is a chronic disease potentially affecting all ages. It is initially reversible and can be halted at any stage. Whether dental caries progresses, stops or reverses depends on the balance between demineralisation (minerals diffuse out of the tooth surface) and remineralisation (minerals diffuse into the tooth surface) (Selwitz *et al*., 2007). The potential dental health benefit of calcium is underpinned by the theory that increased calcium in the mouth may have a beneficial/catalytic effect on remineralising the tooth surface (see Box 1).

Box 1: Teeth and calcium

Teeth are made predominantly of the minerals: calcium, fluoride and phosphate. Dental caries progression or reversal depends upon the balance between demineralisation and remineralisation.

Demineralisation (which can lead to tooth decay) results from the interaction over time of bacteria that produce acid (and lower pH) and many host factors (such as diet) and saliva. The bacteria make up a biofilm around each tooth – this is known as dental plaque.

Remineralisation is promoted when saliva production is increased. When fluoride is present in the saliva it promotes the diffusion of calcium and phosphate into the tooth although this is limited by the level of these ions in the saliva. Thus, it is postulated that increasing the concentration of calcium and phosphate ions will enhance the probability of remineralisation (Winston and Bhaskar, 1998).

Although the purpose of adding calcium to chewing gum is to speed up the remineralisation process, the form of calcium must be soluble in saliva to enable the exchange of calcium ions between the saliva and the tooth enamel.

3.1 Summary of published evidence of the dental health benefits of calcium-fortified chewing gum (≤0.2% residual sugars)

There are several studies investigating the potential dental health benefits of calcium-fortified chewing gum. These studies involve calcium lactate, calcium carbonate and various forms of calcium phosphate.

A small study (n=8; mean age=37 years) investigating more soluble forms of calcium (5% monocalcium phosphate monohydrate in one gum and 5 % tetracalcium phosphate + dicalcium phosphate anhydrous in another) and their effect on increasing salivary calcium and phosphorus concentrations, concluded that both gums produced significantly higher increases in salivary calcium concentrations ($p<0.05$) compared with the control over the entire experimental period (16 minutes of chewing) (Chow *et al*., 1994).

The authors suggested that the calcium-fortified chewing gums used in this study would have a greater remineralising and anticarious potential than chewing gum containing less soluble forms of calcium such as dicalcium phosphate dihydrate.

In a study (n=14; aged 25-53 years) investigating chewing gum containing 2.5% α-tricalcium phosphate, Vogel *et al*. (1998) reported similar plaque fluid mineral concentrations after seven and 15 minutes of chewing the control and experimental gums. However, following a sucrose rinse, administered after saliva collection at 15 minutes, there was a significant increase in plaque fluid concentrations of free and total calcium and total phosphate compared with the experimental gum and the control ($p<0.01$ for each parameter). In another small study (n=10; aged 22-27 years) by Suda *et al*. (2006), a chewing gum containing xylitol[64] (a noncariogenic sweetener) and calcium lactate (94 mg per 16 g of gum) resulted in a greater degree of remineralisation (0.46 ± 0.10) than the xylitol gum alone (0.33 ± 0.10) or no gum (0.16 ± 0.14).

More recent research involving two randomised, double blind cross-over trials compared the ability of casein phosphopeptide-amorphous calcium phosphate (CPP-ACP) in 'sugar-free' chewing gum to remineralise enamel sub-surface lesions *in situ* with other forms of calcium (one containing calcium carbonate and one containing both calcium hypophosphate + calcium carbonate) (Reynolds *et al*., 2003). Both the non CPP-ACP gums contained 5-13 times the total amount of calcium than the CPP-ACP gum but the CPP-ACP gum contained the highest levels of water soluble calcium.

The results indicated that the CPP-ACP gum produced the highest level of subsurface lesion remineralisation, independent of chewing frequency or duration; although all three gums did result in enamel remineralisation. The authors attribute this to *CPP* 'delivering' *ACP* to the tooth surface (deposited in the naturally occurring film of bacteria-rich plaque that coats each tooth) and the importance of CPP in stabilising ACP producing a highly water-soluble calcium phosphate phase. The level of enamel remineralisation across all gums correlated with the level of water-soluble calcium phosphate per piece of gum used per treatment.

Despite the anticaries potential of the above forms of calcium in the short-term among adults, Lingstrom *et al*. (2003), in their systematic review of dietary factors in the prevention of dental caries (involving studies of at least two years duration) concluded that a preventive effect from adding calcium phosphate or dicalcium phosphate dihydrate to chewing gums has yet to be demonstrated in either adults or children in the longer term.

To conclude, the evidence from a limited number of small but well-controlled studies investigating the immediate effects of chewing gum, fortified with predominantly soluble forms of calcium, consistently report a short-term dental health benefit. This is supported by increased salivary and plaque fluid calcium concentrations and remineralisation of enamel sub-surface lesions.

As not all forms of calcium permitted in the Code are soluble in water, their potential dental health benefit in chewing gum may be limited. In addition, the benefit may be dependent on the extent of contact of the tooth surface with the fortified chewing gum. There is insufficient evidence to date that calcium-fortified chewing gum (≤0.2% residual sugars) prevents dental caries in the long term.

[64] Xylitol reduces demineralisation of subsurface tooth enamel and increases its hardness *in vitro* and *in vivo* (Hayes, 2001).

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Attachment 3

Dietary Intake Assessment

Summary

An Application was received by FSANZ to amend the Australia New Zealand Food Standards Code (the Code) to permit the addition of calcium to chewing gum (containing no more than 0.2% residual sugars). A dietary intake assessment was necessary in order to estimate the current dietary intake of calcium and the impact of allowing the calcium fortification of chewing gum (≤0.2% residual sugars) on public health and safety.

The Nutrient Reference Values for Australia and New Zealand (NRVs) (NHMRC and NZ MoH, 2006) were used as a guide in selecting the age and sex groups to assess. The estimated calcium intakes were compared with the NRVs to assess the adequacy and safety of the intakes.

The dietary intake assessment scenarios included:

'Baseline' – calcium intakes from food and beverages in the current regulatory environment, based on both naturally occurring calcium and the current uptake of voluntary calcium fortification permissions by industry, other than chewing gum.

'Current technology' – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in **21.3 mg releasable calcium per gram of chewing gum**.

'Anticipated future technology' – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in **41.7 mg releasable calcium per gram of chewing gum**.

The 1995 Australian and 1997 New Zealand National Nutrition Surveys (NNSs) reported very low consumer numbers of chewing gum (<1% of the population). More recent information indicates more people are now chewing gum consumers (other research from the Applicant[65] indicated approximately 55%, whilst consumer research study data[66] 35-40%). The consumer research study data[67] were used to obtain the mean daily amount of chewing gum (≤0.2% residual sugars) consumed for the dietary intake assessments. This was combined with calcium intakes from all other foods derived using the NNS data. A different consumption amount of chewing gum was derived for each age and sex sub-group assessed for the dietary intake assessment.

The dietary intake assessment results are presented below based on two model types:

Type A: A projected population average intake of calcium from the product was calculated by applying the proportion who stated that they would use the product to the mean daily amount of gum consumed across the population. Calcium from the gum was added to the calcium intakes derived from NNS data.

[65] Source: IPSOS Chewing Gum Volume and Penetration Study, June 2004
[66] Roy Morgan Research (2007).
[67] Roy Morgan Research (2007).

Type B: A chewing gum consumer-only model was generated by adding the calcium intake from the mean daily consumption amount of chewing gum (≤0.2% residual sugars) reported by consumers to the distribution of calcium intakes derived from the NNS data (i.e. for every respondent), on the assumption that dietary intakes from other foods do not vary for those consuming gum.

(A) Population groups/ sub-groups, assuming a mean daily amount of chewing gum (≤0.2% residual sugars) weighted according to the proportion of the population consuming chewing gum

- The increase in estimated mean calcium intakes from 'Baseline' for all Australian population sub-groups was in the range of:

  - 0-17 mg calcium per day (up to 2% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and
  - 1-34 mg calcium per day (up to 4% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario;

  and for all New Zealand population sub-groups was in the range of:

  - 0-36 mg calcium per day (up to 5% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and
  - 1-71 mg calcium per day (up to 9% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

- At 'Baseline', the proportion of the population with inadequate dietary calcium intakes was >3% of Australians aged 4 years and above (4-95% of sub-population groups) and ≥40% of New Zealanders aged 15 years and above (40-95% of sub-population groups). Generally, a greater proportion of females had inadequate calcium intakes in both countries and the proportion increased as age increased. Australian children aged 2-3 years were estimated to have adequate dietary calcium intakes.

- Under both fortification scenarios, there was little to no change in the proportions of Australian population groups (aged 9 years and above) and New Zealand population groups (aged 15 years and above) with inadequate dietary calcium intakes.

- For Australian children aged 4-8 years, the proportion with inadequate calcium intakes fell slightly to 4-7% under the 'Current technology' scenario and to 3-5% under the 'Anticipated future technology' scenario (from 4-10%).

- The proportion of the Australian and New Zealand populations with estimated calcium intakes above the Upper Level (UL) changed minimally from 'Baseline' to the two fortification scenarios considered (at 3% or less exceeding the UL across all population groups and scenarios assessed).

(B) Among consumers of chewing gum (≤0.2% residual sugars)

- The increase in estimated mean calcium intakes from 'Baseline', among consumers of calcium-fortified chewing gum, for all Australian population sub-groups, was in the range of:

- 30-55 mg calcium per day (up to 6% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and
- 60-105 mg calcium per day (up to 12% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario;

and for all New Zealand population sub-groups was in the range of:

- 30-85 mg calcium per day (up to 11% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and
- 55-160 mg calcium per day (up to 22% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

- The proportion of population groups with inadequate dietary calcium intakes remained substantial under both fortification scenarios considered for Australian population groups (aged 9 years and above) (30-90% of the population group) and New Zealand population groups (aged 15 years and above) (35-95% of the population group). Despite this, there was a decrease in the proportion of some population groups with inadequate intakes of up to 10% or 15% depending on the scenario.

- For Australian children aged 4-8 years, the proportion of calcium-fortified chewing gum consumers with inadequate calcium intakes fell (from 4-10%) to 2-3% under the 'Current technology' scenario and to <1% under the 'Anticipated future technology' scenario.

- The proportion of the Australian and New Zealand chewing gum consumers with estimated calcium intakes above the UL changed minimally from 'Baseline' to the two fortification scenarios considered (at 7% or less exceeding the UL across all population groups and scenarios assessed).

Whilst there are currently large proportions of the Australian and New Zealand population groups estimated to have inadequate calcium intakes, the fortification of chewing gum (≤0.2% residual sugars) with calcium appears to have minimal impact on estimated calcium intakes for the Australian and New Zealand populations for the whole population and a modest impact among consumers of calcium fortified chewing gum (≤0.2% residual sugars).

1. Dietary modelling conducted to estimate calcium intakes

1.1 What is dietary modelling?

Dietary modelling is a tool used to estimate exposures to food chemicals, including nutrient intakes, from the diet as part of the FSANZ risk assessment process. To estimate dietary intake of food chemicals such as nutrients, records of what foods people have eaten are needed along with reports of how much of the food chemical of interest is in each food. The accuracy of these dietary intake estimates depends on the quality of the data used in the dietary models. Sometimes, all of the data needed are not available or their accuracy is uncertain so assumptions have to be made, either about the foods eaten or about chemical levels, based on previous knowledge and experience. The models are generally set up according to international conventions for food chemical exposure estimates. However, each modelling process requires decisions to be made about how to set the model parameters and what assumptions to make. Different decisions may result in different answers.

Therefore, FSANZ documents clearly all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the data available and so that FSANZ risk managers can make informed decisions.

1.2 Population groups assessed

The NRVs for Australia and New Zealand (NHMRC & NZMoH, 2006) were used as a guide in selecting the age groups to assess. As different NRVs were given for different age and gender groups for calcium, conducting the dietary modelling based on the NRV age groups allowed for comparison of the estimated calcium intakes with the relevant NRVs.

Dietary intake assessments were conducted for the following Australian population groups for males and females:

- 2 years and above
- 2-3 years
- 4-8 years
- 9-13 years
- 14-18 years
- 19-29 years
- 30-49 years
- 50-69 years
- 70 years and above.

Dietary intake assessments were conducted for the following New Zealand population groups for males and females:

- 15 years and above
- 15-18 years
- 19-29 years
- 30-49 years
- 50-69 years
- 70 years and above.

1.3 Dietary survey data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4,636 people aged 15 years and above.

Both of these surveys used a 24-hour food recall methodology. A second 24-hour recall was conducted on a subset of respondents in both surveys for a non-consecutive day.

It is recognised that these survey data have several limitations (see Section 6).

1.3.1 Additional dietary survey data or other relevant data

The 1995 and 1997 NNSs reported very low consumer numbers of chewing gum (<1% of the population).

Information provided by the Applicant in their application indicated that approximately 55% of the population are now chewing gum consumers, which is spread broadly across all population groups. Due to the differences between the NNS data and that provided by the Applicant, FSANZ requested the Applicant to provide current consumption data for chewing gum (containing no more than 0.2% residual sugars) for various population sub-groups both in Australia and New Zealand. Data sought included: (1) the prevalence of consumption (e.g. the proportion of males aged 14-18 years consuming chewing gum (≤0.2% residual sugars)); (2) the frequency of consumption (e.g. three times per week); and (3) the number of pieces of chewing gum (≤0.2% residual sugars) consumed per eating occasion. From this research, it was possible to predict the additional calcium intakes from calcium-fortified chewing gum (≤0.2% residual sugars) for each population sub-group, were the Application to be approved.

FSANZ also requested data on the proportion of the population who would be interested in purchasing chewing gum (≤0.2% residual sugars) that was fortified with calcium, to determine the likely uptake of the product in the market.

The Applicant commissioned Roy Morgan Research Pty Ltd (RMR) to collect this data for the Australian and New Zealand populations aged 14 years and above. Prior research by the Applicant found that the younger population have lower levels of frequency and number of pieces of chewing gum consumed per eating occasion. Therefore, the Applicant specified that the population aged less than 14 years is not a target group for calcium-fortified chewing gum (≤0.2% residual sugars) and so the younger age group were not included in the consumer research study commissioned by the Applicant.

The data collected by RMR were analysed using the following age groups (males only, females only, and males and females) since they most closely matched the NRV age groups:

- 14 years and above
- 14-19 years
- 20-29 years
- 30-49 years
- 50-69 years
- 70 years and above.

Due to the fact that the population aged less than 14 years may still consume chewing gum (≤0.2% residual sugars), FSANZ included the population aged 2-13 years in the dietary intake assessments for Australia by extrapolating data on the amount of chewing gum (≤0.2% residual sugars) consumed and interest in purchasing calcium-fortified chewing gum (≤0.2% residual sugars) from the results for the population aged 14-19 years. This may overestimate dietary calcium intakes from chewing gum for the population aged 2-13 years. No estimations were possible for children aged <14 years in New Zealand as the New Zealand NNS only included the population aged 15 years and above.

The consumer research study used the term ‘sugar-free’ chewing gum to refer to the technically correct term of ‘chewing gum containing no more than 0.2% residual sugars’. To ensure consistency in the use of the terminologies, the term ‘chewing gum (≤0.2% residual sugars)’ is used throughout the report with the exception of instances referring to the exact question asked in the consumer research study.

Mean daily chewing gum (≤0.2% residual sugars) consumption (grams per day) was calculated using recent RMR data for samples representative of the total populations of Australia and New Zealand, and for samples of consumers of chewing gum (≤0.2% residual sugars) only, for both countries. A different amount of chewing gum consumed was derived for each age and sex sub-group assessed for the dietary intake assessment in order to make the assessment as specific as possible.

The method used to generate the mean daily consumption of chewing gum (≤0.2% residual sugars) in grams per day is outlined below:

- Respondents were identified as consumers of chewing gum (≤0.2% residual sugars) if they indicated consuming either chewing gum (≤0.2% residual sugars) tabs or pellets. Non-consumers were identified as such if they indicated zero consumption of chewing gum (≤0.2% residual sugars) pellets or tabs, or indicated that they eat gum other than chewing gum containing ≤0.2% residual sugars.

- Mean daily chewing gum (≤0.2% residual sugars) consumption among consumers was calculated using data for:

  - frequency of consumption occasions of chewing gum (≤0.2% residual sugars) pellets and tabs (i.e. includes the days where chewing gum was consumed and days where it was not); and
  - the number of pellets and tabs consumed per occasion, converted into number of grams of gum per occasion;

  and by multiplying frequency and grams per occasion together, summing over all consumers in the study and dividing by the number of consumers in the study; this was done within age-sex groups and for the total population and the calculated means are shown in Appendix 2, Table A2.2.

- Mean daily chewing gum (≤0.2% residual sugars) consumption for the study population was calculated from the mean consumption for consumers, after applying suitable post-weights. The calculated means are shown in Appendix 2, Table A2.1.

Respondents were asked how interested they would be in buying 'sugar-free' chewing gum with added calcium, with the response options being: (1) very interested; (2) somewhat interested; (3) not interested at all; and (4) can't say. The response options of 'very interested' and 'somewhat interested' were combined to give a single count for respondents 'interested in purchasing chewing gum (≤0.2% residual sugars) with calcium'.

The results from the consumer research study revealed that approximately 40% of Australians and 35% of New Zealanders aged 14 years and above consume chewing gum (≤0.2% residual sugars), which varies across age groups and is generally higher in females. See Attachment 4 for more detailed results. This was higher than the NNS data and slightly lower than that indicated by the Applicant.

1.4 Dietary modelling approach

The dietary intake assessments for this Application were conducted using dietary modelling techniques that combine food consumption data with food calcium concentration data to estimate the intake of calcium from the diet. The dietary intake assessment for 'Baseline' calcium intakes was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary intake = food calcium concentration x food consumption amount

'Baseline' calcium intakes were estimated by combining usual patterns of food consumption, as derived from NNS data, with current concentrations of calcium in food. Standard methodologies were used to estimate nutrient intakes based on consumption data from the first 24 hour recall (day one) from the NNS, which were then adjusted to estimate 'usual intake' by using consumption information from the second 24 hour recall (day two) from the NNS. For further information on second-day nutrient adjustments, see Appendix 1.

As discussed in Section 1.3.1, the 1995 and 1997 NNSs reported very low consumer numbers of chewing gum (<1% of the population) and information provided by the Applicant indicated that approximately 55% of the population are now chewing gum consumers. In order for dietary calcium intakes to be estimated, should permission be given to fortify chewing gum (≤0.2% residual sugars) with calcium, it was assumed that chewing gum is eaten in amounts derived from recent consumer research study data in addition to the foods as recorded in the NNSs. The method used to estimate dietary calcium intakes under the various fortification scenarios is outlined in Figure 1 below.

For each respondent in the NNS, determine:

1. The current (*'Baseline'*) intake of calcium.

2. The additional calcium that would be provided by the consumption of calcium-fortified chewing gum (≤0.2% residual sugars) for their relevant age/sex group for each model type and scenario. The amounts of chewing gum and the concentrations of calcium in the gum are discussed in detail in Section 2.

3. For each model type and scenario, add together the results from Step 1 and Step 2.

Following these 3 steps, the results (e.g. proportion with inadequate dietary calcium intakes) for the population groups/ sub-groups could be derived.

Figure 1: Method used to estimate dietary calcium intakes under the fortification scenarios examined

2. Scenarios assessed and calcium concentration levels

An overview of the dietary intake assessments is given in Figure 2. For the two main model types ((A) and (B)), a number of scenarios were investigated to reflect both current intakes of calcium and intakes following the permission to fortify chewing gum (≤0.2% residual sugars) with calcium. Both models use the assumption that dietary calcium intake from other foods does not vary by chewing gum practice.

