FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

12 December 2007
[8-07]

DRAFT ASSESSMENT REPORT

APPLICATION A577

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

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 February 2008
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

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

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 both dental and bone health.

- At Draft Assessment, FSANZ has undertaken a robust and extensive assessment of the public health and safety implications of this Application. A summary of the key risk assessment findings and risk management issues are detailed below. The proposed draft Standard is provided at Attachment 1.

Risk Assessment

At Draft Assessment, the key risk assessment findings include:

the majority of males and females in Australia and New Zealand have inadequate calcium intakes;

- 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 have the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability;
- some evidence exists of a short-term benefit to dental health through increased tooth remineralisation;
- 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; and

[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.

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

The key risk assessment issues are discussed in Section 7 of this Report. Additional information is provided at Attachment 2 – Dietary Intake Assessment Report and Attachment 3 – Risk Assessment Report.

Consumer research, conducted on behalf of the Applicant, was used extensively to inform the Risk 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 on the consumer research is at Attachment 4.

Risk Management

This Draft Assessment Report considers, in the context of the findings from the Risk Assessment, a number of issues relevant to the regulation of calcium-fortified chewing gum (≤0.2% residual sugars) including:

- the consistency of the proposed fortification with Ministerial policy guidance on *Fortification of Foods with Vitamins and Minerals*;
- the appropriateness of chewing gum (≤0.2% residual sugars) as a food vehicle for voluntary fortification;
- the potential for consumers to be misled as to the nutritional value of calcium-fortified chewing gum (≤0.2% residual sugars);
- the nature of chewing gum as a food;
- issues relating to the amount of calcium *contained* in the product compared to the amount of calcium *released* during chewing; and
- the need for specific labelling requirements for calcium-fortified chewing gum (≤0.2% residual sugars)

In addition, other issues raised by submitters in response to the Initial Assessment Report have been addressed in this Report. A summary of submissions to the Initial Assessment Report is at Attachment 5.

Preferred Approach

At Draft Assessment, the preferred regulatory approach is to 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.

Reasons for Preferred Approach

FSANZ supports the preferred regulatory approach to permit the addition of calcium to chewing gum (≤0.2% residual sugars) as it:

- 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 the fortified food;
- may provide consumers with a short-term dental benefit;
- does not raise any safety concerns for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) or the general population;
- is consistent with FSANZ's statutory objectives including Ministerial policy guidance on voluntary fortification;
- supports industry innovation;
- provides consumers with adequate information on the product label 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.

Consultation

FSANZ is seeking comment on this Draft Assessment Report from all interested parties, particularly in relation to the expected impact(s) of the preferred regulatory approach. Comments received will assist in the preparation of a Final Assessment, including a recommended regulatory approach for calcium-fortified chewing gum (≤0.2% residual sugars).

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as confidential commercial information. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 6 February 2008.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing standards.management@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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[3].

This Draft Assessment Report discusses issues on the fortification of chewing gum (≤0.2% residual sugars) with calcium, addresses issues raised in submissions to the Initial Assessment Report, and proposes a preferred regulatory approach.

FSANZ is seeking comment on this Draft Assessment Report from all interested parties, particularly in relation to the expected impact(s) of the preferred regulatory approach. Comments received will assist in the preparation of a Final Assessment, including a recommended regulatory approach for calcium-fortified chewing gum (≤0.2% residual sugars).

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 both dental and bone 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)[4]) 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.

[3] 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)'.
[4] The current RDI for calcium is 800 mg, as stated in the Schedule to Standard 1.1.1.

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.

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' will be 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'. Since Initial Assessment, the Applicant has 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

Since Initial Assessment, FSANZ has requested further information from the Applicant to support the assessment of their Application. Additional information provided by the Applicant and used at Draft 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 use of 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);

- consumer research data relating to consumers' current consumption of chewing gum (≤0.2% residual sugars); and

- consumer research data relating to consumers' likely response to calcium-fortified chewing gum (≤0.2% residual sugars).

The Applicant commissioned Roy Morgan Research Pty Ltd to undertake a survey to obtain the consumer research data on consumers' current consumption levels and their likely response to the proposed 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 teeth and bones 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.

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, soymilk and 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. Just 2% reported using calcium supplements, although usage was higher among women aged 65-74 years (9%) (Russell *et al*., 1999). In the 1995 Australian National Nutrition Survey about 10% of women aged 45 years reported taking a calcium supplement on the day before the survey (ABS, 1997). Neither survey collected information about dose or frequency. 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 Therapeutic Goods Administration as substances that can be added to supplements for supply in Australia (TGA, 2006). 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 2,000 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.*, 1989a). 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) (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 different forms of calcium as part of Application A424 – Fortification of Foods with Calcium[5]. 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 dose and the presence of other foods is more important than differential bioavailability.

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.

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

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 shows the EARs, RDIs and ULs for calcium for various age and sex 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).

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 in the Code 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[6].

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.

[6] 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.

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.

The New Zealand Food Safety Authority is currently reviewing the Dietary Supplement Regulations. A discussion document released in February 2007[7] outlined a proposal to separate the regulation of food-type dietary supplements and therapeutic-type supplements. The intention of the proposed changes is to align food-type dietary supplements more closely with the Code where possible.

3.1.3 Therapeutic goods regulation in Australia

The Therapeutic Goods Administration 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).

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. 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[8].

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.

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[7] New Zealand Food Safety Authority, discussion paper *Proposed Changes to the Regulation of Dietary Supplements,* February 2007.

[8] 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. Found at: http://www.health.gov.au/internet/wcms/publishing.nsf/content/2087CDEAEE7C703CCA256F190003AF4B/$File/vitamins-minerals.pdf

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:*

  - *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 9.

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[9]. 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.

[9] General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987 (Amended 1989,1991).

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[10]. The *Fortification Policy* states that the FDA does not consider it appropriate to fortify snack foods such as candies. The *Fortification Policy* provides guidance only, rather than regulates fortification, and must be adhered to if a nutrient content claim is made on a food product.

In addition, the *Code of Federal Regulations* provides 'reference amounts customarily consumed per eating occasion' for food labelling[11]. 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 not permitted for sale in Canada.

In 2005, Health Canada released a proposed policy and implementation plan for developing new food fortification regulations[12]. The policy is yet to be adopted. If adopted, the policy on the addition of vitamins and minerals to foods would provide for the voluntary fortification of chewing gum products[13].

Similarly to the USA, Canada also stipulates reference amounts for labelling of foods[14]. 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[15], 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[16].

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[10] U.S. Food and Drug Administration. Code of Federal Regulations. Fortification Policy: Title 21, Chapter 1, Subchapter B, Part 104.20.
[11] U.S. Food and Drug Administration. Code of Federal Regulations. Food Labelling: Title 21, Volume 2, Part 101.12.
[12] Health Canada. Addition of Vitamins and Minerals to Foods: Proposed policy and implementation plans (2005).
[13] Personal communication. Nutrition Evaluation Division, Health Canada (September 2006).
[14] Health Canada. Food and Drug Regulations. Reference amounts: Part D, Schedule M.
[15] 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.
[16] Personal communication. Nutrition Division, United Kingdom Food Standards Agency (October 2006).

Council Directive 90/496/EEC regulates nutrition labelling for foodstuffs[17]. 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. The Directive is currently under review.

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 99% market share[18,19]. Growth in the chewing gum market in Australia is coming from 'innovative' products such as Wrigley's Extra Professional and Extra White[18].

Chewing gum can be widely purchased in grocery stores, convenience stores and other retail outlets. Total annual chewing gum sales are worth approximately $AUD180 million in Australia and $NZ40 million in New Zealand[19]. Total sales for chewing gum (≤0.2% residual sugars) account for approximately 70% of units sold in Australia and New Zealand[19].