The two model types investigated were as follows:

(A) A population average for the whole population and various subgroups was derived by weighting the mean gum consumption in the total consumer research study population by the proportion of the population who indicated an interest in purchasing calcium-fortified chewing gum (≤0.2% residual sugars). Two calcium concentrations were examined: 21.3 mg releasable calcium per gram ('Current technology' scenario) and 41.7 mg releasable calcium per gram ('Anticipated future technology' scenario). Calcium intake from gum was added to the calcium intakes derived from the NNS data.

(B) A consumers-only average was derived for the whole population and various subgroups using the gum consumption data from the consumer research study findings. Two calcium concentrations were examined: 21.3 mg releasable calcium per gram ('Current technology' scenario) or 41.7 mg releasable calcium per gram ('Anticipated future technology' scenario). Calcium intake from gum was added to the calcium intakes derived from the NNS data.

The three scenarios investigated for the two model types were:

1. **'Baseline'** – calcium intakes from food and beverages in the current regulatory environment, based on both naturally occurring calcium in the food supply and the current uptake of voluntary calcium fortification permissions by industry, other than chewing gum;

2. **'Current technology'** – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in **21.3 mg releasable calcium per gram of chewing gum**. This level represents the amount of calcium that can be delivered using current technology.

3. **'Anticipated future technology'** – as per 'Baseline' plus the introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) that results in **41.7 mg releasable calcium per gram of chewing gum**. This level represents the amount of releasable calcium that might be possible in the future.

These three scenarios are summarised in Table 1 below.

Table 1: Summary of the calcium fortification scenarios assessed

	Scenario		
	'Baseline'	***'Current technology'***	***'Anticipated future technology'***
Naturally occurring calcium concentrations included	✓	✓	✓
Current voluntary calcium fortification included	✓	✓	✓
Calcium concentration in chewing gum (≤0.2% residual sugars)	***zero***	***21.3 mg/gram***	***41.7 mg/gram***
Calcium intakes from supplements included	✗	✗	✗

For Model type (A), only the market share model was investigated.

For Model type (B), two further models were assessed for each of the scenarios listed in Table 1:

(a) market share model; and
(b) consumer behaviour model where behaviour with respect to choice of non-gum calcium-fortified foods is examined.

These models are discussed in detail in Sections 2.1.2 and 2.2 below.

In all scenarios, models and options, calcium intakes from the use of calcium supplements or multi-vitamin supplements containing calcium were not considered.

2.1 Model Types (A) and (B)

2.1.1 (A) Australian and New Zealand population groups

To calculate the average intake of calcium in the total population, it was assumed that Australian and New Zealand chewing gum consumers (≤0.2% residual sugars) have the same dietary patterns as those for non-chewing gum consumers. The mean daily consumption of gum in the consumer research study population (see Section 1.3.1) was assigned a calcium content and up-weighted using the proportion of respondents who indicated that they would eat the product if it were available (Roy Morgan Research, 2007):

Calcium concentration in one gram of chewing gum (≤0.2% residual sugars) (e.g. 21.3 mg under the 'Current technology' Scenario)	X	Mean chewing gum (≤0.2% residual sugars) consumption (grams) per day (Consumption averaged over respondents in the Roy Morgan survey)	X	Proportion of respondents indicating interest in purchasing calcium-fortified chewing gum (≤0.2% residual sugars)

The estimated mean intake of calcium from gum was added to the calcium intake from the diet derived from the NNS data for all persons of the appropriate population group. This was done for the whole population, and by age-sex subgroups.

2.1.2 (B) Australian and New Zealand chewing gum (≤0.2% residual sugars) consumers

To calculate calcium intake in chewing gum (≤0.2% residual sugars) consumers, it was assumed that chewing gum consumers have the same dietary patterns as those for non-chewing gum consumers. Mean gum consumption per consumer (see Section 1.3.1) for all groups combined and by age-sex subgroups was multiplied by calcium concentration as follows:

Calcium concentration in one gram of chewing gum (≤0.2% residual sugars) (e.g. 21.3 mg under the 'Current technology' Scenario)	X	Mean chewing gum (≤0.2% residual sugars) consumption (grams) per day (Consumption for consumers only in the Roy Morgan survey)

The estimated mean intake of calcium from gum in consumers was added to the calcium intake derived from the NNS data from all other foods or all persons of the appropriate population group.

This was done for the whole population, and by age-sex subgroups.

The calculations described above indicate that the mean gum consumption in the population overall is lower (A) than the mean among consumers (B). Appendix 2, Table A2.1 shows, for example, that the mean chewing gum (≤0.2% residual sugars) consumption for Australians aged 20-29 years (A) was 1.16 g/day overall whereas among consumers of the same age (B) it was 1.96 g/day.

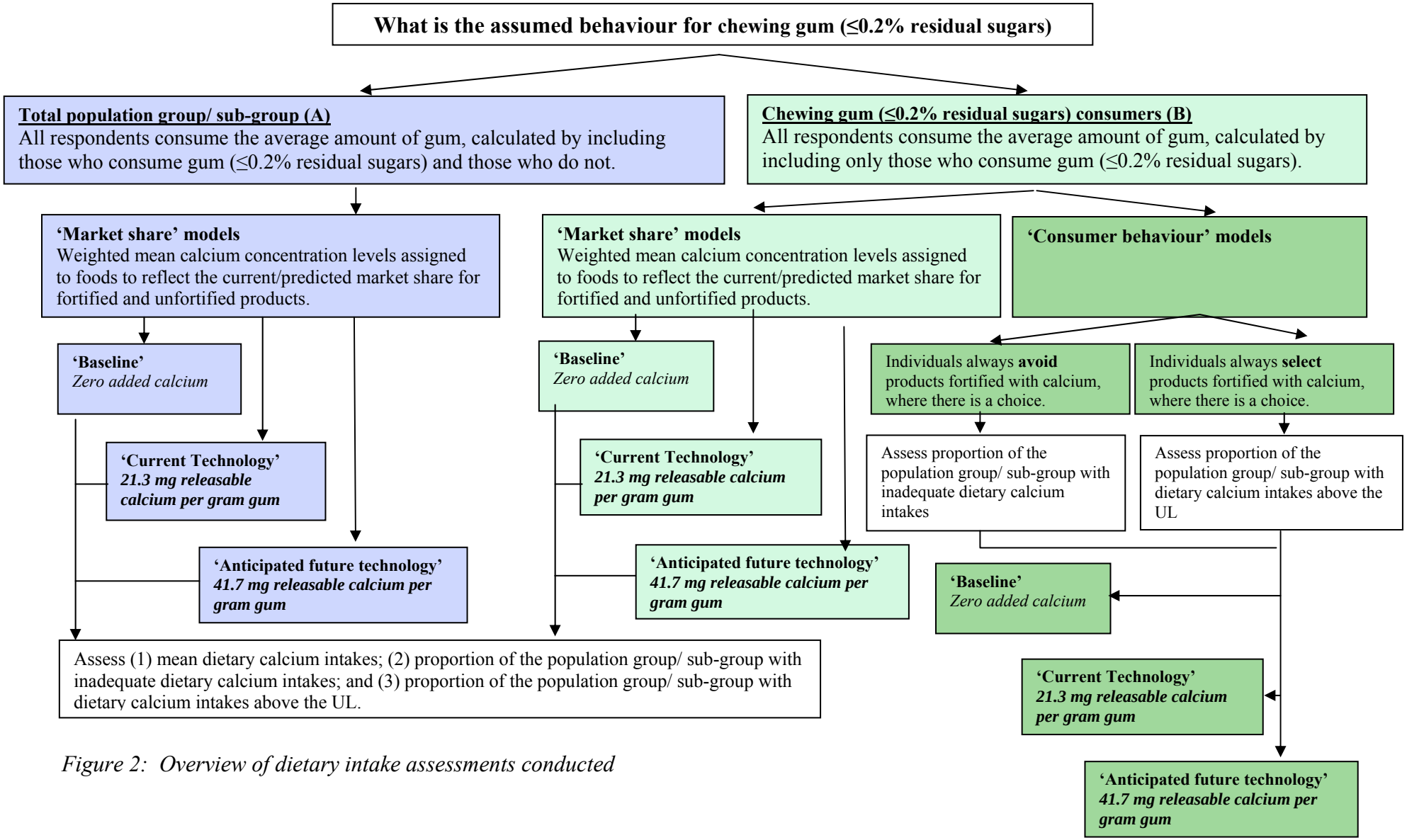

Figure 2: Overview of dietary intake assessments conducted

2.2 Market share and consumer behaviour models

2.2.1 Market share model (or population estimate)

This model aims to represent calcium intakes for the average consumer for a whole population or population sub-group over time; in this case, (A) the Australian and New Zealand populations and sub-groups as a whole; and (B) respondents who were assumed to be calcium-fortified chewing gum (≤0.2% residual sugars) consumers.

Weighted mean calcium concentration levels were assigned to foods within specific categories to reflect the current or predicted market share for fortified and unfortified products within each category (e.g. calcium-fortified breakfast juice). If a fortified version of a food was not specifically identified within the NNS, but it is known that a proportion of the food category in the market place is now fortified with calcium, a weighted calcium concentration was assigned to the food which reflected the proportion of the market that is now believed to be fortified. Some foods in the NNSs were described as being calcium-fortified; however as these surveys were conducted in 1995 in Australia and 1997 in New Zealand, it was necessary to assign a revised calcium concentration to reflect the change in the calcium-fortified food/beverage market since 1995/1997. This method was not applied to food categories in which the market share was assumed to have remained the same since 1995/1997.

Example

The Australian NNS does not distinguish between the consumption of calcium-fortified breakfast juice and non calcium-fortified breakfast juice. The market share for calcium-fortified breakfast juice in Australia was estimated at 10% of all breakfast juices, based on sales information from a major fruit juice manufacturer. The calcium concentration for all breakfast juices was calculated as outlined in Section 2.3, Figure 3.

A limitation of the market share model is that it only gives an estimate of **population intakes** over time. The model can not estimate individual behaviour or estimate calcium intakes for individuals due to the use of weighted mean calcium concentration values.

The 'market share' model results for (A) were used to determine the answers to the following questions for the **Australian and New Zealand populations/ population sub-groups as a whole**:

- What is the evidence for calcium inadequacy in the Australian and New Zealand populations?
- Will the fortification of chewing gum (≤0.2% residual sugars) with calcium have the potential to address inadequate calcium intakes in the Australian and New Zealand populations?
- Will the fortification of chewing gum (≤ 0.2% residual sugars) with calcium pose a risk of excess calcium intakes in the Australian and New Zealand populations?

The 'market share' model results for (B) were used to determine the answers to the following questions for respondents assumed to be **chewing gum (≤0.2% residual sugars) consumers**:

- What is the estimated calcium intake from calcium-fortified chewing gum (≤0.2% residual sugars) for chewing gum consumers?

- Will this level of intake address inadequate calcium intakes among chewing gum consumers?

- Is there a risk of excess calcium intake for chewing gum consumers?

2.2.2 Consumer behaviour model (or individual choices model)

The voluntary permission to fortify some foods with calcium presents the grocery buyer with a choice, to avoid or select these foods according to the needs of their household. To reflect the potential differences in **individual** consumer behaviour, two options were investigated for these foods:

(a) where it was assumed that individuals always **avoid** the products that are fortified with calcium, where there is a choice. This option represents groups of individuals with the lowest calcium intakes, therefore only the estimated proportions of the population groups with inadequate dietary calcium intakes were investigated, as a 'worst case' scenario for inadequate calcium intakes; and

(b) where it was assumed that individuals always **select** the products that are fortified with calcium, where there is a choice. This option represents groups of individuals with the highest calcium intakes, therefore only the estimated proportions of the population groups with dietary calcium intakes above the UL were investigated, as a 'worst case' scenario for high calcium intakes.

These options were given for the foods reported as consumed in the NNS that either (1) did not have a sufficiently detailed description to determine whether the food was fortified with calcium or not, yet it is known that there are fortified foods currently in the market place, or (2) the NNS specifies fortification yet it was presumed that the level of fortification since 1995/1997 has changed.

A limitation of the consumer behaviour model is that it assumes that respondents ate as reported in the 1995 Australian and 1997 New Zealand NNSs and did not change or substitute one kind of food for another. Consumer behaviour options were not applied to food known to have been fortified at the time of the NNSs (e.g. breakfast cereals).

Consumer models do not provide population estimates but are a sensitivity analysis and indicate the top and bottom ends of a range of possible intakes depending on the consumer behaviours included in the model.

2.3 Comparison of concentration data used in different models

For the majority of foods, the calcium concentrations that were used to analyse the 1995 and 1997 NNSs were used in the dietary intake assessment for this Application. Concentrations of calcium were assigned to individual foods from the NNSs using the NNS food codes.

Example: Breakfast Juice

Currently, 10% of breakfast juice on the market contains calcium at 70 mg calcium/100 g.

The calcium concentration in unfortified breakfast juice is 3 mg calcium/100 g.

Market share model calcium concentration:

Calcium concentration = ***(calcium concentration in fortified juice x market share) + (calcium concentration in unfortified juice x market share)***

= ***(70 mg calcium/100 g x 10%) + (3 mg calcium/100 g x 90%)***

= ***9.7 mg calcium/100 g***

Consumer behaviour model calcium concentrations:

a) Consumer avoids fortified products where there is a choice:
Calcium concentration = 3 mg/100 g

b) Consumer selects fortified products, where there is a choice:
Calcium concentration = 70 mg/100 g

Figure 3: Derivation of 'market share' and 'consumer behaviour' model calcium concentrations

Figure 3 outlines how calcium concentrations for foods that are currently fortified with calcium but were not in the 1995/1997 NNSs were calculated to be assigned to calcium-fortified foods for the 'market share' and 'consumer behaviour' models.

2.4 Scenarios

2.4.1 'Baseline'

This scenario represents current estimated calcium intakes for various population sub-groups before an extension of voluntary fortification permissions to include calcium-fortification of chewing gum (≤0.2% residual sugars) in Australia and New Zealand is given. This scenario considers both naturally occurring calcium and the voluntary calcium fortification permissions outlined in Standard 1.3.2 that have been taken up by industry, as evidenced by products available on the supermarket shelves. This scenario does not include foods or food groups where voluntary fortification of calcium is permitted in the Code but has not been taken up by industry. It also does not include the intake of calcium from the use calcium of supplements or multi-vitamin supplements containing calcium.
For the market share model, the concentration of calcium in fortified foods was adjusted according to the proportion of the market that was assumed to be calcium-fortified. This process involved identifying the products currently available and deriving market share information, through sources such as the food manufacturers or the publication 'Retail World's Australasian Grocery Guide' (Flanagan, 2006).

2.4.2 'Current technology' and 'Anticipated future technology' scenarios

The Applicant states that it is technologically feasible to add 21.3 mg releasable calcium per gram of gum at present but that it is anticipated that it will be possible to add 41.7 mg releasable calcium per gram of gum. Therefore both of these calcium concentrations were added to the 'Baseline' scenario and modelled separately.

3. Assumptions made in the dietary intake assessments

The aim of the dietary intake assessments was to make as realistic an estimate of dietary calcium intakes as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

The assumptions made in the dietary intake assessment are listed below, broken down by category.

3.1 Concentration data

- Where there were no New Zealand calcium concentration data for specific food groups, it was assumed that Australian data were representative of these food groups.

- Where a food or food group has a zero concentration of calcium, it was not included in the intake assessment.

- Where there were no New Zealand market share data for specific food groups, it was assumed that Australian data were representative of these food groups.

- There was no contribution to calcium intake through the use of complementary medicines (Australia) or dietary supplements (New Zealand).

- The concentration of calcium in chewing gum (≤0.2% residual sugars) relates to the amount released from the chewing gum during 20 minutes of chewing.

- Calcium will be added to both pellet and tab forms of chewing gum (≤0.2% residual sugars).

3.2 Consumer behaviour

- With the exception of chewing gum and calcium-fortified and enriched products, consumption of foods as recorded in the NNS represents current food consumption patterns.

- Chewing gum (≤0.2% residual sugars) consumers have the same dietary patterns as those for non-chewing gum consumers (i.e. it was assumed that 100% of respondents in the 1995 and 1997 NNSs would be consumers of chewing gum (≤0.2% residual sugars)).

- Consumers always select chewing gum (≤0.2% residual sugars) with calcium in addition to those foods as recorded in the NNS.

- Consumers do not alter their consumption of foods upon calcium-fortified chewing gum (≤0.2% residual sugars) becoming available.

- The consumer does not swallow the chewing gum cud.

- For the total population group/ sub-group assessments (A), all respondents consumed the mean amounts of chewing gum (≤0.2% residual sugars) as recorded for the whole population sub-group, irrespective of whether chewing gum was consumed or not.

- For the chewing gum (≤0.2% residual sugars) consumer assessments (B), all respondents consumed the mean amount of chewing gum (≤0.2% residual sugars) as recorded for consumers of chewing gum.

3.3 General

- For the purpose of this assessment, it was assumed that 1 mL is equal to 1 g for all liquid and semi-liquid foods (e.g. milk, yoghurt).

- The introduction of voluntary calcium fortification of chewing gum (≤0.2% residual sugars) will have no impact on the current uptake of voluntary calcium permissions by industry.

These assumptions are likely to lead to a conservative estimate for calcium dietary intake.

4. Assessment for Australian and New Zealand population groups/ sub-groups (Type A)

4.1 (A) Estimated mean dietary calcium intakes

4.1.1 Australia

The increase in estimated mean calcium intakes from 'Baseline' for all Australian population sub-groups was in the range of:

- 0-18 mg calcium per day (up to 2% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and

- 1-34 mg calcium per day (up to 4% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

Australian males aged 2-18 years showed the highest increase in calcium intakes from 'Baseline' (17 mg/day under the 'Current technology' scenario and 34 mg/day under the 'Anticipated future technology' scenario). Australian males aged 70 years and above showed the lowest increase in calcium intakes (0 mg/day under the 'Current technology' scenario and 1 mg/day under the 'Anticipated future technology' scenario). Further details are available in Table 2a.

4.1.2 New Zealand

The increase in estimated mean calcium intakes from 'Baseline' for all New Zealand population sub-groups was in the range of:

- 1-36 mg calcium per day (up to 5% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and

- 1-71 mg calcium per day (up to 9% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

New Zealand females aged 15-18 years showed the highest increase in calcium intakes from 'Baseline' (36 mg/day under the 'Current technology' scenario and 71 mg/day under the 'Anticipated future technology' scenario). New Zealanders aged 70 years and above showed the lowest increase in calcium intakes (1 mg/day under the 'Current technology' scenario and 1 mg/day under the 'Anticipated future technology' scenario). See Table 2b for further details.

In New Zealand, the increase in mean calcium intakes for chewing gum consumers was generally higher for females than males in each population sub-group. This could be attributed to: (1) a higher proportion of females stating they would be interested in purchasing chewing gum (≤0.2% residual sugars) with added calcium; and (2) mean intakes of chewing gum (≤0.2% residual sugars) being higher for females.

4.1.3 Summary

As can be seen in Figure 4 below, there was a minimal increase in mean calcium intakes under both fortification scenarios ('Current technology' and 'Anticipated future technology') for Australians aged 2 years and above and for New Zealanders aged 15 years and above.