The survey conducted by Roy Morgan Research on behalf of the Applicant revealed that approximately 40% of Australians and 35% of New Zealanders aged 14 years and above consume chewing gum (≤0.2% residual sugars)[20]. 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[21].

FSANZ is not aware of chewing gum (≤0.2% residual sugars) with added calcium being sold in Australia or New Zealand for the purpose of contributing towards calcium intake. However, some chewing gums (sweetened polyols and intense sweeteners) that contain calcium are available that aim to improve dental health. It appears that these products are marketed as therapeutic goods. Recaldent™, which contains calcium phosphopeptide-amorphous calcium phosphate (CPP-ACP), is manufactured in Australia from milk protein and provides bioavailable minerals to tooth enamel to help prevent decay[22]. Recaldent™ (CPP-ACP) has been incorporated into a chewing gum (sweetened polyols and intense sweeteners) and is available in Australia and New Zealand over the internet and in Australia through some dentists.

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[17] 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.
[18] Retail World's Australasian Grocery Guide (2006).
[19] Synovate AZTEC data: moving annual total figures for New Zealand (as at 26 March 2006).
[20] 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.
[21] Roy Morgan Research (2007).
[22] 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.

The 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[23]. The amount of calcium (as CPP-ACP) in Recaldent™ is 1.2 mg per 1.4 g piece of gum. Another product available over the internet is B-Fresh® Gum (sweetened with 100% xylitol) which contains two forms of calcium: calcium hydroxide and calcium gluconate, which raise the pH level in the saliva. Bacteria that cause tooth decay cannot survive in the altered pH environment[24]. There is approximately 0.5 mg of calcium per piece (unknown quantity) of chewing 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[25].

Only one calcium-fortified chewing gum (sweetened with 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 with 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[26].

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 to 73% total market share. 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 survey conducted by Roy Morgan Research 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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[23] New Zealand Defence Update, Issue 49, June/July 2007.
[24] www.xylitolnow.com/B-fresh.html Accessed 21 August 2007.
[25] www.wrigley.com. Accessed 4 September 2007.
[26] 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 9.1.2.

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);
- ensure adequate information is provided to enable consumers to make informed choices; and
- have regard to the Policy Guideline on *Fortification of Foods with Vitamins and Minerals*[27], as outlined previously in Section 3.2.

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

[27] 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.

- 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. Risk Assessment Issues

This section assesses the prevalence of inadequate calcium intakes and describes the potential health benefits and risks based on estimated increases in calcium intake among various population sub-groups from calcium-fortified chewing gum (≤0.2% residual sugars). The potential dental benefits and risks arising from a topical effect of calcium-fortified chewing gum (≤0.2% residual sugars) are also discussed (see Attachment 3 – Risk Assessment).

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.

7.1 Prevalence of inadequate calcium intake

7.1.1 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 products on the market in Australia and New Zealand including: orange juice, low-fat milk, breakfast cereal, soy milk, and formulated beverages and one dairy blend spread. Therefore, consumers can voluntarily choose these products to boost their calcium intakes. It was assumed that dietary calcium intakes (excluding supplements) in the Australian and New Zealand populations were 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)[28].

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.

[28] 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)

This estimate has been determined by FSANZ on the basis of inherent limitations in the dietary intake assessments in the Australian and New Zealand National Nutrition Surveys[29] (NNS).

Table 2 shows the estimated mean dietary calcium intakes for each age group and the proportion of the population with intakes below the EAR.

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

	Males		Females	
Age (years)	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
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 weighted 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 round 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, women of all ages and older men in both countries are particularly at risk of inadequate intakes.

[29] 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 allowances are made to reflect these inherent limitations.

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.

Some other population sub-groups, which FSANZ is not able to investigate through its dietary intake assessments, 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). 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).