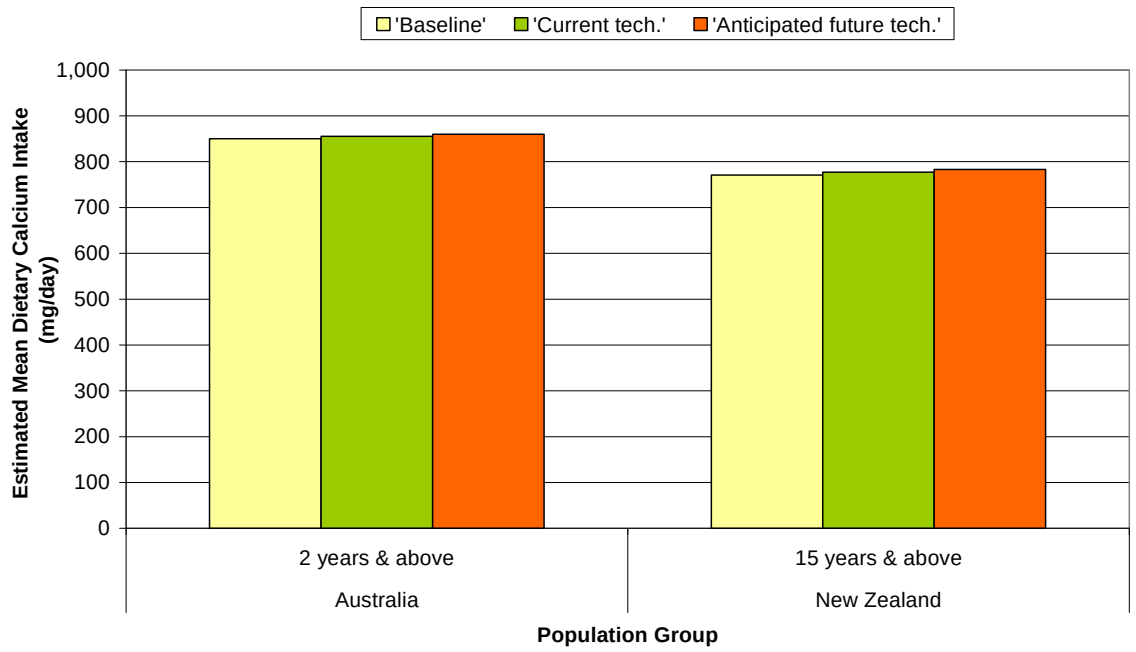

Figure 4: Estimated mean calcium intakes from food at Baseline and under the Current technology and Anticipated future technology scenarios for Australia and New Zealand (A)

Table 2: Estimated mean calcium intakes at 'Baseline' and increase in mean calcium intakes from 'Baseline' under the 'Current technology' and 'Anticipated future technology' fortification scenarios (A)

a. Australia

Pop group	Gender	Mean dietary calcium intake (mg/day)	Estimated increase in mean dietary calcium intakes from 'Baseline'[1] [mg/day] (% 'Baseline' intake)	
		'Baseline'	'Current technology'	'Anticipated future technology'
2 yrs & above	M	960	+4 (+<1)	+7 (+<1)
	F	750	+6 (+<1)	+12 (+2)
2-3 yrs	M	932	+17 (+2)	+34 (+4)
	F	807	+15 (+2)	+30 (+4)
4-8 yrs	M	901	+17 (+2)	+34 (+4)
	F	759	+15 (+2)	+30 (+4)
9-13 yrs	M	1,018	+17 (+2)	+34 (+3)
	F	802	+15 (+2)	+30 (+4)
14-18 yrs	M	1,180	+17 (+1)	+34 (+3)
	F	789	+15 (+2)	+30 (+4)
19-29 yrs	M	1,136	+14 (+1)	+27 (+2)
	F	797	+11 (+1)	+22 (+3)
30-49 yrs	M	952	+3 (+<1)	+5 (+<1)
	F	744	+7 (+<1)	+14 (+2)
50-69 yrs	M	861	+1 (+<1)	+2 (+<1)
	F	721	+4 (+<1)	+7 (+1)

Pop group	Gender	Mean dietary calcium intake (mg/day)	Estimated increase in mean dietary calcium intakes from 'Baseline'[1] [mg/day] (% 'Baseline' intake)	
		'Baseline'	'Current technology'	'Anticipated future technology'
70 yrs & above	M	779	+0 (+0)	+1 (+<1)
	F	679	+1 (+<1)	+1 (+<1)

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).
[2] There are separate recommendations for children aged 9-11 years and 12-13 years because of growth needs; 9-11 year olds who are growing and maturing at much greater rates than average may need the intakes recommended for 12-13 year olds.

b. New Zealand

Pop. group	Gender	Mean dietary calcium intake (mg/day)	Increase in mean dietary calcium intake from 'Baseline'[1] [mg/day] (% 'Baseline' intake)	
		'Baseline'	'Current technology'	'Anticipated future technology'
15 yrs & above	M	862	+4 (+<1)	+7 (+<1)
	F	706	+10 (+1)	+19 (+3)
15-18 yrs	M	966	+11 (+1)	+21 (+2)
	F	770	+36 (+5)	+71 (+9)
19-29 yrs	M	962	+7 (+<1)	+13 (+1)
	F	766	+18 (+2)	+34 (+4)
30-49 yrs	M	888	+2 (+<1)	+5 (+<1)
	F	712	+7 (+1)	+14 (+2)
50-69 yrs	M	798	+3 (+<1)	+5 (+<1)
	F	667	+6 (+<1)	+11 (+2)
70 yrs & above	M	737	+0 (+0)	+1 (+<1)
	F	642	+1 (+<1)	+2 (+<1)

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

4.2 (A) Estimated proportion of Australians and New Zealanders with inadequate dietary calcium intakes

In order to determine if the proposed level of addition of calcium to chewing gum (≤0.2% residual sugars) will have the potential to address any inadequate calcium intakes in Australian and New Zealand population groups, the estimated dietary calcium intakes were compared with the Estimated Average Requirement (EAR). The EAR is 'a daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group' (NHMRC & NZMoH, 2006). The EARs used in this assessment were from the NRVs released in 2006 for Australia and New Zealand (NHMRC & NZMoH, 2006). When certain conditions are met, the proportion of the population group with intakes below the EAR can be used to estimate the prevalence of inadequacy (Health Canada, 2006). For each scenario, the proportions of the population groups with dietary calcium intakes below the EAR were assessed and used as an estimation of the prevalence of inadequate calcium intakes.

The estimated dietary intakes for calcium were determined for each individual respondent and were compared to the relevant EAR for their age group and gender. The estimated proportion of each population group with inadequate dietary calcium intakes was then determined.

4.2.1 Australia

It was estimated that > 3% of Australians aged 4 years and above had inadequate 'Baseline' dietary calcium intakes (4-95% of sub-population groups), generally with a greater proportion of females having inadequate calcium intakes in comparison to males (see Table A3.1a in Appendix 3). The population group of Australian children aged 2-3 years was estimated to have no respondents with inadequate dietary calcium intakes. Australians aged 70 years and above had the highest proportion of respondents with inadequate calcium intakes (90-95%) at 'Baseline'.

The consideration of calcium fortification of chewing gum (≤ 0.2% residual sugars) resulted in minimal to no reduction in the proportions of the population groups with inadequate dietary calcium intakes from 'Baseline' (see Figure 7 and Table A3.1a in Appendix 3). For Australian children aged 4-8 years, the proportion with inadequate calcium intakes fell slightly to 4-7% under the 'Current technology' scenario and to 3-5% under the 'Anticipated future technology' scenario (from 4-10%).

4.2.2 New Zealand

It was estimated that ≥40% of New Zealanders aged 15 years and above had inadequate 'Baseline' dietary calcium intakes (40-95% of sub-population groups), generally with a greater proportion of females having inadequate calcium intakes in comparison to males (see Table A3.1b in Appendix 3). New Zealanders aged 70 years and above had the highest proportion of respondents with inadequate calcium intakes (90-95%).

The consideration of calcium fortification of chewing gum (≤0.2% residual sugars) resulted in minimal to no reduction in the proportions of the population groups with inadequate dietary calcium intakes from 'Baseline' (see Figure 7 and Table A3.1b in Appendix 3).

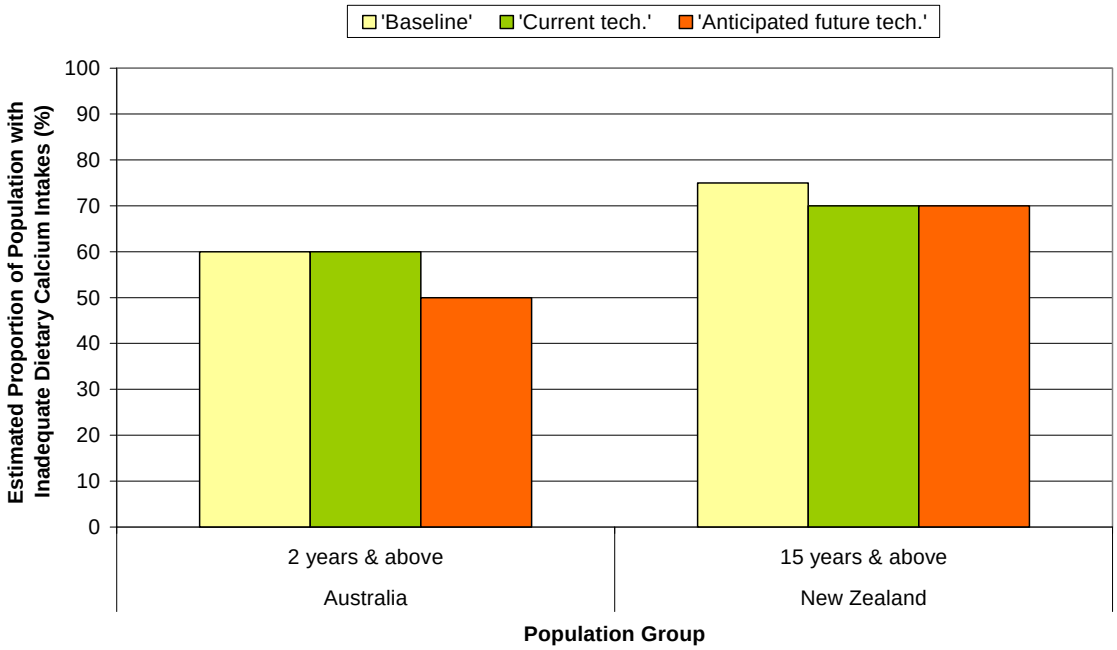

Figure 5: Estimated proportion of the population with inadequate dietary calcium intakes at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios (A)

4.2.3 Summary

The consideration of the calcium fortification of chewing gum (≤0.2% residual sugars) resulted in minimal to no reduction in the proportions of the population groups with inadequate dietary calcium intakes from 'Baseline' for Australians aged 9 years and above and New Zealanders aged 15 years and above. The proportion of New Zealanders aged 15 years and above and Australians aged 9 years and above with inadequate dietary calcium intakes remained substantial (30-95% of the population group) under both fortification scenarios considered.

4.3 (A) Comparison of estimated dietary calcium intakes with the Upper Level

In order to determine if the proposed level of addition of calcium to chewing gum (≤0.2% residual sugars) will have the potential to be a concern to public health and safety, estimated dietary calcium intakes were compared with the Upper Level (UL). The UL is 'The highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population' (NHMRC & NZMoH, 2006). The estimated dietary intakes of calcium were determined for each individual and compared to the UL of 2,500 mg per day, which has been set for the whole population.

The proportion of the Australian and New Zealand population groups with estimated calcium intakes above the UL changed minimally from 'Baseline' to the various fortification scenarios (see Table A3.2a in Appendix 3 for Australia and Table A3.2b for New Zealand). The proportion of the population sub-groups with estimated calcium intakes greater than the UL was typically less than 1%. Australian males aged 14-18 years were the population sub-group with highest proportion of the population with estimated calcium intakes above the UL, at 3% (at 'Baseline' and under both fortification scenarios).

5. Assessment for Australian and New Zealand respondents assumed to be consumers of chewing gum (≤0.2% residual sugars) (Type B)

5.1 (B) Estimated mean dietary intakes of calcium for respondents assumed to be consumers of chewing gum (≤0.2% residual sugars)

5.1.1 Australia

The increase in estimated mean calcium intakes from 'Baseline' for calcium-fortified chewing gum (≤0.2% residual sugars) consumers in all Australian population sub-groups was in the range of:

- 30-55 mg calcium per day (up to 6% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and

- 60-105 mg calcium per day (up to 12% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

Australian males aged 2-29 years showed the highest increase in calcium intakes from 'Baseline' (53 mg/day under the 'Current technology' scenario and 104 mg/day under the 'Anticipated future technology' scenario).

Australian females aged 19-29 years and 70 years and above and Australian males aged 30-49 years showed the lowest increase in calcium intakes (31 mg/day under the 'Current technology' scenario and 60 mg/day under the 'Anticipated future technology' scenario). See Table 3a for further details. The increase in calcium intakes for Australians aged 2 years and above is shown in Figure 6.

With an increase in age, there was generally a lower increase in calcium intakes for chewing gum consumers, reflective of lower mean chewing gum consumption with age.

5.1.2 New Zealand

The increase in estimated mean calcium intakes from 'Baseline' for calcium-fortified chewing gum (containing no more than 0.2% residual sugars) consumers in all New Zealand population sub-groups was in the range of:

- 30-85 mg calcium per day (up to 11% of 'Baseline' calcium intakes) under the 'Current technology' scenario; and

- 55-160 mg calcium per day (up to 22% of 'Baseline' calcium intakes) under the 'Anticipated future technology' scenario.

New Zealand males aged 70 years and above showed the highest increase in calcium intakes from 'Baseline' (81 mg/day under the 'Current technology' scenario and 159 mg/day under the 'Anticipated future technology' scenario). New Zealand males aged 30-49 years showed the lowest increase in calcium intakes (30 mg/day under the 'Current technology' scenario and 59 mg/day under the 'Anticipated future technology' scenario). See Table 3b for further details. The increase in calcium intakes for New Zealanders aged 15 years and above is shown in Figure 6.

In New Zealand, the increase in mean calcium intakes for chewing gum consumers was generally higher for females than males in each population sub-group. This can be attributed to mean daily chewing gum consumption for chewing gum consumers being generally higher for females than for males.

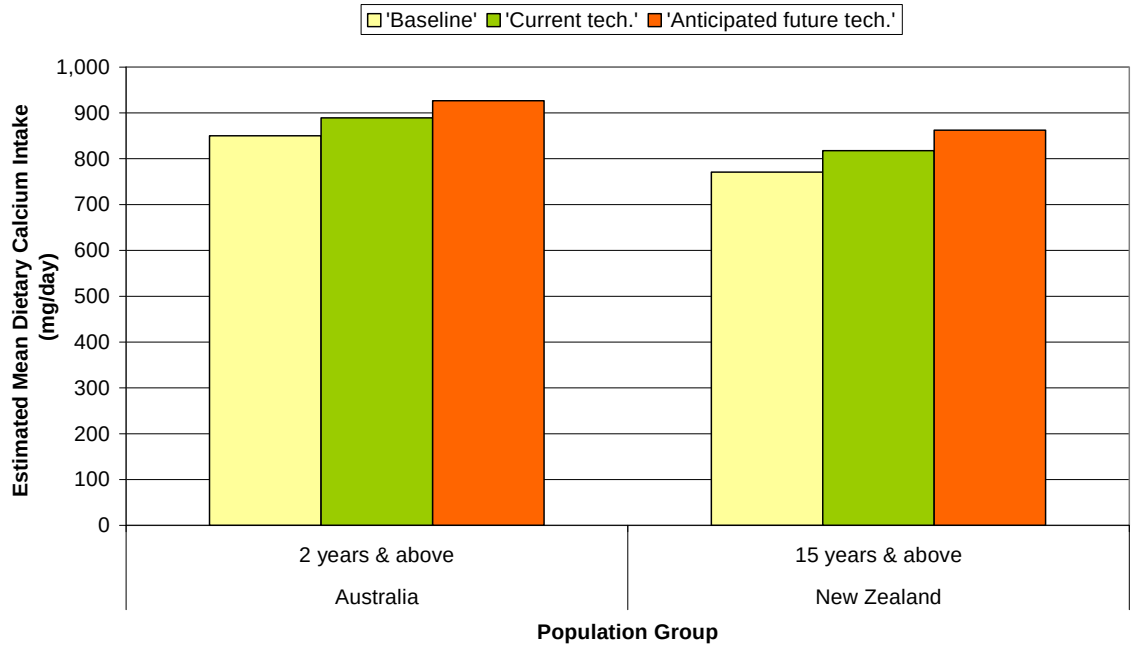

Figure 6: Estimated mean calcium intakes from food at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios, for consumers of calcium-fortified chewing gum (≤0.2 % residual sugars) (B)

Table 1: Estimated increase in dietary calcium intakes from 'Baseline' for calcium-fortified chewing gum (≤0.2% residual sugars) consumers (B)

a. Australia

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated mean dietary calcium intakes for chewing gum consumers (mg/day)[1]	Estimated increase in mean dietary calcium intakes from 'Baseline' for chewing gum consumers[1] [mg/day] (% 'Baseline' intake)	
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616		960	+43 (+4)	+83 (+9)
	F	7,242		750	+36 (+5)	+70 (+9)
2-3 yrs	M	170	360	932	+53 (+6)	+104 (+11)
	F	213	360	807	+44 (+5)	+85 (+11)
4-8 yrs	M	513	520	901	+53 (+6)	+104 (+12)
	F	464	520	759	+44 (+6)	+85 (+11)
9-13 yrs	M	474	800-1,050[2]	1,018	+53 (+5)	+104 (+10)
	F	439	800-1,050[2]	802	+44 (+5)	+85 (+11)
14-18 yrs	M	378	1,050	1,180	+53 (+5)	+104 (+9)
	F	356	1,050	789	+44 (+6)	+85 (+11)

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated mean dietary calcium intakes for chewing gum consumers (mg/day)[1]	Estimated increase in mean dietary calcium intakes from 'Baseline' for chewing gum consumers[1] [mg/day] (% 'Baseline' intake)	
				'Baseline'	'Current tech.'	'Anticipated future technology'
19-29 yrs	M	1,014	840	1,136	+53 (+5)	+104 (+9)
	F	1,189	840	797	+31 (+4)	+61 (+8)
30-49 yrs	M	2,080	840	952	+31 (+3)	+60 (+6)
	F	2,317	840	744	+33 (+5)	+65 (+9)
50-69 yrs	M	1,442	840	861	+40 (+5)	+78 (+9)
	F	1,577	1,100	721	+41 (+6)	+81 (+11)
70 yrs & above	M	545	1,100	779	+38 (+5)	+74 (+9)
	F	687	1,100	679	+31 (+5)	+61 (+9)

[1] The concentration of calcium in foods was weighted according to the proportion of a food group that is fortified, excluding calcium-fortified chewing gum (≤0.2% residual sugars). Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤ 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

[2] There are separate recommendations for children aged 9-11 years and 12-13 years because of growth needs; 9-11 year olds who are growing and maturing at much greater rates than average may need the intakes recommended for 12-13 year olds.

b. New Zealand

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated mean dietary calcium intakes for chewing gum consumers (mg/day)[1]	Estimated increase in mean dietary calcium intakes from 'Baseline' for chewing gum consumers[1] [mg/day] (% 'Baseline' intake)	
				'Baseline'	'Current technology'	'Anticipated future technology'
15 yrs & above	M	1,927		862	+35 (+4)	+69 (+8)
	F	2,709		706	+55 (+8)	+108 (+15)
15-18 yrs	M	109	1,050	966	+33 (+3)	+65 (+7)
	F	137	1,050	770	+79 (+10)	+155 (+20)
19-29 yrs	M	286	840	962	+42 (+4)	+81 (+8)
	F	518	840	766	+43 (+6)	+89 (+12)
30-49 yrs	M	787	840	888	+30 (+3)	+59 (+7)
	F	1,096	840	712	+42 (+6)	+82 (+11)
50-69 yrs	M	538	840	798	+39 (+5)	+75 (+9)
	F	609	1,100	667	+76 (11)	+148 (+22)

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated mean dietary calcium intakes for chewing gum consumers (mg/day)[1]	Estimated increase in mean dietary calcium intakes from 'Baseline' for chewing gum consumers[1] [mg/day] (% 'Baseline' intake)	
				'Baseline'	'Current technology'	'Anticipated future technology'
70 yrs & above	M	207	1,100	737	+81 (+11)	+159 (+22)
	F	349	1,100	642	+65 (+10)	+127 (+20)

[1] The concentration of calcium in foods was weighted according to the proportion of a food group that is fortified, excluding calcium-fortified chewing gum (≤ 0.2% residual sugars). Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤ 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

5.2 (B) Estimated proportion of the population with inadequate dietary calcium intakes for respondents assumed to be consumers of chewing gum (≤0.2% residual sugars)

5.2.1 Australia

It was estimated that >3% of Australian respondents assumed to be chewing gum (≤0.2% residual sugars) consumers aged 4 years and above had inadequate 'Baseline' dietary calcium intakes (4-95% of sub-population groups). Generally, a greater proportion of females had inadequate calcium intakes in comparison to males (see Table A4.1a in Appendix 4). The population group of Australian children aged 2-3 years was estimated to have no respondents with inadequate dietary calcium intakes. Australians aged 70 years and above had the highest proportion of respondents with inadequate calcium intakes (90-95%).