7.1.2 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 each of these forms of calcium was described in the previous FSANZ Applications: 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 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 (Lau *et al*., 2002; Reid, 2005).

In general, the absorption of calcium supplements, and 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.

7.2 Potential health benefits and risks from ingested calcium

7.2.1 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?

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

The survey conducted by Roy Morgan Research showed very similar chewing gum (≤0.2% residual sugars) consumption patterns in Australia and New Zealand (see Attachment 4 - Consumer Research Report). 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)[30]. Slightly more women than men in the survey reported consuming chewing gum (≤0.2% residual sugars). 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.

Survey respondents 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.

7.2.1.2 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;

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

- '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.

7.2.1.3 Additional calcium from fortified chewing gum (≤0.2% residual sugars) in various population sub-groups

FSANZ estimated additional dietary calcium intakes based on the results from the Roy Morgan survey (see Section 7.2.1.1). 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 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), on the assumption 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 chewing gum consumption patterns of individuals. (See Attachment 2 –Dietary Intake Assessment Report for further information about the methodology undertaken to determine these estimates.)

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 (see Attachment 2 – Dietary Intake Assessment Report).

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

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

The 1995 Australian and 1997 New Zealand NNSs reported very low consumer numbers of chewing gum (<1% of the population). However, information provided in the Roy Morgan survey 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) (See Attachment 2 – Dietary Intake Assessment Report for further information about the methodology undertaken to determine these estimates.)

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[1]	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 data from the Roy Morgan survey.
* Chewing gum consumption patterns were not collected for children less than 14 years in the NNSs.

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.

7.3 Is there a risk of excess calcium intake?

The NHMRC and NZMoH (2006) has set an upper level of intake (UL) 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 of 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 data from the Roy Morgan survey.
* 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.

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.

7.4 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 risk of consumers substituting a product naturally high in a vitamin or mineral with one that is fortified because other nutrients might be displaced.

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[31].

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 impact on overall energy intakes.

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[32], 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).

7.4.1 Risk of nutrient deficits or imbalances resulting from milk substitution

The survey conducted by Roy Morgan Research also 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. Of these respondents a small sub-sample of 9 Australians (5%) and 11 New Zealanders (7%) indicated that they would replace milk, yoghurt or cheese with calcium-fortified chewing gum (≤0.2 % residual sugars).

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 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).

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

There is considerable clinical evidence to support the use of chewing gum (≤0.2% residual sugars) as part of a daily dental health care plan but not in place of regular daily brushing. There is some evidence that chewing gum (≤0.2% residual sugars) with added calcium may offer an additional dental benefit.

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[31] 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

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

The evidence from 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 findings of increased salivary and plaque fluid calcium concentrations and remineralisation of enamel sub-surface lesions. Chewing gums containing casein phosphopeptide-amorphous calcium phosphate (<1-3% of CPP-ACP) 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 containing other forms of calcium. However, there is insufficient evidence to conclude that calcium-fortified chewing gum (≤0.2% residual sugars) reduces the risk of dental caries in the long-term[33] (Lingstrom *et al*., 2003c).

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

In addition to the observed dental health benefits of CPP-ACP (which is not listed in the Schedule to Standard 1.1.1), soluble forms of calcium that contribute to increases in salivary and plaque fluid calcium concentrations and remineralisation of enamel sub-surface lesions are:

- calcium lactate (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 carbonate or calcium lactate to chewing gum (≤0.2% residual sugars), although they are seeking permission for each of the 14 forms permitted in the Schedule to Standard 1.1.1. Not all permitted forms are soluble in water, thus limiting their potential dental health benefit.

7.7 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 7.5) were reported for chewing gums containing between <1-5% of the forms of calcium listed in Section 7.6. 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 3 – Risk Assessment Report). 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 (i.e. about 7% for a 3 g serve).

[33] Based on studies of at least two years' duration.

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

One submission to the Initial Assessment Report from an expert in dental health raised 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 on the issues raised in the submission. 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.