The consideration of calcium fortification of chewing gum (≤0.2% residual sugars) resulted in slight reductions in the proportion of the population groups (of chewing gum consumers) with inadequate dietary calcium intakes from 'Baseline'. However, the proportion of Australian calcium-fortified chewing gum consumers aged 9 years and above with inadequate dietary calcium intakes remained substantial for (30-90% of the population group) under both fortification scenarios considered (see Table A4.1a in Appendix 4). For Australian children aged 4-8 years, the proportion of calcium fortified chewing gum consumers with inadequate calcium intakes fell (from 4-10%) to 2-3% under the 'Current technology' scenario and to <1% under the 'Anticipated future technology' scenario. The change in proportion of population groups of chewing gum (≤0.2% residual sugars) consumers for Australians aged 2 years and above is shown in Figure 7.

5.2.2 New Zealand

It was estimated that ≥40% of New Zealanders aged 15 years and above had inadequate 'Baseline' dietary calcium intakes (40-95% of sub-population groups), generally with a greater proportion of females having inadequate calcium intakes in comparison to males (see Table A4.1b in Appendix 4). New Zealanders aged 70 years and above had the highest proportion of respondents with inadequate calcium intakes (90-95%).

The consideration of calcium fortification of chewing gum (containing no more than 0.2% residual sugars) resulted in slight reductions in the proportion of the population groups (of chewing gum consumers) with inadequate dietary calcium intakes from 'Baseline'. However, the proportion of New Zealand calcium-fortified chewing gum consumers aged 15 years and above with inadequate dietary calcium intakes remained substantial for (35-95% of the population group) under both fortification scenarios considered. The change in proportion of population groups of chewing gum (≤0.2% residual sugars) consumers for New Zealanders aged 15 years and above is shown in Figure 7.

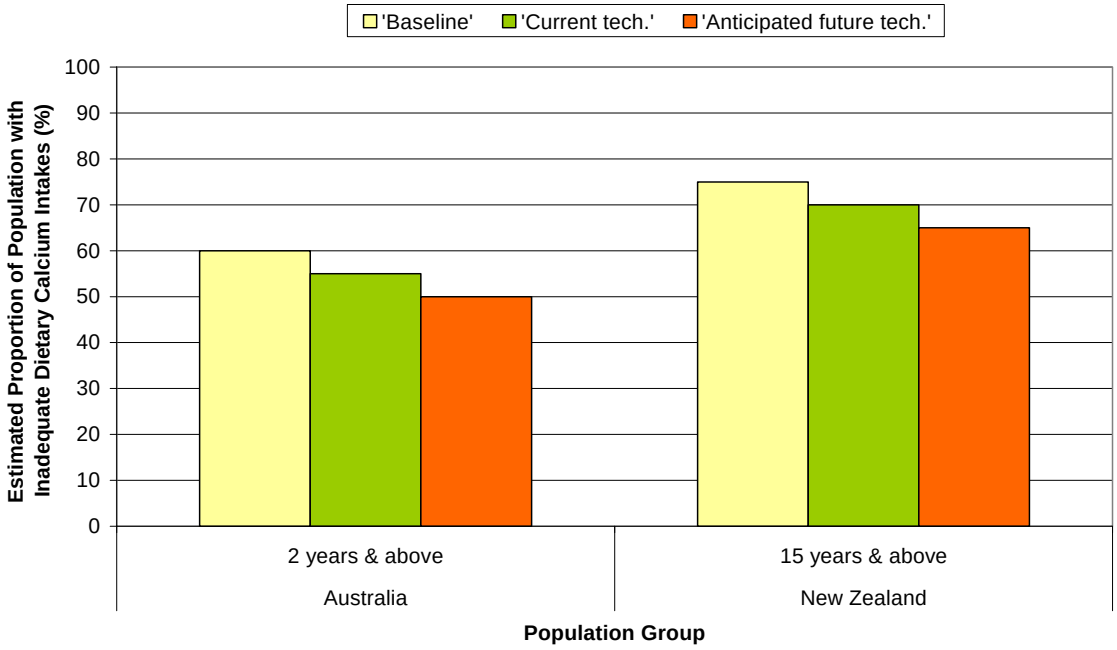

Figure 7: Estimated proportion of the population with inadequate dietary calcium intakes at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios, for consumers of calcium-fortified chewing gum (≤0.2 % residual sugars) only (B)

5.2.3 Consumer behaviour model results

The impact of calcium fortification of chewing gum (≤0.2% residual sugars) on groups of individuals who never choose products that are fortified/enriched with calcium, where there is a choice, was assessed. This model represents groups of individuals with the lowest calcium intakes, therefore a 'worst case' scenario for investigating inadequate calcium intakes.

Under the 'Current technology' scenario, there was little to no reduction in the proportion of Australian population groups with inadequate dietary calcium intakes (see Table A4.2a in Appendix 4). Under the 'Anticipated future technology' scenario, there was a greater reduction in the proportion of Australian population groups with inadequate dietary calcium intakes (5-10%) in comparison to 'Baseline'.

For New Zealand population groups, there was also little to no reduction in the proportion of the population group with inadequate dietary calcium intakes in comparison to 'Baseline' (see Table A4.1b in Appendix 4). Under the 'Anticipated future technology' scenario, the proportion of the population groups with inadequate dietary calcium intakes was reduced, in comparison to 'Baseline', by 0-15% of the population group.

5.3 (B) Comparison of estimated dietary calcium intakes with the Upper Level

The proportion of the Australian and New Zealand population groups with estimated calcium intakes above the UL changed minimally from 'Baseline' to the various fortification scenarios (see Table A4.3a in Appendix 4 for Australia and Table A4.3b for New Zealand) for those respondents assumed to be consumers of calcium-fortified chewing gum (≤0.2% residual sugars).

The proportion of the population sub-groups with estimated calcium intakes greater than the UL was typically less than 1%. Australian males aged 14-18 years were the population sub-group with highest proportion of the population with estimated calcium intakes above the UL, at 3%.

5.3.1 Consumer behaviour model results

The impact of the calcium fortification of chewing gum (≤0.2% residual sugars) was also assessed for groups of individuals who always choose foods/beverages that are fortified with calcium, where there is a choice. This model represents groups of individuals with the highest calcium intakes, therefore a 'worst case' scenario for investigating calcium intakes that exceed the UL. The consumption of chewing gum (≤0.2% residual sugars) was assumed to be at the mean amount for consumers of gum only (Roy Morgan Research, 2007).

In comparison to the market share estimate, the estimate that assumed consumers always choose other calcium fortified products had higher proportions of the population group with dietary calcium intakes that exceeded the UL, as might be expected. However, the proportion of the groups with dietary calcium intakes above the UL changed minimally between 'Baseline' and the two fortification scenarios ('Current technology' and 'Anticipated future technology'). The groups with the highest proportion of dietary calcium intakes above the UL were males aged 14-18 years for Australia and males aged 15-18 years for New Zealand. See Table A4.4a and b in Appendix 4 for further details.

5.3.2 Estimated maximum calcium intakes, as a proportion of the UL

The maximum calcium intakes, as a proportion of the UL, were estimated to provide an indication of the level of risk **for an individual** who goes out of their way to select the calcium-fortified/enriched various of a food, including chewing gum (≤0.2% residual sugars), where there is a choice.

In Australia and New Zealand, maximum calcium intakes as a proportion of the UL changed minimally from 'Baseline' to the fortification scenarios. In Australia, the highest maximum intake as a proportion of the UL was for a male aged 30-49 years (230% UL under all scenarios), whilst in New Zealand the highest maximum intake was for a female aged 19-29 years (180% under all scenarios). See Table A4.5a and b in Appendix 4 for further details.

6. Limitations of the dietary intake assessment

Dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated dietary intake of a nutrient for the population. However, the NNS data does have its limitations. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997 (Cook *et al*., 2001a; Cook *et al*., 2001b).

However, there is uncertainty associated with the consumption of foods that may have changed in consumption since 1995/1997, or that have been introduced to the market since 1995/1997.

Through the market share model, FSANZ sought to accommodate for changes in both the availability and consumption of calcium-fortified foods since 1995/1997. This was done by applying a market weight to entire food groups identified as having calcium-fortified products, and represents the contribution that the fortified version makes to calcium intakes.

Data generated from label values was not adjusted to take into account the potential addition of extra calcium (overages). The market share information used to weight calcium concentrations according to the proportion of the food group observed to be fortified may not fully reflect actual fortification practices.

The advantage of the market share model is that it only gives an estimate of population intakes over time. However, this means that it cannot estimate individual behaviour or estimate calcium intakes for individuals due to the use of weighted mean calcium concentration values. A limitation of the consumer behaviour model is that it is not a population estimate but rather gives the top and bottom ends of a range of possible intakes for an individual because it is not known how respondents in the NNS would actually have behaved had they been presented with a choice of products.

A limitation of estimating dietary intake over a period time using information from food recalls is that people may over- or under-report food consumption, particularly for certain types of foods. Over- and under-reporting of food consumption has not been accounted for in this dietary intake assessment. However, adjusting intakes based on two days of food consumption data accounts for some variation both within individuals and between individuals.

FSANZ does not currently hold food consumption data for New Zealand children aged 2-14 years in DIAMOND, therefore calcium intakes could not be estimated for this group.

Although some data on the use of complementary medicines (Australia) or dietary supplements (New Zealand) was collected in the NNSs, it was either not in a robust enough format to include in DIAMOND or has simply not been included in the DIAMOND program to date. Consequently, intakes of substances consumed via complementary medicines or dietary supplements could not be included directly in the dietary intake assessment conducted using DIAMOND.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In addition, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs which make the data representative of the actual population as a whole. Maori and Pacific peoples were over-sampled in the 1997 New Zealand NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary intake assessment because population weights were not used.

7. References

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Appendix 1

Calculation of estimated dietary calcium intakes

'Baseline' calcium intakes were calculated for each individual in the NNSs using their individual food consumption records from the dietary survey. The DIAMOND program multiplies the specified concentration of calcium for an individual food by the amount of the food that an individual consumed in order to estimate the intake of calcium from each food. Once this has been completed for all of the foods specified to contain calcium, the total amount of calcium consumed from all foods is summed for each individual. Adjusted nutrient intakes are first calculated (see below) and population statistics (such as mean and high percentile intakes) are then derived from the individuals' ranked intakes.

Adjusted nutrient intakes, which better reflect 'usual' daily nutrient intakes, were calculated since NRVs such as the estimated average requirement (EAR) and the upper level of intake (UL) are based on usual or long term intakes. It is therefore more appropriate to compare adjusted or 'usual' nutrient intakes with NRVs.

A1.1 Calculating adjusted intakes

To calculate usual daily nutrient intakes, more than one day of food consumption data are required. Information for a second (non-consecutive) day of food consumption was collected from approximately 10% of Australian NNS respondents and 15% of New Zealand NNS respondents. In order to estimate usual nutrient intakes using both days of food consumption data, an adjustment was made to each respondent's calcium intake based on the first day of food consumption data from the NNS. The adjustment takes into account several pieces of data including each person's day one nutrient intake, the mean nutrient intake from the sample on day one, the standard deviation from the day one sample and the between person standard deviation from the day two sample. This calculation is described in Figure A1.1 below. For more information on the methodology of adjusting for second day intakes, see the Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File (Australian Bureau of Statistics, 1998).

Adjusted value = $x + (x_1 - x) * (S_b/S_{obs})$
Where: x is the group mean for the Day 1 sample
x_1 is the individual's day 1 intake
S_b is the between person standard deviation; and
S_{obs} is the group standard deviation for the Day 1 sample

Source: (Australian Bureau of Statistics, 1998)

Figure A1.1: Calculating adjusted nutrient intakes

The age-gender groups used to calculate the second day adjusted calcium intakes were as outlined in Table A1.1.

Table A1.1: Age-gender groups used to calculate second day adjusted calcium intakes

Country	*Age Group*	*Gender*	
		Male	*Female*
Australia	*2-13 years*	✓	✓
	14-34 years	✓	✓
	35 years and above	✓	✓
New Zealand	*15-34 years*	✓	✓
	35 years and above	✓	✓

As a part of the two-day adjustment methodology, each individual intake below the mean in an intake distribution for day one will have an addition made to their calcium intakes in order to calculate the adjusted intake over two days, as every individual's intakes are brought towards the mean. This applies to the intakes from respondents which are zero for day one.

The benefit in being able to more accurately estimate 'usual intake' by using the two day adjustment factor outweighs the possible over estimation of intakes for low consumers for risk assessment purposes.

A1.2 Comparison of one day and usual intake distributions

The range of intakes from respondents is broader based on a single day of food consumption data than the range of usual intakes (Figure A1.2) as the latter takes into consideration the day-to-day variation in intakes within each person as well as the difference between each person.

Using adjusted intakes provides better information for risk characterisation purposes. Adjusted (or usual) nutrient intakes will have little or no impact on estimated mean nutrient intakes, but would result in an estimated 95th percentile intake that is lower than the 95th percentile intake from a single day only, or a 5th percentile intake that is higher than the 5th percentile intake based on day one intakes only.

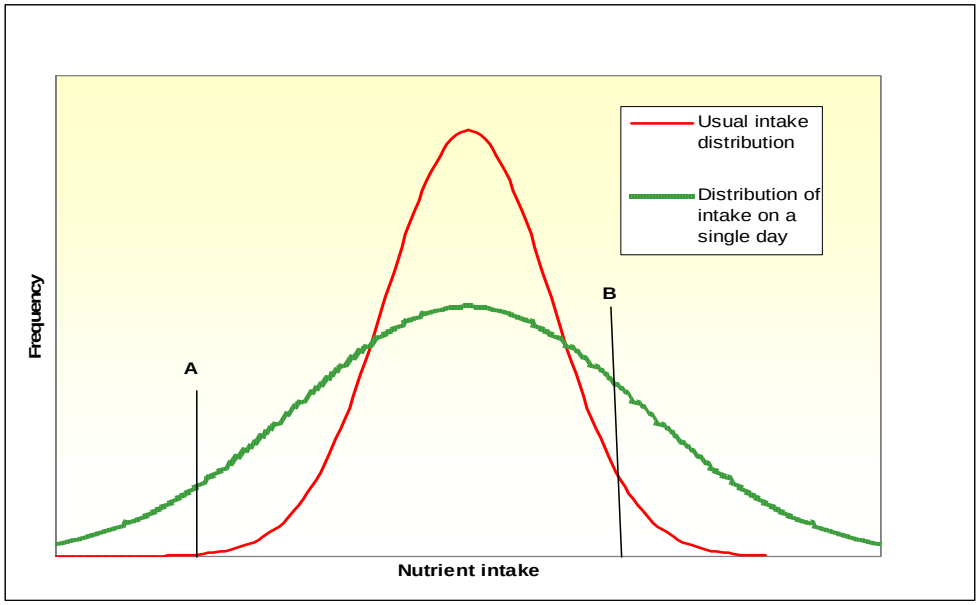


Figure A1.2: Comparison of one day and usual intake distributions

A1.3 Comparison of intakes with NRVs

If the reference value is below the population median intake, then intakes based on a single day of food consumption data would result in a larger proportion of the population having intakes below a specified level (e.g. Figure A1.2, point A), which may overestimate the level of deficiency or inadequate intakes. A broader distribution from a single day of data also means a greater proportion of a population would exceed an upper cut off level, such as the UL (e.g. Figure A1.2, point B), which overestimates the level of risk to this group of the population.

Note that where estimated intakes are expressed as a percentage of the NRV, each individual's total adjusted intake is calculated as a percentage of the NRV (using the total intakes in units per day) corresponding to their age and gender, the results are then ranked, and population statistics derived.

A1.4 Calculation of foods contributing to calcium intakes

'Baseline' calcium intakes were calculated for each individual in the NNSs using their individual food consumption records from the dietary survey. The DIAMOND program multiplies the specified concentration of calcium for an individual food by the amount of the food that an individual consumed in order to estimate the intake of calcium from each food. Once this has been completed for all of the foods specified to contain calcium, the total amount of calcium consumed from all foods is summed for each individual. This is based on a single 24-hour recall only. Percentage contributions from individual foods are then calculated for food groups. Population statistics are then derived from the individuals' result.

Appendix 2

Complete information on risk assessment

Table A2.1: Mean consumption of chewing gum (≤0.2% residual sugars) by Australian and New Zealand population groups and sub-groups[1] (Type A models)

Pop. group	Gender	Estimated population ('000)*		Mean chewing gum (containing no more than 0.2% residual sugars) consumption (g/day)[1]	
		Aus	NZ	Aus	NZ
14 yrs & above	All	16,928	3,298	0.72	0.77
	M	8,349	1,590	0.71	0.52
	F	8,579	1,708	0.74	1.01
14-19 yrs	All	1,809	421	1.59	1.71
	M	921	229	1.62	0.97
	F	888	192	1.55	2.59
20-29 yrs	All	2,597	481	1.16	0.97
	M	1,355	227	1.41	0.65
	F	1,242	254	0.90	1.25
30-49 yrs	All	6,103	1,220	0.64	0.63
	M	3,000	580	0.52	0.44
	F	3,103	640	0.75	0.80
50-69 yrs	All	4,479	896	0.46	0.60
	M	2,148	403	0.34	0.40
	F	2,330	493	0.57	0.75
70 yrs & above	All	1,940	280	0.18	0.22
	M	925	150	0.21	0.24
	F	1,016	130	0.15	0.19

* Data post-weighted from 1,311 participants (Australia) and 1,084 participants (New Zealand).

[1] includes both those who consume chewing gum (≤0.2% residual sugars) and those who do not.

Source: (Roy Morgan Research, 2007) (raw data analysed by FSANZ to produce mean consumption of chewing gum (≤0.2% residual sugars) per day)

Table A2.2: Mean consumption of chewing gum (≤0.2% residual sugars) by Australian and New Zealand consumers of chewing gum (≤ 0.2% residual sugars)[#] (Type B models)

Pop. group	Gender	Mean chewing gum (≤0.2% residual sugars) consumption for consumers of calcium-fortified gum only[#] (g/day)	
		Aus	NZ
14 yrs & above	All	1.83	2.19
	M	2.00	1.66
	F	1.69	2.59
14-19 yrs	All	2.25	2.60
	M	2.49	1.55
	F	2.04	3.72
20-29 yrs	All	1.96	2.02
	M	2.49	1.99
	F	1.43	2.04
30-49 yrs	All	1.52	1.73
	M	1.45	1.42
	F	1.57	1.96
50-69 yrs	All	1.91	2.74
	M	1.86	1.81
	F	1.94	3.54
70 yrs & above	All	1.61	3.46
	M	1.77	3.81
	F	1.46	3.04

* Data post-weighted from 1,311 participants (Australia) and 1,084 participants (New Zealand).
# for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) only.
Source: (Roy Morgan Research, 2007) (raw data analysed by FSANZ to produce mean consumption of chewing gum (≤0.2% residual sugars) per day)

Appendix 3

Complete information on risk characterisation for Australian and New Zealand population groups (Type A models)

Table A3.1: Market share model: Estimated proportion of Australian and New Zealand population groups with inadequate calcium intakes at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' fortification scenarios (Type A model)

a. Australia

Pop. group	Gender	No. of respondents in NNS	EAR (mg/day)	Estimated proportion of population with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616		45	45	45
	F	7,242		70	70	70
2-3 yrs	M	170	360	0	0	0
	F	213	360	0	0	0
4-8 yrs	M	513	520	4	4	3
	F	464	520	10	7	5
9-13 yrs	M	474	800-1,050[2]	45	40	40
	F	439	800-1,050[2]	65	65	65
14-18 yrs	M	378	1,050	45	45	45
	F	356	1,050	80	80	80
19-29 yrs	M	1,014	840	30	30	30
	F	1,189	840	65	60	60
30-49 yrs	M	2,080	840	45	45	45
	F	2,317	840	70	70	65
50-69 yrs	M	1,442	840	55	55	55
	F	1,577	1,100	90	90	90
70 yrs & above	M	545	1,100	90	90	90
	F	687	1,100	95	95	95

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

[2] There are separate recommendations for children aged 9-11 years and 12-13 years because of growth needs; 9-11 year olds who are growing and maturing at much greater rates than average may need the intakes recommended for 12-13 year olds.

b. New Zealand

Pop. group	Gender	No of respondents in NNS	EAR (mg/day)	Proportion of population with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927		60	60	60
	F	2,709		90	90	90
15-18 yrs	M	109	1,050	70	65	65
	F	137	1,050	85	85	85
19-29 yrs	M	286	840	50	45	45
	F	518	840	70	70	65
30-49 yrs	M	787	840	55	50	50
	F	1,096	840	75	75	75
50-69 yrs	M	538	840	40	40	40
	F	609	1,100	95	95	95
70 yrs & above	M	207	1,100	90	90	90
	F	349	1,100	95	95	95

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

Table A3.2: Market share model: Estimated proportion of Australian and New Zealand population groups with dietary calcium intakes exceeding the Upper Level at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' fortification scenarios (Type A model)

a. Australia

Pop. group	Gender	No. of respondents	UL (mg/day)	Proportion of population with dietary calcium intakes > UL[1] (%)		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616	2,500	<1	<1	1
	F	7,242	2,500	<1	<1	<1
2-3 yrs	M	170	2,500	0	0	0
	F	213	2,500	0	0	0
4-8 yrs	M	513	2,500	0	0	0
	F	464	2,500	0	0	0
9-13 yrs	M	474	2,500	1	1	1
	F	439	2,500	0	0	0
14-18 yrs	M	378	2,500	3	3	3
	F	356	2,500	<1	<1	<1
19-29 yrs	M	1,014	2,500	2	2	2
	F	1,189	2,500	<1	<1	<1
30-49 yrs	M	2,080	2,500	<1	<1	<1
	F	2,317	2,500	<1	<1	<1
50-69 yrs	M	1,442	2,500	<1	<1	<1
	F	1,577	2,500	<1	<1	<1
70 yrs & above	M	545	2,500	0	0	0
	F	687	2,500	0	0	0

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

b. New Zealand

Pop. group	Gender	No. of respondents	UL (mg/day)	Proportion of population with dietary calcium intakes > UL[1] (%)		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927	2,500	<1	<1	<1
	F	2,709	2,500	<1	<1	<1
15-18 yrs	M	109	2,500	2	2	2
	F	137	2,500	0	0	0
19-29 yrs	M	286	2,500	2	2	2
	F	518	2,500	<1	<1	<1
30-49 yrs	M	787	2,500	<1	<1	<1
	F	1,096	2,500	<1	<1	<1
50-69 yrs	M	538	2,500	0	0	0
	F	609	2,500	0	0	0
70 yrs & above	M	207	2,500	0	0	0
	F	349	2,500	0	0	0

[1] Concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

Appendix 4

Complete information on risk characterisation for consumers of calcium-fortified chewing gum (≤0.2% residual sugars)

Table A4.1: Market share model: Estimated proportion of calcium-fortified chewing gum (≤0.2% residual sugars) consumers with inadequate calcium (Type B model)

a. Australia

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated proportion of consumers with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616		45	40	35
	F	7,242		70	65	65
2-3 yrs	M	170	360	0	0	0
	F	213	360	0	0	0
4-8 yrs	M	513	520	4	2	<1
	F	464	520	10	3	<1
9-13 yrs	M	474	800-1,050[2]	45	35	30
	F	439	800-1,050[2]	65	65	55
14-18 yrs	M	378	1,050	45	40	35
	F	356	1,050	80	80	75
19-29 yrs	M	1,014	840	30	25	20
	F	1,189	840	65	60	55
30-49 yrs	M	2,080	840	45	45	40
	F	2,317	840	70	65	60
50-69 yrs	M	1,442	840	55	50	45
	F	1,577	1,100	90	90	85
70 yrs & above	M	545	1,100	90	85	85
	F	687	1,100	95	95	90

[1] The concentration of calcium in foods was weighted according to the proportion of a food group that is fortified, excluding calcium-fortified chewing gum (≤0.2% residual sugars). Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).
[2] There are separate recommendations for children aged 9-11 years and 12-13 years because of growth needs; 9-11 year olds who are growing and maturing at much greater rates than average may need the intakes recommended for 12-13 year olds.

b. New Zealand

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated proportion of consumers with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927		60	55	50
	F	2,709		90	85	80
15-18 yrs	M	109	1,050	70	65	60
	F	137	1,050	85	80	80
19-29 yrs	M	286	840	50	45	35
	F	518	840	70	65	60
30-49 yrs	M	787	840	55	50	45
	F	1,096	840	75	70	65
50-69 yrs	M	538	840	40	40	35
	F	609	1,100	95	90	90
70 yrs & above	M	207	1,100	90	90	85
	F	349	1,100	95	95	95

[1] The concentration of calcium in foods was weighted according to the proportion of a food group that is fortified, excluding calcium-fortified chewing gum (≤0.2% residual sugars). Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Table A4.2: Consumer behaviour model: Estimated proportion of respondents assumed to be consumers of calcium-fortified chewing gum (≤0.2% residual sugars) with inadequate calcium intakes (Type B model)

a. Australia

Pop. group	Gender	No. of respondents	EAR (mg/day)	Estimated proportion of consumers with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current technology'	'Anticipated future technology'
2 yrs & above	M	6,616		45	45	40
	F	7,242		70	70	65
2-3 yrs	M	170	360	0	0	0
	F	213	360	0	0	0
4-8 yrs	M	513	520	4	2	<1
	F	464	520	10	3	<1
9-13 yrs	M	474	800-1,050[2]	45	40	30
	F	439	800-1,050[2]	70	65	60
14-18 yrs	M	378	1,050	45	40	35
	F	356	1,050	80	80	75
19-29 yrs	M	1,014	840	30	30	25
	F	1,189	840	65	60	55
30-49 yrs	M	2,080	840	45	45	40
	F	2,317	840	70	65	65
50-69 yrs	M	1,442	840	55	55	50
	F	1,577	1,100	90	90	85
70 yrs & above	M	545	1,100	90	85	85
	F	687	1,100	95	95	90

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that **do not** contain calcium where there is a choice; however choose to consume calcium-fortified chewing gum (≤0.2% residual sugars). Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

[2] There are separate recommendations for children aged 9-11 years and 12-13 years because of growth needs. 9-11 year olds who are growing and maturing at much greater rates than average may need the intakes recommended for 12-13 year olds.

b. New Zealand

Population group	Gender	Number of respondents	EAR (mg/day)	Estimated proportion of consumers with inadequate dietary calcium intakes (%)[1]		
				'Baseline'	'Current technology'	'Anticipated future technology'
15 yrs & above	M	1,927		60	55	50
	F	2,709		90	85	80
15-18 yrs	M	109	1,050	70	65	60
	F	137	1,050	85	80	80
19-29 yrs	M	286	840	50	45	35
	F	518	840	70	65	60
30-49 yrs	M	787	840	55	50	45
	F	1,096	840	75	70	65
50-69 yrs	M	538	840	40	40	35
	F	609	1,100	95	90	90
70 yrs & above	M	207	1,100	90	90	85
	F	349	1,100	95	95	95

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that **do not** contain calcium where there is a choice; however choose to consumer chewing gum (≤0.2% residual sugars) with calcium. Calcium intakes for the scenarios were based on mean consumption of chewing gum (≤0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Table A4.3: Market share model: Estimated proportion of calcium-fortified chewing gum (≤0.2% residual sugars) consumers with dietary calcium intakes exceeding the Upper Level (Type B model)

a. Australia

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated proportion of consumers with dietary calcium intakes > UL (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616	2,500	<1	1	1
	F	7,242	2,500	<1	<1	<1
2-3 yrs	M	170	2,500	0	0	0
	F	213	2,500	0	0	0
4-8 yrs	M	513	2,500	0	0	0
	F	464	2,500	0	0	0
9-13 yrs	M	474	2,500	1	1	1
	F	439	2,500	0	0	0
14-18 yrs	M	378	2,500	3	3	3
	F	356	2,500	<1	<1	<1
19-29 yrs	M	1,014	2,500	2	2	3
	F	1,189	2,500	<1	<1	<1
30-49 yrs	M	2,080	2,500	<1	<1	<1
	F	2,317	2,500	<1	<1	<1
50-69 yrs	M	1,442	2,500	<1	<1	<1
	F	1,577	2,500	<1	<1	<1
70 yrs & above	M	545	2,500	0	0	0
	F	687	2,500	0	0	0

[1] Market weighted: concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

b. New Zealand

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated proportion of consumers with dietary calcium intakes > UL (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927	2,500	<1	<1	<1
	F	2,709	2,500	<1	<1	<1
15-18 yrs	M	109	2,500	2	2	2
	F	137	2,500	0	0	0
19-29 yrs	M	286	2,500	2	2	2
	F	518	2,500	<1	<1	<1
30-49 yrs	M	787	2,500	<1	<1	<1
	F	1,096	2,500	<1	<1	<1
50-69 yrs	M	538	2,500	0	0	<1
	F	609	2,500	0	0	0
70 yrs & above	M	207	2,500	0	0	0
	F	349	2,500	0	0	0

[1] Market weighted: concentration of calcium in foods was weighted according to the proportion of a food group that is fortified. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Table A4.4: Consumer behaviour model: Estimated proportion of consumers of calcium-fortified chewing gum (≤0.2% residual sugars) with dietary calcium intakes exceeding the UL (Type B model)

a. Australia

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated proportion of consumers with dietary calcium intakes > UL (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616	2,500	2	3	3
	F	7,242	2,500	<1	<1	<1
2-3 yrs	M	170	2,500	0	1	1
	F	213	2,500	0	0	0
4-8 yrs	M	513	2,500	<1	<1	<1
	F	464	2,500	0	0	0
9-13 yrs	M	474	2,500	3	4	4
	F	439	2,500	0	0	0
14-18 yrs	M	378	2,500	6	7	7
	F	356	2,500	1	1	1
19-29 yrs	M	1,014	2,500	5	6	6
	F	1,189	2,500	<1	1	1
30-49 yrs	M	2,080	2,500	3	3	3
	F	2,317	2,500	<1	<1	<1
50-69 yrs	M	1,442	2,500	1	1	2
	F	1,577	2,500	<1	<1	<1
70 yrs & above	M	545	2,500	<1	<1	<1
	F	687	2,500	<1	<1	<1

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that are fortified with calcium. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

b. New Zealand

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated proportion of consumers with dietary calcium intakes > UL (%)[1]		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927	2,500	2	2	2
	F	2,709	2,500	<1	<1	<1
15-18 yrs	M	109	2,500	4	4	4
	F	137	2,500	0	0	0
19-29 yrs	M	286	2,500	3	4	4
	F	518	2,500	<1	<1	<1
30-49 yrs	M	787	2,500	2	2	2
	F	1,096	2,500	<1	<1	<1
50-69 yrs	M	538	2,500	<1	<1	<1
	F	609	2,500	<1	<1	<1
70 yrs & above	M	207	2,500	0	0	0
	F	349	2,500	0	0	0

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that are fortified with calcium. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Table A4.5: Consumer behaviour model: Estimated maximum calcium intakes consumers of calcium-fortified foods chewing gum (≤0.2% residual sugars) (Type B model)

a. Australia

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated maximum calcium intake[1] (% UL)		
				'Baseline'	'Current tech.'	'Anticipated future technology'
2 yrs & above	M	6,616	2,500	230	230	230
	F	7,242	2,500	200	200	200
2-3 yrs	M	170	2,500	100	100	100
	F	213	2,500	80	80	80
4-8 yrs	M	513	2,500	110	110	110
	F	464	2,500	85	85	85
9-13 yrs	M	474	2,500	160	160	160
	F	439	2,500	85	85	85
14-18 yrs	M	378	2,500	190	190	190
	F	356	2,500	200	200	200
19-29 yrs	M	1,014	2,500	180	190	190
	F	1,189	2,500	180	180	180
30-49 yrs	M	2,080	2,500	230	230	230
	F	2,317	2,500	130	130	130
50-69 yrs	M	1,442	2,500	210	210	210
	F	1,577	2,500	120	120	130
70 yrs & above	M	545	2,500	110	120	120
	F	687	2,500	110	110	110

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that are fortified with calcium. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

b. New Zealand

Pop. group	Gender	No. of respondents	UL (mg/day)	Estimated maximum calcium intake[1] (% UL)		
				'Baseline'	'Current tech.'	'Anticipated future technology'
15 yrs & above	M	1,927	2,500	170	180	180
	F	2,709	2,500	180	180	180
15-18 yrs	M	109	2,500	140	140	140
	F	137	2,500	80	80	85
19-29 yrs	M	286	2,500	170	180	180
	F	518	2,500	180	180	180
30-49 yrs	M	787	2,500	170	170	180
	F	1,096	2,500	170	170	170
50-69 yrs	M	538	2,500	120	130	130
	F	609	2,500	110	120	120
70 yrs & above	M	207	2,500	80	85	85
	F	349	2,500	75	80	80

[1] Consumer behaviour: concentration of calcium in foods is based on the 'consumer behaviour' model for calcium-fortified and enriched foods: where it is assumed that individuals always choose the products that are fortified with calcium. Calcium intakes for the scenarios were based on mean consumption of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Attachment 4

Consumer Research Report

Summary of key findings

Who consumes chewing gum (≤0.2% residual sugars)?

Around 40% of Australians and 35% of New Zealanders were estimated to be consumers of chewing gum (≤0.2 % residual sugars). The largest proportion of consumers of this chewing gum were aged between 14 and 19 years (over 65% of Australians and New Zealanders in this age group); and the smallest proportion of consumers of this chewing gum were aged 50 years and over, (21% of Australians and 18% of New Zealanders in this age group).

How often do people eat chewing gum (≤0.2% residual sugars)?

Of Australians and New Zealanders who are self-reported consumers of pellet or tab chewing gum (≤0.2% residual sugars), over 30% of consumers in each country eat pellets on three or more occasions per week; around 30% of consumers eat pellets on either one or two occasions per week; and over 35% of consumers in each country eat pellets on less than one occasion per week. Over 23% of consumers in each country eat tabs of this chewing gum on three or more occasions per week; between 25 and 30% of consumers eat tabs on either one or two occasions per week; and over 40% of consumers in each country eat tabs of this chewing gum on less than one occasion per week.

How many pellets or tabs of chewing gum (≤0.2% residual sugars) do people consume per eating occasion?

For self-reported consumers of pellet chewing gum (≤0.2% residual sugars), the highest proportion of people consume one or two pellets per eating occasion (over 85% of both Australians and New Zealanders). The mean consumption of pellet chewing gum (≤0.2% residual sugars) per eating occasion was around one and a half pellets per eating occasion for both Australians and New Zealanders.

For consumers of tab chewing gum (≤0.2% residual sugars), the highest proportion of people consume one tab per eating occasion (around 90% of Australians and New Zealanders). The average consumption of tab chewing gum (≤0.2% residual sugars) per eating occasion was just under one and a half tabs for both Australians and New Zealanders.

How many grams of chewing gum (≤0.2% residual sugars) do people eat on average each day?

Data shows that self-reported consumers of chewing gum (≤0.2% residual sugars) in Australia eat on average 1.83 g of this chewing gum per day, compared with 2.19 g per day in New Zealand. The calculation of daily consumption levels of chewing gum (≤0.2% residual sugars) averages an individual's chewing gum consumption across days when chewing gum (≤0.2% residual sugars) is consumed and days when no chewing gum is consumed. Thus, the figures listed will be underestimates than if calculated for 'consumption days' only.

Who is interested in buying calcium-fortified chewing gum (≤0.2% residual sugars)?

The study revealed that more than 30% of Australians and more than 35% of New Zealanders are interested in buying calcium-fortified chewing gum (≤0.2% residual sugars). Interest in buying the calcium-fortified chewing gum product declines with increasing age for both Australians and New Zealanders. Of Australians already consuming chewing gum (≤0.2% residual sugars), just over half surveyed indicated interest in buying the calcium-fortified chewing gum product. This compares with over 60% of New Zealanders. Of Australians who did not consume chewing gum (≤0.2% residual sugars), less than 20% indicated interest in buying this calcium-fortified chewing gum, compared with almost 25% of New Zealanders.

Will people substitute foods in their diet for calcium-fortified chewing gum (≤0.2 % residual sugars)?

Approximately 40% of Australians and 38% of New Zealanders who were interested in buying the calcium-fortified chewing gum (≤0.2% residual sugars) indicated they would substitute some foods in their diet with this chewing gum. Around 50% of Australians and New Zealanders who were interested, indicated that a calcium-fortified gum would be chewed in addition to other foods in their diet.

Of the 170 Australian and 164 New Zealand respondents who claimed they would replace foods in their diet with a calcium-fortified chewing gum, the majority of Australian respondents (n=75) and New Zealand respondents (n=68) reported they would replace other chewing gum products with the calcium-fortified chewing gum product. Thirty-five Australians and 44 New Zealand respondents reported they would replace lollies or mints with the calcium-fortified chewing gum. Nine Australian respondents and 11 New Zealand respondents reported they would replace calcium-rich foods such as milk, cheese or yoghurt with the calcium-fortified chewing gum product.

1. Background

The Wrigley Company Pty Ltd has applied to amend the Code to permit the addition of calcium to chewing gum (≤0.2% residual sugars). Their Application contained insufficient consumption data, and therefore Food Standards Australia New Zealand (FSANZ) requested additional information. The Applicant commissioned Roy Morgan Research Pty Ltd (RMR) to carry out additional consumer research.

FSANZ assisted with study design and implementation. The data analysis presented below was carried out by FSANZ, with the data supplied by the Applicant.

2. Study objectives

The objectives of the consumer research were to determine consumption levels of chewing gum (≤0.2% residual sugars) and potential behavioural changes if addition of calcium to this chewing gum was to be permitted – the research only looked at 1 element of this: potential substitution for other foods. The research did not look at changes in volume of chewing gum consumption. FSANZ advised the Applicant that additional information was needed to determine:

- the percentage who consume chewing gum (≤0.2% residual sugars), across age groups, gender, income level and Australia/New Zealand, and as a population total;

- the frequency of pellet and tab chewing gum (≤0.2% residual sugars) consumption, across Australia and New Zealand;

- the number of pellets and tabs of chewing gum (≤0.2% residual sugars) currently eaten per occasion, across Australia and New Zealand

- the estimated mean daily consumption of chewing gum (≤0.2% residual sugars); both pellet and tab combined, expressed in grams, for existing consumers of this chewing gum, and for the overall population, across age groups, gender, income level and Australia and New Zealand;

- whether people are interested in buying calcium-fortified chewing gum (≤0.2% residual sugars); and

- whether people would substitute some foods in their diet, for calcium-fortified chewing gum (≤0.2% residual sugars).

3. Methodology

A telephone omnibus (CATIBUS) was conducted by RMR to collect data. Separate surveys were conducted for Australia and New Zealand. The target population was a random representative sample of individuals aged 14 years and over. Younger children were not included in the study due to the difficulties in gaining permission.

The Applicant provided additional data from existing sources for those under 14 years of age (8-12 year olds), demonstrating that this group consumes relatively low levels of chewing gum (any type), in terms of gum consumption frequency per week and number of pieces eaten per occasion, compared with older age groups.