Therefore, the risk of promoting calculus formation is small compared with the caries-preventive effect of consuming chewing gum (≤0.2% residual sugars).

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.

7.9 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), the molecular weight of each of these forms of calcium is different. 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. The Applicant has indicated that calcium carbonate is added to the base of their chewing gum to maintain softness.

7.10 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 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.

7.11 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.

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 intake. 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 (JECFA, 1974). A pellet of chewing gum (≤0.2% residual sugars)[34] 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.

8. 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.

8.1 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.

8.2 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 has very little impact on reducing the proportion of the population with inadequate calcium intakes (maximum of 5% reduction).

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

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.

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) but long-term dental health benefits remain uncertain. Calcium lactate, a form the Applicant is proposing to add initially, is one of the forms identified as providing a short-term dental health benefit.

8.3 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 (up to 3% of young males in Australia and New Zealand) and 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 not a concern.

RISK MANAGEMENT

9. 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.

9.1 Patterns of consumption

9.1.1 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.

9.1.2 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 across the general population, as chewing gum is consumed broadly across the population.

Some submitters 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 survey conducted by Roy Morgan Research showed approximately 40% of Australians and 35% of New Zealanders are consumers of chewing gum (≤0.2% residual sugars)[35]. 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 Roy Morgan survey 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.

[35] 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.

9.1.3 Amount consumed per eating occasion

At Initial Assessment, the Applicant described a serving size for chewing gum as five pellets. The majority of submitters considered five pellets to be an unrealistic serving size and suggested a serving size of 1-2 pellets was more appropriate. Many submitters recommended that information be gathered to demonstrate what consumers perceive to be 'a normal serve' of chewing gum.

Since Initial Assessment, the Applicant has stated that the best compromise for a serving size of chewing gum is 3 g, which equates to approximately 2 pellets, 1.5 tabs or 1 stick of chewing gum. 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 Roy Morgan survey gathered data on the number of pellets and tabs of chewing gum (≤0.2% residual sugars) consumed per eating occasion. 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.

9.2 Consistency with the Policy Guideline

The Ministerial Policy Guideline provides guidance on the voluntary addition of vitamins and minerals to food. 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 Policy Guideline.

9.2.1 Potential benefits

9.2.1.1 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 meets the above condition to permit the fortification of foods with calcium, if all other policy principles are met.

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

The risk assessment found that 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, 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.

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*

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

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

In addition to nutritional benefit, the risk assessment identified a potential short-term dental benefit from consuming calcium-fortified chewing gum (≤0.2% residual sugars) for certain forms of calcium. However, there is insufficient evidence to conclude that calcium-fortified chewing gum (≤0.2% residual sugars) reduces the risk of dental caries in the long-term.

The potential short-term dental benefit from increased tooth remineralisation may provide a health benefit to consumers of calcium-fortified chewing gum (≤0.2% residual sugars), in addition to the nutritional benefit. The Policy Guideline supports fortification of foods that have potential to deliver a *health benefit*.

9.2.2 Potential risks

9.2.2.1 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.

9.2.2.2 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 is not a concern.

9.2.3 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.*

The Applicant considers that chewing gum (≤0.2% residual sugars) is the *perfect food vehicle for calcium fortification*, as it has a low energy and negligible sugar content, and contains no salt or fat. While the composition of chewing gum (≤0.2% residual sugars) addresses the policy principle of *not promoting increased consumption of foods high in salt, sugar or fat*, some submitters to the Initial Assessment Report expressed concern in relation to the proposed food vehicle. These 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. It was also noted by some submitters that chewing gum is a vehicle for some complementary medicines.

The introduction of a newly fortified food or food category into the market can result in four possible scenarios[36]. 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) 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 undertaken by the Applicant[37] 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.