Both surveys across Australia and New Zealand used the same questionnaire which is reproduced in Box 1. The questionnaire covered the following topics:

- frequency of chewing gum (≤0.2% residual sugars) consumption occasions;

- quantity of chewing gum (≤0.2% residual sugars) consumed per occasion;

- interest in consuming chewing gum (≤0.2% residual sugars) that is fortified with calcium; and

- foods likely to be substituted by chewing gum (≤0.2% residual sugars) that is fortified with calcium.

3.1 Australian Survey

To gain an Australian sample, two rounds of the Roy Morgan CATI Omnibus survey were conducted with a representative sample of more than 600 people each round, aged 14 years and over. The sample was stratified by area (urban and remote areas of states and territories), with quotas controlled by sex and age (Table 1).

3.2 New Zealand Survey

To gain a New Zealand sample, half of one round of the Roy Morgan CATI Omnibus survey was conducted in order to obtain a representative sample of approximately 1000 people aged 14 years and over. The sample was stratified by area (regions across both the North and South Islands) with quotas controlled by sex and age (Table 1).

Table 1: Breakdown of survey respondents, by gender and age group

	Number of respondents	
	Australia	**New Zealand**
Gender		
Male	646	506
Female	665	578
Age groups		
14-19 years	142	149
20-29 years	194	164
30-49 years	480	437
50 years and over	495	334
Total	**1311**	**1084**

Note: Table 1 presents unweighted numbers of interviews conducted.

Data was post-weighted from the 1311 Australian participants and 1084 New Zealand participants to accurately represent the general population (14 years and over) of each country.

Box 1: Questionnaire used

ASK EVERYONE

1. How often would you eat 'sugar-free' pellet gum (small pillow shaped pieces) in a week?
    1) Less than once a week
    2) 1-2 times per week
    3) 3-4 times per week
    4) 5-6 times per week
    5) Once a day
    6) 2-3 times per day
    7) 4-5 times per day
    8) More than 5 times per day
    9) EAT OTHER TYPE/S OF GUM (E.G. TAB, LONG FLAT PIECES) (Do not read out)
    10) DO NOT EAT CHEWING GUM (Do not read out)

2. IF EAT PELLET GUM (code 1-8 on Q1) How many pieces of 'sugar-free' pellet gum would you eat per gum eating occasion?
    1) ONE PIECE
    2) TWO PIECES
    3) THREE PIECES
    4) FOUR PIECES
    5) FIVE OR MORE PIECES

REPEAT QUESTIONS 1-2 FOR 'SUGAR FREE' TAB GUM

ASK EVERYONE
3. How interested would you be in buying a 'sugar–free' chewing gum with added calcium? (Read out response options)
    1) Very Interested
    2) Somewhat Interested
    3) Not at all interested

IF VERY/ SOMEWHAT INTERESTED
4. Would you eat this gum in addition to other gums or foods you already eat now, or as a replacement for these?
    1) IN ADDITION
    2) AS A REPLACEMENT
    3) DON'T KNOW

IF EAT AS A REPLACEMENT
5. What other gums or food products would 'sugar-free' chewing gum with added calcium replace?
    1) OTHER CHEWING GUM
    2) MINTS
    3) LOLLIES/CONFECTIONARY
    4) CALCIUM RICH FOODS LIKE MILK, YOGHURT OR CHEESE
    5) OTHER FOODS (please specify_____)

Note: the term 'sugar-free' was used in the questionnaire to describe chewing gum containing no more than 0.2% residual sugars.

3.3 Analysis of data and reporting

Data was post-weighted to accurately represent the general population of each country. Weighted quantities are predominantly reported throughout this report, and represent estimated proportions and means of the population of Australia and New Zealand.

Following advice from RMR, proportions and means have been calculated for cell sizes of 30 cases and over, and weighted quantities have been reported.

For cell sizes of less than 30 cases, cells have been combined where possible (specified where applicable), and weighted quantities have been reported. Means and proportions have not been calculated for cell sizes of less than 30 cases where combination of data was not possible. Instead, results have been reported as unweighted numbers of responses (specified where applicable).

3.3.1 Comparison of data with previous research

Data provided by the Applicant from a report produced by IPSOS in 2004, outlining proportions of people across Australia who indicated they consumed chewing gum (any type of chewing gum or bubble gum), was compared to analyses conducted by FSANZ of the RMR data (of chewing gum containing no more than 0.2% residual sugars). Both sets of data were congruent and showed a decline in chewing gum consumption with increasing age.

3.3.2 Calculating mean chewing gum consumption - grams per day

Mean daily consumption of chewing gum (≤0.2% residual sugars) was calculated for samples of consumers of this chewing gum only (Section 5.4.1), and for samples representative of the total populations of Australia and New Zealand (Section 5.4.2).

Generation of the mean daily consumption of chewing gum (≤0.2% residual sugars) in grams per day is outlined below:

- Respondents were identified as consumers of this chewing gum if they indicated they consumed either pellets or tabs of this chewing gum. Non-consumers were identified as such if they indicated zero consumption of pellets or tabs of this chewing gum, or indicated they eat other types of chewing gum.

- Mean daily consumption of this chewing gum, in pellets and in tabs per day was calculated using data for:

    - frequency of consumption occasions of pellets and tabs of this chewing gum; and
    - number of pellets and tabs consumed per eating occasion.

- The mean daily consumption of this chewing gum, in grams was calculated by converting daily pellet and daily tab consumption into grams and then summing.

Mean daily consumption of chewing gum (≤0.2% residual sugars) for the overall population (Section 5.4.2) was calculated for dietary modelling purposes, as the relevant database does not have adequate data on individual chewing gum consumption. The calculation of daily consumption levels of chewing gum (≤0.2% residual sugars) averages an individual's chewing gum consumption across days when chewing gum (≤0.2% residual sugars) is consumed and days when no chewing gum is consumed. Thus, the figures listed will be underestimates than if calculated for 'consumption days' only.

4. Socio-demographic overview of the sample

All data below is reported in weighted quantities unless specified otherwise.

4.1 Age groups

The median[68] age group of Australian respondents and New Zealand respondents was 40-44 years. Table 2 presents a breakdown of the sample by age groups that were collected in the study.

Table 2: Overview of age groups of sample respondents

	%	
Age groups	**Australia**	**New Zealand**
14-19 years	10.7	12.8
20-29 years	15.3	14.6
30-49 years	36.1	37.0
50 years and over	37.9	35.7
Total	**100.0**	**100.0**

4.2 Gender

Table 3 displays the sample distribution by gender. Proportions of males and females were roughly even for each country.

Table 3: Gender breakdown of sample

	%	
Gender	**Australia**	**New Zealand**
Male (14 years +)	49.3	48.2
Female (14 years +)	50.7	51.8
Total	**100.0**	**100.0**

4.3 Personal income

The median personal annual income group of Australian and New Zealand respondents was $35,000-$39,999.

For analysis, personal income was divided into quartiles (Table 4). In reporting responses for individuals of lower or higher incomes, the first and fourth quartiles[69] were used for each country.

Table 4: Annual personal income quartiles

	$ Range	
Quartiles	**Australia**	**New Zealand**
1st Quartile	0-14,999	0-14,999
2nd Quartile	20,000-39,999	20,000-39,999
3rd Quartile	40,000-69,999	40,000-59,999
4th Quartile	70,000-130,000+	60,000-130,000+

[68] The median is the midpoint of a distribution or a series of numbers; such that half of the data values are above the median, and half are below.

[69] Quartiles are divisions of data into four equal parts, so that each quartile represents 1/4th of the sample or population.

5. Consumption of chewing gum (≤0.2% residual sugars)

As the proposed calcium-fortified chewing gum product does not exist, this report cannot present levels of consumption of this proposed product. Thus, this report presents self-report measures of current consumption levels of chewing gum (≤0.2% residual sugars).

5.1 Who consumes chewing gum (≤0.2% residual sugars)?

Table 5 shows that an estimated 40% of Australians and 35% of New Zealanders consume chewing gum (≤0.2% residual sugars).

Table 5: Percentage of people who consume chewing gum (≤0.2% residual sugars), by gender, income and age group

Estimated % population consume chewing gum (≤0.2 % residual sugars)	% Australia	New Zealand
Total (14 years +)	**40.1**	**35.2**
Gender		
Male (14 years +)	35.9	31.2
Female (14 years +)	44.1	38.9
Individual Income		
1st quartile	46.4	43.3
4th quartile	36.5	35.1
Age group		
14-19 years	70.8	65.7
20-29 years	59.8	47.8
30-49 years	42.4	36.2
50 years and over	21.2	18.0

The largest proportion of consumers of this chewing gum consisted of those in the lowest age group, 14-19 years (70.8% of Australians, and 65.7% of New Zealanders in that age group), and the smallest proportion of consumers of this chewing gum consisted of respondents in the highest age group, 50 years and over (13.8% of Australians, and 6.3% of New Zealanders in that age group). A decline in consumption with increasing age group can be observed in Figure 1.

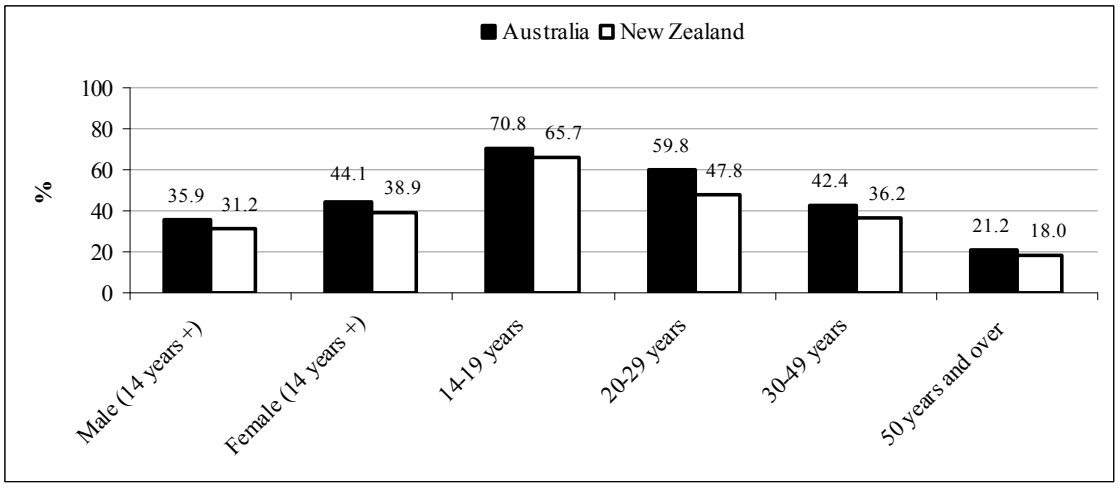
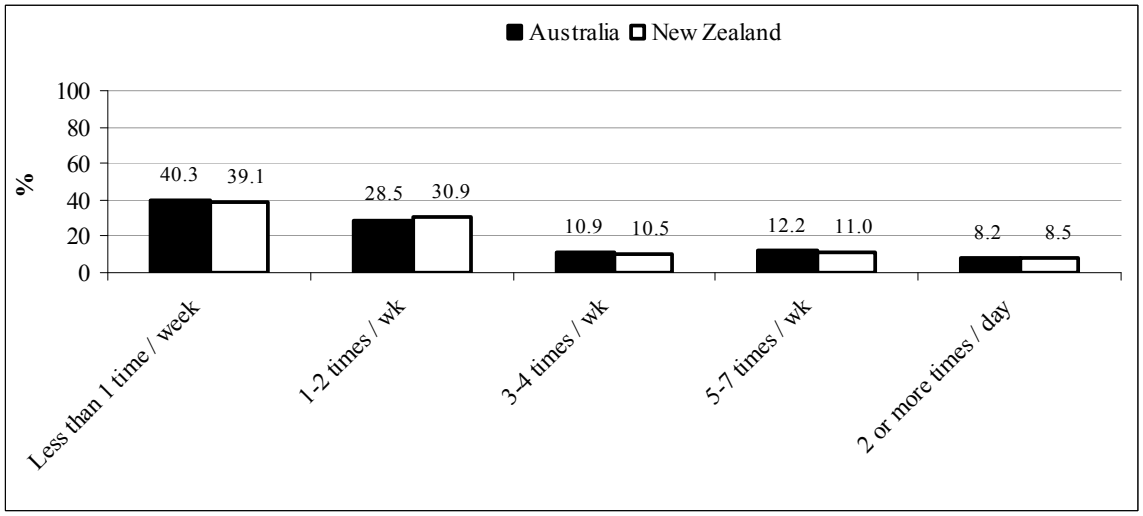


Figure 1: Proportion of Australians and New Zealanders who consume gum (≤0.2% residual sugars), by gender and age group

5.2 How often do people eat chewing gum (≤0.2% residual sugars)?

For self-reported consumers of pellets and tabs of chewing gum (≤0.2% residual sugars), frequency of consumption of this chewing gum was calculated using data from the first question of the questionnaire (See Box 1).

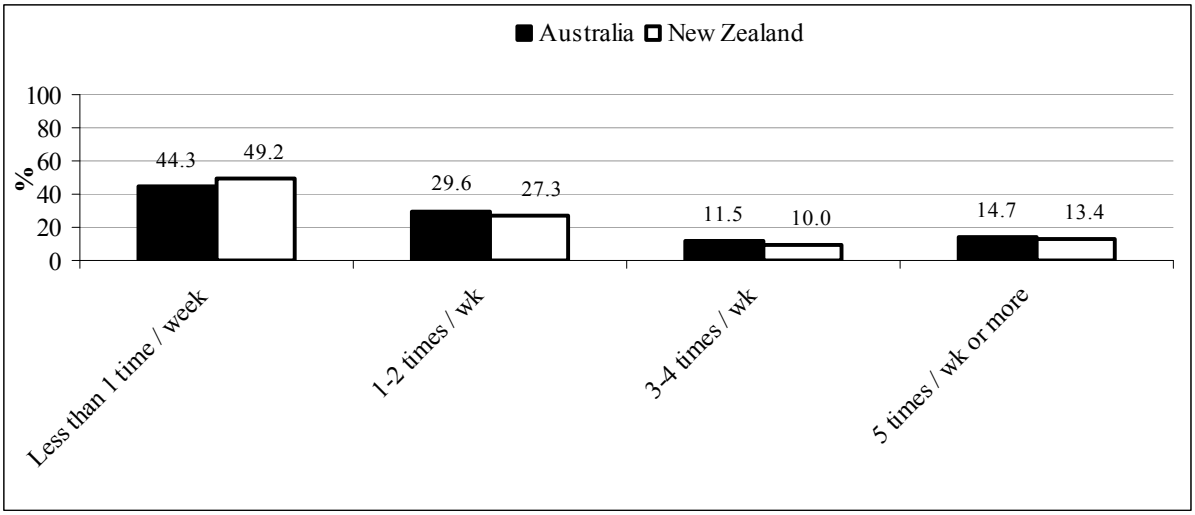
Figure 2 shows that of Australians and New Zealanders who are self-reported consumers of pellet chewing gum (≤0.2% residual sugars), around 40% consume this chewing gum less than one time per week. Around 30% consume pellets between one and two times per week. There is an observed decline in consumers of pellets of this chewing gum with increasing consumption frequency.



Note: Data have been combined into larger groups were cell sizes were less than 30 (as specified in Section 3.3). Responses of pellet consumption 5-6 times per week and once per day were combined; and responses of 2-3 times per day, 4-5 times per day and more than 5 times per day were combined.

Figure 2: Frequency of consumption of pellet chewing gum (≤0.2% residual sugars) across Australia and New Zealand

Figure 3 shows that of Australians and New Zealanders who are self-reported consumers of tab chewing gum (≤0.2% residual sugars), almost half consume this chewing gum less than one time per week. Almost 30% consume tabs between one and two times per week. There is an observed decline in consumers of tabs of this chewing gum with increasing consumption frequency.

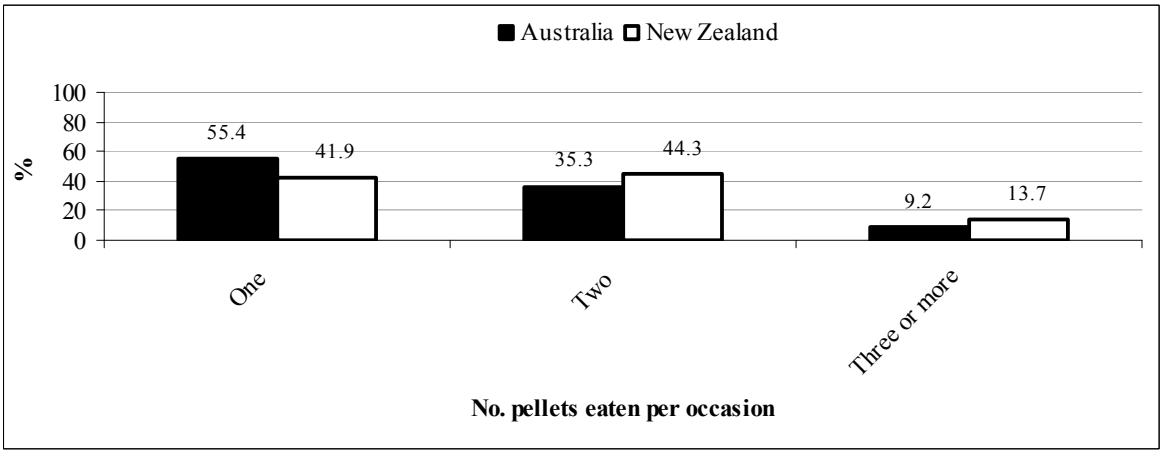


Note: Data have been combined into larger groups were cell sizes were less than 30 (as specified in Section 3.3). Responses of tab consumption 5-6 times per week, once per day, 2-3 times per day, 4-5 times per day and more than 5 times per day were combined.

Figure 3: Frequency of consumption of tab chewing gum (≤0.2% residual sugars) across Australia and New Zealand

5.3 How many pellets or tabs of chewing gum (≤0.2% residual sugars) do people consume per eating occasion?

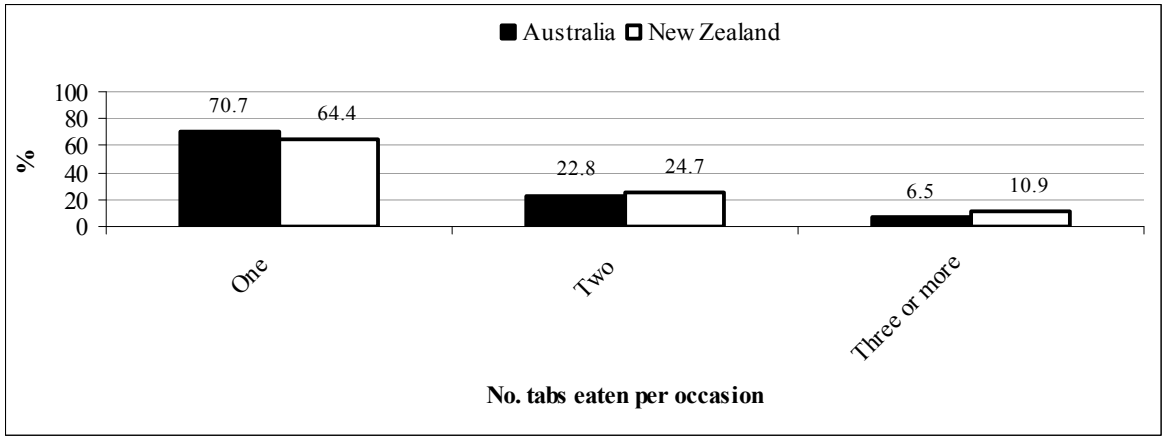
Figure 4 indicates that for self-reported consumers of pellet chewing gum (≤0.2% residual sugars), the highest proportion of people consume one or two pellets per eating occasion. The mean consumption of pellet chewing gum (≤0.2% residual sugars) per eating occasion was around one and a half pellets per eating occasion for both Australians and New Zealanders.



Note: Data have been combined into larger groups were cell sizes were less than 30 (as specified in Section 3.3). Responses of 3, 4, and 5 or more pellets eaten per occasion were combined.

*Figure 4: Number of pellets of chewing gum (≤0.2% residual sugars) consumed per eating occasion by **chewing gum consumers**, across Australia and New Zealand*

Figure 5 indicates that for self-reported consumers of tab chewing gum (≤0.2% residual sugars), the highest proportion of people consume one or two tabs per eating occasion (over 60% of Australians and New Zealanders). The mean consumption of tab chewing gum (≤0.2% residual sugars) per eating occasion was just under one and a half tabs for both Australians and New Zealanders.



Note: Data have been combined into larger groups where cell sizes were less than 30 (as specified in Section 3.3). Responses of 3, 4, and 5 or more pellets eaten per occasion were combined.

*Figure 5: Number of tabs of chewing gum (≤0.2% residual sugars) consumed per eating occasion by **chewing gum consumers**, across Australia and New Zealand*

5.4 How many grams of chewing gum (≤0.2% residual sugars) do people eat on average each day?

Consumption of chewing gum (≤0.2% residual sugars) in grams was calculated as a daily average using the method outlined in Section 3.3.2, for consumers of this chewing gum, and for all respondents, across Australia and New Zealand. As noted earlier (section 3.3.2), the calculation of daily consumption levels of chewing gum (≤0.2% residual sugars) averages an individual's chewing gum consumption across days when chewing gum (≤0.2% residual sugars) is consumed and days when no chewing gum is consumed. Thus, the figures listed will be underestimates than if calculated for 'consumption days' only.

5.4.1 Grams of chewing gum (≤0.2% residual sugars) eaten per day on average, by chewing gum consumers only

Figure 6 and Table 6 show that mean daily consumption of chewing gum (≤0.2% residual sugars) for self-reported consumers of this chewing gum in Australia was 1.83 g, compared with 2.19 g in New Zealand.

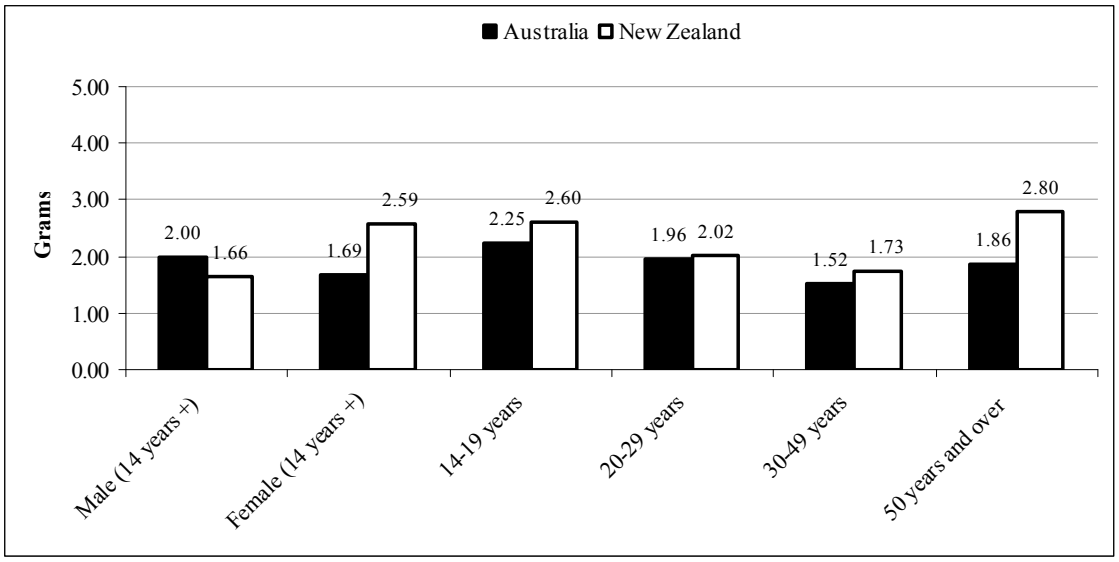


Figure 6: Mean daily consumption of chewing gum (≤0.2% residual sugars), ***chewing gum consumers only****, by gender and age group*

Table 6: Mean daily consumption of chewing gum (≤0.2% residual sugars), chewing gum consumers only, by gender, income and age group

	Mean (grams)	
	Australia	**New Zealand**
Total (14 years +)	**1.83**	**2.19**
Gender		
Male (14 years +)	2.00	1.66
Female (14 years +)	1.69	2.59
Individual Income		
1st quartile	1.66	2.29
4th quartile	1.69	2.33
Age group		
14-19 years	2.25	2.60
20-29 years	1.96	2.02
30-49 years	1.52	1.73
50 years and over	1.86	2.80

5.4.2 Grams of chewing gum (≤0.2% residual sugars) eaten per day on average, by the overall population

Mean daily consumption of chewing gum (≤0.2% residual sugars) for the overall population was calculated. Population data was required for dietary modelling purposes, as the relevant database does not have adequate data on individual chewing gum consumption. Population data was also required to assess the impact of the proposed fortification on the proportion of the population with inadequate calcium intakes and the risk of excess calcium intake.

Figure 7 and Table 7 show that mean daily consumption of chewing gum (≤0.2% residual sugars) in Australian was similar to that in New Zealand (0.72 g in Australia and 0.77 g in New Zealand).

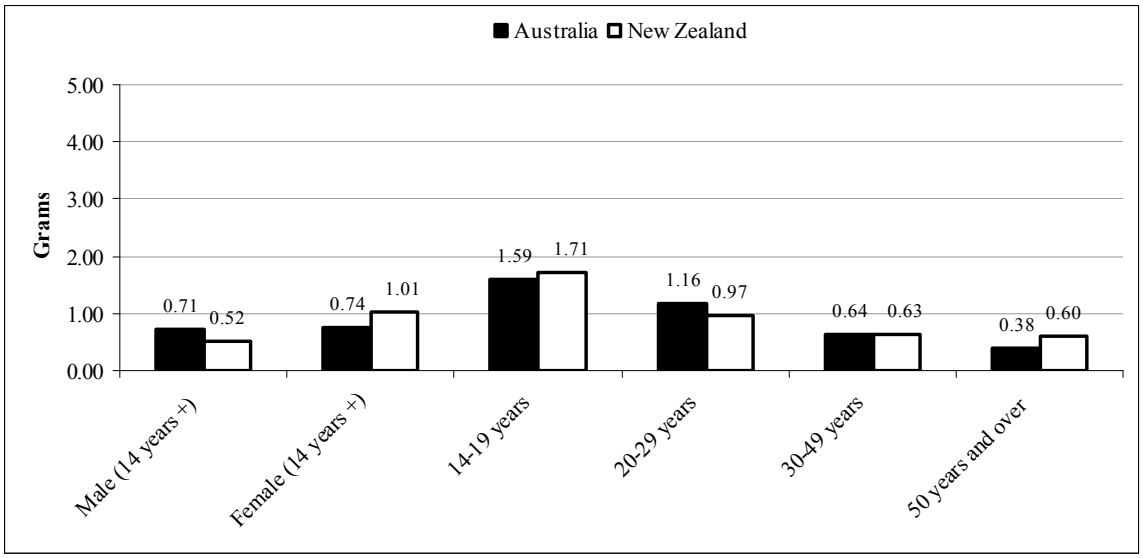


Figure 7: Mean daily consumption of chewing gum (≤0.2% residual sugars), ***overall population****, by gender and age group*

Table 7: Mean daily consumption of chewing gum (≤0.2% residual sugars), overall population, by gender, income and age group

	Mean (grams)	
	Australia	**New Zealand**
Total (14 years +)	**0.72**	**0.77**
Gender		
Male (14 years +)	0.71	0.52
Female (14 years +)	0.74	1.01
Individual Income		
1st quartile	0.75	0.99
4th quartile	0.61	0.82
Age group		
14-19 years	1.59	1.71
20-29 years	1.16	0.97
30-49 years	0.64	0.63
50 years and over	0.38	0.60

6. Interest in buying calcium-fortified chewing gum (≤0.2% residual sugars)

Respondents were asked if they would be interested in buying calcium-fortified chewing gum (≤0.2% residual sugars).

6.1 Who is interested in buying calcium-fortified chewing gum (≤0.2% residual sugars)?

Figure 8 and Table 8 present a breakdown of Australians and New Zealanders who indicated they were either 'very' or 'somewhat' interested in purchasing a calcium-fortified chewing gum (≤0.2% residual sugars). More than 30% of Australians and more than 35% of New Zealanders are interested in buying calcium-fortified chewing gum (≤0.2% residual sugars).

As shown in Figure 8, interest in buying calcium-fortified chewing gum declines with increasing age for both Australians and New Zealanders.

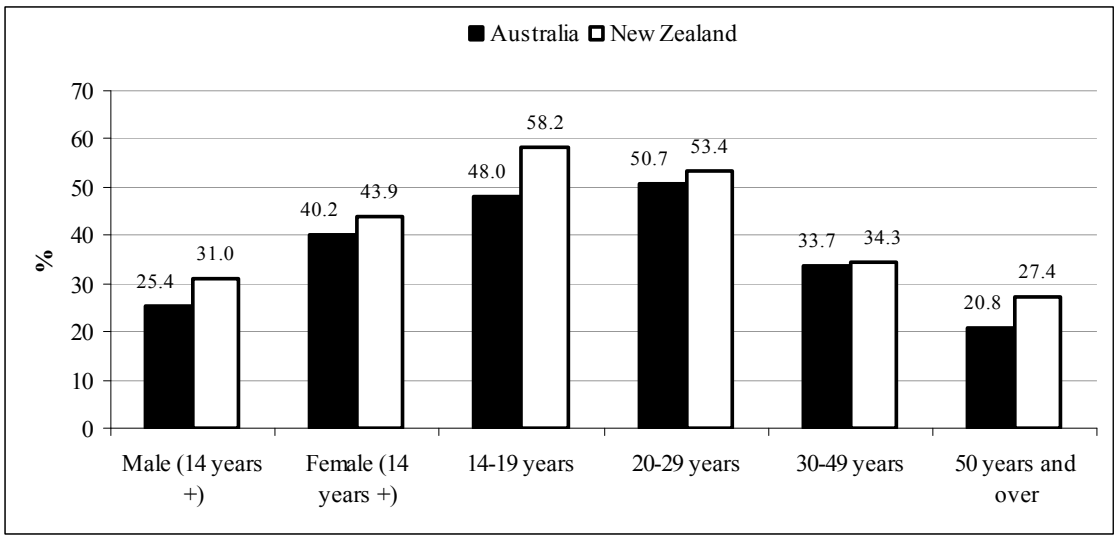


Figure 8: Proportion of those interested in buying calcium-fortified chewing gum (≤0.2% residual sugars)

Table 8 displays estimates of proportions of the overall population who are interested in buying calcium-fortified chewing gum (≤0.2% residual sugars). Of Australians already consuming chewing gum (≤0.2% residual sugars), just over half indicated they were interested in buying calcium-fortified chewing gum. This compares with over 60% of New Zealanders. Of Australians who did not consume chewing gum, less than 20% indicated they were interested in buying this calcium-fortified chewing gum (≤0.2% residual sugars), compared with almost 25% of New Zealanders.

Table 8: Percentage of those interested in buying calcium-fortified chewing gum (≤0.2% residual sugars), by gender, income, gum consumption status and age group

% interested	%	
	Australia	New Zealand
Total (14 years +)	32.9	37.7
Gender		
Male (14 years +)	25.4	31.0
Female (14 years +)	40.2	43.9
Individual Income		
1st quartile	35.7	41.3
4th quartile	25.9	33.9
Status		
Chewing gum consumer*	56.1	62.5
Non-consumer	17.4	24.2
Age group		
14-19 years	48.0	58.2
20-29 years	50.7	53.4
30-49 years	33.7	34.3
50 years and over	20.8	27.4

* Consumer of chewing gum (≤0.2 % residual sugars)

7. Substitution of other foods with calcium-fortified chewing gum (≤0.2% residual sugars)

7.1 Will people substitute some foods in their diet for calcium-fortified chewing gum (≤0.2% residual sugars)?

Respondents who indicated they were interested in purchasing calcium-fortified chewing gum (≤0.2% residual sugars), were then asked if they would eat this chewing gum in addition to other chewing gums or foods already in their diet, or as a replacement for these foods.

Table 9 shows that an estimated 51% of Australians and 49% of New Zealanders who indicated interest in purchasing a calcium fortified chewing gum, reported that they would eat this gum in addition to the foods they currently consumed. Overall, 40% of Australians and 38% of New Zealanders who indicated interest in purchasing calcium-fortified chewing gum (≤0.2 % residual sugars), reported that they would eat this chewing gum as a replacement; substituting it for some foods in their diet. The foods that may be replaced are presented in Section 7.3, with the majority being other chewing gum, mints and lollies.

Table 9: Consumption behaviour, of those who were interested in purchasing calcium-fortified chewing gum (≤0.2% residual sugars)

	%	
	Australia	New Zealand
In addition	50.7	49.2
As a replacement	40.0	38.1
Don't know	9.3	12.7
Total	**100.0**	**100.0**

7.2 Of those people who would substitute foods, how often do they eat chewing gum (≤0.2% residual sugars)?

Of those who indicated they would substitute foods for calcium-fortified chewing gum (≤0.2% residual sugars), consumption patterns for existing consumers of chewing gum (≤0.2% residual sugars) were determined.

The majority of the above Australian respondents consume pellet chewing gum (≤0.2% residual sugars) up to two times per week (62%). This figure was similar for New Zealanders (61%). Results were very similar for consumption of tab chewing gum (≤0.2% residual sugars); 64% of Australians and 70% of New Zealanders consume tab chewing gum (≤0.2% residual sugars) up to two times per week[70]. The remaining numbers of Australians and New Zealanders who consume pellet or tab chewing gum (≤0.2% residual sugars) more frequently than two times per week, are too small to report in weighted proportions.

7.3 What foods would be substituted for calcium-fortified chewing gum (≤0.2% residual sugars)?

If respondents reported that they would substitute foods in their diet for calcium-fortified chewing gum (≤0.2% residual sugars), they were asked which foods they would replace[71].

Results below are unweighted numbers of responses as cell sizes are predominantly less than 30 (see Section 3.3).

170 Australian respondents and 164 New Zealand respondents indicated they would replace foods in their diet with calcium-fortified chewing gum (≤0.2% residual sugars). 75 Australians and 68 New Zealanders interviewed indicated they would replace other chewing gum products with the calcium-fortified chewing gum product; 35 Australians and 44 New Zealand respondents reported they would replace lollies or mints; and 9 Australian respondents and 11 New Zealand respondents reported they would replace calcium-rich foods such as milk, cheese or yoghurt with the calcium-fortified chewing gum product.

8. Use of consumer research information

The data from this research have been used to:

- Calculate the additional calcium intake per population sub-group through the addition of calcium to chewing gum (≤0.2% residual sugars) (see Attachment 3 – Dietary Intake Assessment Report).

- Assess whether the addition of calcium to chewing gum (≤0.2% residual sugars) has the potential to assist in addressing inadequate calcium intakes in the population group that consumes the product (see Attachment 3 – Dietary Intake Assessment Report).

[70] Weighted quantities presented here.
[71] A single respondent was able to select more than one food.

- Assess whether the addition of calcium to chewing gum (≤0.2% residual sugars) has the potential to result in detrimental excesses or imbalances in calcium intakes in the context of total intake across the general population (see Attachment 2 – Hazard Characterisation and Identification of Potential Health Benefits from a Topical Application of Calcium Report).

- Determine the potential for substitution of other calcium-rich foods in the diet (Attachment 2 – Hazard Characterisation and Identification of Potential Health Benefits from a Topical Application of Calcium Report).

Attachment 5

Summary of Submissions

FSANZ received 18 submissions on the Draft Assessment Report during the 8-week public consultation period of 12 December 2007 to 6 February 2008. A summary of submitter comments is provided in the table below.

Two regulatory options were presented in the Draft Assessment Report:

Option 1 Reject the Application thus maintaining the *status quo*; or

Option 2 Prepare a draft Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

No.	Submitter	Submission Comments
Government		
1	**Department of Human Services Victoria** *Mr Victor Di Paola*	**Supports Option 1** Does not support the progression of this Application. ***Therapeutic good*** Considers the Application should be assessed under the Therapeutic Goods process as the proposed product may provide a positive dental health effect which is therapeutic. Also, the contribution to bone health at a population level will be minimal at the proposed calcium fortification levels. Considers directives such as recommending that the gum is chewed immediately after the ingestion of food to increase bioavailability are more aligned with a therapeutic good than a food. ***Serving size*** Notes the discrepancy between the Applicant's serving size and the actual average amount consumed as shown by the consumer research study (i.e. 3 g vs. 2.1 g), and the amount of calcium each serving size would provide. Considers the serving size or reference amount of a food for labelling purposes must be realistic and in accordance with actual consumer intake practices. ***Potential benefits*** Considers the claim that the proposed product will benefit dental health appears valid. Considers the argument for a bone health benefit is weak in practical terms – a 3g serving size would provide 60 mg calcium (6% RDI), however the average serving size of 1.5 pellets would provide a reduced amount of approximately 44 mg calcium.

No.	Submitter	Submission Comments
		Considers 44-60 mg of additional calcium from chewing gum is insignificant in terms of contributing to alleviating the population calcium deficiency in Australia. ***Labelling & claims*** Notes that 44-60 mg calcium is less than the minimum requirement of 10% RDI to make a calcium content claim on the label. Questions the benefit of the fortification for the consumer if the consumer is not aware of the fortification. Questions if it is the intention of the Applicant to provide the maximum permissible amount of 200 mg releasable calcium per serve in the future. Asks if it would be prudent to wait until technology can deliver between 80 to 200 mg calcium per 3 g serve in order to make a claim before this Application proceeds. Questions what evidence there is regarding the average length of time that chewing gum is usually chewed, noting 20 minutes has been proposed for claims purposes. Suggests that should the Application be approved, information on the required chewing time to obtain the stated amount of releasable calcium and the recommendation to chew immediately after the ingestion of food should be provided in the form of advisory statements on the label. ***Bioavailability*** Challenges the claim that all 14 forms of calcium currently permitted in the Code have approximately equitable absorption as dairy foods in terms of the physiological outcome of bone mineral density. Notes the Lau reference used to support this contention assesses a fortified product containing calcium as well as other nutrients, which combined positively affect bone mineral density. Notes this Application is for the addition of calcium only, and so is difficult to support in terms of a bone health effect. ***Food vehicle*** Considers that if approved this Application will set an undesirable precedent that would potentially allow the fortification of other low nutrient density products such as sweetened or intensely sweetened confectionery and soft drinks with additives such as calcium. ***Policy guideline*** Considers the fortification of chewing gum (≤0.2 % residual sugars) would possibly contravene the Policy Guideline on fortification as it has the potential to 'promote consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand'. ***Enforcement*** Concerns that the current draft Standard may be difficult to enforce in relation to releasable calcium and the information that the manufacturer must hold to substantiate claims.

No.	Submitter	Submission Comments
		Suggests that guidelines to assist companies to comply by defining substantiation may be warranted. Suggests that FSANZ consider a deeming provision that states that if a food manufacturer or importer not hold records for the substantiation of the product content and/or refuse to release the details of the methodologies and composition, then that manufacturer will be deemed to be not complying with the standard.
2	**New South Wales Food Authority** *Mr Craig Sahlin*	**Supports Option 1** Does not support progression of this Application. Considers the Application does not comply with the Policy Guideline on fortification and that 'releasable calcium' is not enforceable in practical or resource terms. ***Forms of calcium*** Questions why permissions for all fourteen forms of calcium are sought when the Applicant has indicated that initial fortification would be limited to two forms – calcium lactate and calcium carbonate. Notes that the data provided by the Applicant is predominantly based on calcium release from these two forms of calcium. ***Dietary modelling*** Suggests using the average quantity of chewing gum consumed per day (1.83 g) as shown by the consumer research, rather than 3g. ***Policy guideline*** Does not consider chewing gum to be an essential or necessary part of a balanced diet. Notes that the Policy Guideline states that voluntary permissions must not 'promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand. Agrees that chewing gum 'has little or no nutritional value', and therefore considers it to be an inappropriate food vehicle for voluntary fortification with any vitamin or mineral. Considers this Application does not comply with the Policy Guideline on fortification as the consumer will not receive a significant dietary benefit from calcium-fortified chewing gum (approximately 4.9% of the RDI), compared to the many nutritive sources of calcium in the diet. ***Food vehicle*** Considers chewing gum is an inappropriate food vehicle for fortification with any vitamins and minerals as it provides little to no nutritive benefit to the consumer. ***Serving size*** Notes that allowing manufacturers to base labelling claims on unrealistic serving sizes is misleading. Suggests mandating a standard serving size for calcium-fortified chewing gum to prevent unrealistic serving sizes being used.

No.	Submitter	Submission Comments
		Suggests that calcium claims be made in reference to the average quantity of gum consumed per day (1.83g), not the value the applicant claims (3g). ***Labelling & claims*** Does not support fortification of chewing gum as it is not a claimable food and is not a food of significant nutritive benefit. Considers vitamin and mineral nutrient content claims should be limited to claimable foods, as defined in Standard 1.3.2. Does not support calcium-fortified chewing gum carrying any health claim, including nutrient content claims and general level claims, as it is an inappropriate food vehicle. Notes that current technology is unable to achieve 80 mg of calcium per serve (10% RDI), which is required to make a content claim. Considers exact wording for the statement regarding 'releasable calcium' is required, to inform compliance/enforcement activities. ***Enforcement*** Considers the concept of 'releasable calcium' to be unenforceable in practical or resource terms. Notes that the Report did not: • articulate a standard process by which industry or government may determine 'releasable calcium'; • provide a clear process of substantiation by which a claim for 'releasable calcium' may be supported; or • provide detail on the quality and/or forms of evidence which are acceptable for substantiation purposes. Considers that in the absence of this information, the Application will place an unreasonable cost burden on jurisdictions and industry in investigation and compliance costs. Concerns that the draft Standard would not appropriately inform the consumer as to the quantity of 'releasable calcium' in a standard serve of a product, as the draft Standard does not require claims to be based on a serving size of 3 g. ***Draft Standard*** Concerns that the draft Standard would not appropriately inform the consumer as to the quantity of 'releasable calcium' in a standard serve of a product, as the draft Standard does not require claims to be based on a serving size of 3 g. Suggests that 'supplier' (cl 3.1 c & d) be limited to manufacturers and importers, as the definition of in Standard 1.1.1 also includes vendors and packers. This would avoid retailers potentially being requested to provide data to a jurisdiction on releasable calcium. However, notes that this may limit the capacity of enforcement agencies to take action where the manufacturer or importer is outside their jurisdiction.

No.	Submitter	Submission Comments
3	**New Zealand Food Safety Authority** *Ms Carole Inkster*	**Supports Option 2 in-principle** Supports Option 2 in principle because of the public health benefit of additional calcium for certain sectors of the population and the risk assessment showed no risk of over consumption of calcium from the proposed product. However does not support creating a stand-alone standard for chewing gum and the manufacturer determining the serving size. ***'Sugar-free'*** Supports the use of the term 'chewing gum containing no more than 0.2% residual sugars' in place of 'sugar-free', as in New Zealand the term 'free' means absolutely free under the Fair Trading Act. ***Serving size*** Does not support the proposed change to permit claims 'per serve' rather than a prescribed reference quantity. Supports setting a reference quantity based on a normal serve. Suggests a reference quantity of two pellets (2.8 g) based on information provided in the Report. Notes that current technology would not allow a claim to be made for a serving of 1-2 pellets. Considers there may be an incentive without a specified reference quantity for manufacturers to increase the serving size to enable the required amount of calcium to be added to make a claim as to its presence, which would be misleading. Considers prescribing a reference quantity for chewing gum would overcome this issue. Supports a serve size of two pellets on which to base any claims – based on consumer research study data[72]. ***Technology*** Questions how chewing gums sold as therapeutic goods (e.g. Recaldent™ and B-Fresh Gum) are able to achieve higher levels of calcium per pellet of gum than what the Applicant states is technologically possible at present. ***Draft Standard*** Does not support the development of a stand-alone standard for chewing gum. Considers the aim of the standards setting process should be to achieve minimal necessary standards, while ensuring FSANZ objectives are met. Considers all requirements in the proposed draft Standard can be covered by general permissions for voluntary fortification in the Code, except for the concept of calcium released during 20 minutes of chewing. Considers this requirement could be included in Standard 1.3.2 by qualifying the values in columns 4 and 5 of the Table to clause 3. Notes that if a stand-alone standard is used, the stated purpose of Standard 1.3.2 will need to be altered in relation to the list of foods that the Standard does not apply.

No.	Submitter	Submission Comments
4	**Queensland Health (on behalf of the Queensland Government)** *Mr Gary Bielby*	**Supports Option 1** ***Food vehicle*** States that chewing gum is a food of little to no nutritive value. Considers chewing gum is an inappropriate food vehicle for vitamin and mineral fortification as it is a confectionery product. Concern that if this Application is approved it may set a precedent by permitting the fortification of confectionery, particularly in light of Cadbury Schweppes comment on the Initial Assessment Report about expanding the Application to include other artificially sweetened products such as hard confectionery candy and beverages. ***Potential benefits*** Quotes the Report that at a population level the proposed product has very little impact on reducing the proportion of the population with inadequate calcium intakes. Quotes the Report that there is insufficient evidence to conclude the proposed product reduces the risk of dental caries in the long-term. Quotes the Report that the impact on health care expenditure of government is likely to be negligible. States that it is the intention of Queensland Health to continue to promote an adequate intake of calcium from more nutritious sources than chewing gum, such as dairy products. Considers that the contribution to total calcium intake would be minimal, based on data provided in the DAR. ***Serving size*** Notes the Applicant's revised serving size of 3g and the average serving size shown by the consumer research. Notes that the proposed product is to be marketed to be consumed immediately after meals, and questions whether this would occur and at the recommended serving size. ***Labelling & claims*** Notes that 80 mg of releasable calcium per serving would be required in order to make a 'source' claim, and that current technology is unable to achieve this level. ***Enforcement*** Considers the concept of 'releasable calcium' to be unenforceable. Considers details about a standard method for determining 'releasable calcium' in a food and a standard process of substantiation for justifying nutrient content claims based on 'releasable calcium' are required to allow industry and government to accurately determine 'releasable calcium' in food for legal purposes.

No.	Submitter	Submission Comments
5	**South Australian Department of Health** *Ms Elena Anear*	**Preferred Option Not Specified** ***Food vehicle*** Considers chewing gum is not an appropriate food vehicle for calcium fortification. Acknowledges that the proposed product is low in sugar, salt and fat and therefore aligns with the policy principles for fortification, however is concerned about using a food with poor nutritional profile as a food vehicle for fortification. ***Substitution for calcium-rich foods*** Considers a message that it is acceptable to source calcium from a confectionery item is given, despite the evidence that other calcium rich foods will not be replaced by the gum. ***Therapeutic good*** Considers fortified chewing gum is similar to a vitamin tablet and therefore may be better suited to be considered as a complementary medicine under the Therapeutics Good Act. ***Policy guideline*** Considers the evidence supporting an increase in calcium intakes in the general population from fortified chewing gum appears not very robust. Considers more evidence is required to show strong links between the releasable calcium from fortified chewing gum and health benefit. ***Potential benefits*** Notes the Report states that a 'sufficient intake of calcium and vitamin D *together* reduced the risk of osteoporosis among older people'. Notes that in terms of dental health the WHO report (2003) 'did not report any direct links to calcium intake'. Considers there is insufficient evidence that chewing fortified gum will have any impact on dental and bone health, and therefore questions why a permission should be given. ***Enforcement*** Concerns about nutrient claims based on calcium released during 20 minutes of chewing. Notes that FSANZ acknowledged potential enforcement difficulties and that the draft Standard requires the manufacturer to hold substantiating evidence to support the claim. Considers it unacceptable that no information was provided about whether 'chew-out' tests are a validated method and if they could be used by other laboratories for enforcement purposes. Considers enforcement agencies would still be in a difficult position of assessing the quality of substantiating evidence and weighing its relevance.

No.	Submitter	Submission Comments
		Considers that enforcement agencies should *not* be put in a position where they need to justify a *voluntary* claim. ***Labelling & claims*** Considers that if a nutritional claim is to be made, the evidence linking releasable calcium and bone/dental health would need to be pre-approved and unequivocal.
6	**Tasmanian Department of Health and Human Services** *Ms Jennifer Savenake*	**Preferred Option Not Specified** ***Labelling & claims*** Notes that the current level of releasable calcium from a 3 g reference quantity is approximately 6% of the RDI so no source claim would be permitted. ***Serving size*** Notes that if the reference value was increased to achieve 10% RDI this would be misleading to consumers who consume a standard serving. ***Potential benefits*** Considers the contribution of 44-60 mg of additional calcium to be insignificant. Considers that the nutritional impact of calcium-fortified chewing gum is boarder than the market share of chewing gum in terms of consumer perceptions of fortified confectionery. ***Enforcement*** Concerns that the concept of 'releasable calcium' will be difficult to enforce due to lack of standardised methodology for measuring releasable calcium. ***Therapeutic good*** Notes the Applicant's plans to market the product with the recommendation to chew immediately after the ingestion of food. Considers this direction could be contrary to the Policy Guideline as 'food, through fortification, becomes like or taken to be therapeutic goods'. Understands that chewing gum is regulated under the Code, however considers that it may be more appropriately regulated under therapeutic goods controls. ***Policy guideline*** Notes that the proposed product is not high in fat, salt or sugar and therefore not inconsistent with the relevant Policy Guideline principle. However, considers this Application is 'contrary to the intent and spirit' of the Policy Guideline and may establish precedents for the fortification of other confectionery products.

No.	Submitter	Submission Comments
Industry		
7	**Australian Food and Grocery Council** *Mr Kim Leighton*	**Supports Option 2** Considers that the use of chewing gum (≤0.2 % residual sugars) with added calcium does not raise any public health and safety concerns and notes that it would provide a net benefit to both consumers and industry. ***Policy guideline*** Supports the fortification of foods with vitamins and minerals on the basis of demonstrated deficiency, and that the intended fortification has the potential to address the deficit or deliver the benefit. Considers there is a need for increased calcium and that the proposed product has the potential to deliver the benefit with minimal risk to the consumer. Considers this Application meets FSANZ's objectives and the Policy Guideline principles for voluntary fortification. ***Labelling & claims*** Supports the use of a minimum amount of releasable calcium per serve before a claim can be made to discourage the addition of inadequate amounts of calcium. ***'Sugar-free'*** Notes the issues raised by FSANZ with respect to advice from the ACCC and the NZCC regarding 'sugar-free' claims. Considers that if the Code were to stipulate specific criteria for 'free' this would aid in interpretation, and 'sugar-free' specific criteria would aid in consumer understanding and in preventing false and misleading information. Alternatively, the ACCC and the NZCC could develop industry guidelines with safe harbour provisions for the use of 'free' claims.
8	**Cadbury Schweppes** *Mr Neil Smith*	**Supports Option 2 in-principle** Supports Option 2 in principle as a means of increasing dietary calcium intake, but not for a dental benefit. ***Dental benefit/Potential benefits*** Considers increasing dietary calcium intake and dental benefits to be two distinct issues and should be treated separately. However, notes that making dental claims is not part of this Application, but aware that there is the potential for the Applicant to do so at a later time. ***Draft Standard*** Requests clarification of reasons for creating a stand-alone standard, rather than using Standards 1.3.2 and 1.2.8 for the permission and claims respectively. ***Serving size*** Notes the change in serving size and calcium level between the initial application and the Draft Assessment – a four-fold increase.

No.	Submitter	Submission Comments
		Notes that there is an inconsistency between what the Applicant suggests in a normal serving size of chewing gum (i.e. 3 g) and what the consumer research indicates is actually being consumed (i.e. 1.83 g in Australia and 2.19 g in New Zealand). Concerns that the Applicant may select a serving size that does not meet the definition of 'a serving' as outlined in the User Guide to Standard 1.2.8 – '…a realistic portion of food that a person might normally consume'. ***Bioavailability*** Supports claims for chewing gum based on releasable calcium to address the issue that not all permitted forms of calcium have the same level of availability. However, considers the above approach is inconsistent with that used for products regulated under Standard 1.3.2. Notes that the forms of calcium have different levels of bioavailability and that the bioavailability is dependent on the nature of the food type that the calcium is ingested. ***Labelling & claims*** Supports the requirement for claims to relate to the amount of calcium *released* from chewing gum during 20 minutes of chewing and not the amount of calcium *contained* in the product. Considers that claims permissions stated in the draft Standard 2.10.3 appear inconsistent with other claims permissions for vitamins and minerals – 'good source' claim not permitted even though 25% of the RDI for calcium may be present. Asks if a 'good source' claim would be permitted if the chewing gum manufacturer could substantiate the level of calcium. Requests clarification as to whether or not chewing gum (≤0.2 % residual sugars) would be eligible to make a general level health claim, noting that the product would meet the Nutrient Profiling Scoring Criteria. Concerns that the Applicant may lodge an application for a high level health claim in the future under the proposed health claims standard. ***Current market*** Notes a correction to the Report – Recaldent™ Chewing Gum *is not* manufactured in Australia or New Zealand. CPP-ACP is manufactured in Australia and exported to a number of chewing gum manufacture sites globally.

No.	Submitter	Submission Comments
9	**Confectionery Manufacturers of Australasia Ltd** *Ms Jennifer Thompson*	**Supports Option 2 in-principle** ***Potential benefits*** Believes the proposed product has the potential to: • improve calcium intakes by providing an additional source of calcium in the diet; and • deliver nutritional and dental health benefits. Considers Option 2 supports industry innovation in the chewing gum market and increases consumer choice, without posing any public health and safety risk. ***Policy guideline*** Considers this Application is consistent with the policy guideline on fortification of foods with vitamins and minerals.
10	**Dairy Australia** *Dr Malcolm Riley*	**Supports Option 2 in-principle** Supports in principle that calcium be permitted to be added to chewing gum (≤0.2 % residual sugars) on the basis that dental health benefits for gum users may result. Does not consider there is satisfactory evidence that the proposed product would provide a bone health benefit. Acknowledges FSANZ's view that chewing gum is an unusual, possibly unique, food, and assumes that the same recognition is not extended to chewing tobacco and betel. ***Labelling & claims*** Recommends that 'instructions' for use need to be made clear for the consumer including a statement that 20 minutes of chewing is required to release the stated amount of calcium if a content claim is made. Considers the above statement should be required on front of pack and in the NIP. ***Substitution for calcium-rich foods*** Considers it is important to communicate accurate and appropriate messages to consumers. Notes that calcium-fortified chewing gum (≤0.2 % residual sugars) is not an adequate substitute for dairy food. Concerned that up to 5% of Australians may replace a calcium rich food such as dairy food with the proposed product. Considers these consumers needs to be protected by appropriately drafted legislation in relation to innovative food products, and not disadvantaged by it. ***Serving size*** Considers the proposed serving size is vague and should be specified in the Code.

No.	Submitter	Submission Comments
		Considers the serving size should not be at the discretion of the manufacturer. Instead recommends that a practical reference serve size quantity be described in the Code, consistent with fortification permissions in Standard 1.3.2.
11	**Fonterra - Australia and New Zealand** *Ms Victoria Landells*	**Supports Option 2 in-principle** Does not oppose the principle of adding calcium to chewing gum, however requests that issues regarding labelling and serving size are addressed. ***Labelling & claims*** Supports use of a statement to the effect that the average quantity of calcium is released during 20 minutes of chewing. Considers the above statement should appear both on the front of pack and in the NIP, where the size of packaging allows. Considers the above would discourage the inappropriate use of thumbprint %DI as used by the confectionery industry and not rely on consumers reading 'the small print'. ***Serving size*** Notes it is proposed that the manufacturer will determine the serving size, despite that the Applicant initially stating a serving size of 5 pellets in order to make a claim. Notes that the dietary assessment and consumer research indicates that the average serving size is one or two pellets. Suggests, in the interest of consistency and equity with current permissions in Standard 1.3.2, that a reference serving quantity is prescribed that is based on research into usual chewing gum use – 3 g or there about.
12	**Food Technology Association of Australia** *Mr David Gill*	**Supports Option 1** ***Food vehicle*** Concerns that the bioavailability of calcium from chewing gum (≤0.2% residual sugars) would be very limited and considers there are many and better methods of calcium delivery to the target groups. ***Target group*** Comments that anecdotal evidence is that older men and women are not known to be great users of chewing gum.
13	**The Wrigley Company Pty Ltd** *Ms Catherine Pemberton*	**Supports Option 2** Supports Option 2 as currently drafted. Considers the addition of calcium to chewing gum (≤0.2% residual sugars) has the potential to assist in addressing some dietary deficiencies in the population and benefiting the dental health of the community.

No.	Submitter	Submission Comments
Public Health Associations and Academics		
14	**Dietitians Association of Australia** *Ms Annette Byron*	**Supports Option 2** ***Serving size*** Considers the reduced serving size is a more realistic quantity. ***Labelling & claims*** Supports that 'good source' claims not be permitted for calcium-fortified chewing gum (≤0.2 % residual sugars).
15	**John Birkbeck, Adjunct Prof Nutrition, Massey University, New Zealand**	**Supports Option 2** Supports the Draft Assessment.
16	**NSW Centre for Public Health Nutrition** *Mr Jimmy Louie, Dr Vicki Flood and Dr Tim Gill*	**Supports Option 2 in principle** Considers the proposed fortification will be of minimal nutritional benefit, and would prefer the use of soluble forms of calcium to achieve maximum dental health benefits. ***Dietary calcium intake*** Notes that current technology and an average intake of chewing gum of 1.83 g per day would provide approximately 38.5 mg of calcium per day. Considers 38.5 g of calcium negligible in relation to the EAR and RDI and unlikely to significantly increase consumers' calcium intake. Notes that calcium fortified orange juice provides 10-25% of the RDI. ***Dental benefits*** Notes the benefit of teeth remineralisation is for soluble forms of calcium, however some of the proposed forms are insoluble. Considers use of insoluble forms limits the potential dental health benefits, which is one of the reasons for the proposed fortification. Prefers the use of soluble forms of calcium only, though acknowledges there may be some practical limitations in the short term. ***Labelling & claims*** Notes that using current technology the calcium-fortified chewing gum (≤0.2 % residual sugars) will be ineligible to carry a nutrition content claim or health claim. Considers it is unclear how the manufacturer will distinguish their product from others without mentioning words like 'with calcium' on the package. Notes that with improved technology, calcium-fortified chewing gum (≤0.2 % residual sugars) may carry nutrition content claims in the future.

No.	Submitter	Submission Comments
		Substitution for calcium-rich foods Notes that the proposed product may carry a nutrition content claim on the package, and considers it would be useful to monitor any potential effects of consumer behaviour in relation to consumption of foods high in calcium, such as dairy.
17	**New Zealand Dietetic Association** *Ms Jan Milne*	**Supports Option 2** ***Labelling & claims*** Supports that 'good source' claims not be permitted for calcium-fortified chewing gum (≤0.2 % residual sugars). Supports and is reassured that the qualifying criteria for general level health claims for the proposed product will be consistent and relate to releasable calcium.
Consumers		
18	**Country Women's Association of New South Wales** *Ms Erin Robison*	**Supports Option 2 in-principle** ***Labelling & claims*** Not opposed to this Application provided the proposed product is clearly labelled with contents and indicates the chemical source of calcium.