Similarly, the Roy Morgan survey investigated the likelihood of consumers substituting other foods with calcium-fortified chewing gum (≤0.2% residual sugars). These data showed 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 who claimed they would substitute other foods in their diet reported they would substitute other chewing gum products with the proposed product (approximately 44% and 41% of Australians and New Zealanders respectively). Around 21% of Australians and 27% of New Zealanders reported they would replace lollies or mints with the calcium-fortified chewing gum (≤0.2% residual sugars).

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

Few reported that they would replace calcium-rich foods such as milk, cheese or yoghurt with the calcium-fortified chewing gum product (9 Australians (5%) and 11 New Zealanders (7%)).

Therefore, the above data supports 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, or promote consumption patterns inconsistent with national nutrition policies or guidelines.

In addition, 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[38] and 'Wrigley Extra Sugar Free Chewing Gum' is a New Zealand Dental Association approved product[39].

9.2.4 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 Assessment Report 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.

9.2.4.1 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 9.2.3 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. 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.

[38] Australian Dental Association – www.ada.org.au
[39] New Zealand Dental Association – www.nzda.org.nz

The appropriate risk management strategy to address this issue, incorporating the Applicant's request, is discussed in Section 9.3.1.

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.

9.2.4.2 Serving size

The Applicant has requested that claims are based on the amount of releasable calcium *per serve*. 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.

While the possibility exists that a manufacturer may increase the serve size of their product in order to meet the minimum criteria for making a calcium claim, it is considered unlikely that they would do so. If the label reflected an unrealistic serving size it is likely that the manufacturer would lose credibility in the eyes of consumers and may face enforcement action on the grounds of misleading conduct.

Use of *per serve* for the basis of labelling and nutrition claims is discussed further in Section 9.4.

9.2.5 Summary

As demonstrated above, the request to permit the addition of calcium to chewing gum (≤0.2% residual sugars) meets FSANZ's objectives and the Policy Guideline's principles for 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.

9.3 Addition of calcium

9.3.1 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[40]. 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 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 food, as the whole food 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. 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 9.5.

9.3.2 Permitted forms

The Applicant has requested permission to use all 14 forms of calcium currently permitted in the Schedule to Standard 1.1.1. As noted in Section 7.9, it is technically possible to add any of these 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.

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.

9.3.3 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.

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

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 may indirectly limit the amount of calcium that a manufacturer chooses to add.

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 (see Section 9.4.2).

9.4 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 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 have been proposed, as outlined in the following sections and are provided in the draft Standard (see Attachment 1).

9.4.1 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.

It is 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 determines the most appropriate serve size.

The per serve basis is consistent with the approach proposed under Proposal P293 – Nutrition, Health & Related Claims, for vitamin and mineral content claims.

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 must not exceed any prescribed maximum claim level. The Applicant has requested a maximum claim level for releasable calcium equivalent to 25% of the RDI for calcium. For calcium, 10% of the RDI equates to 80 mg of calcium[41]. These 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 amount of releasable calcium should not exceed 200 mg (25% of the RDI). Providing the above criteria are met, a claim such as 'with calcium' or 'contains x mg calcium' would be permitted on the label of calcium-fortified chewing gum (≤0.2% residual sugars).

Standard 1.3.2 also 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. In the case of calcium-fortified chewing gum (≤0.2% residual sugars), as the proposed maximum claim is 200 mg (25% of the RDI) releasable calcium per serve, it is proposed not to allow claims such as 'good source' of calcium or releasable calcium. This is because the boundary of the proposed maximum claim and the minimum level of a 'good source' claim are the same, i.e. 200 mg. However, in practice the average quantity of calcium is unlikely to be precisely 200 mg on a consistent basis due to the practicalities of manufacturing.

9.4.2 Nutrition information panels and wording conditions for claims

Under Standard 1.2.8, a nutrition information panel (NIP), requiring declaration of certain nutrients on a per serve and per 100 g or 100 ml basis, is required on most packaged foods. The same requirement is considered appropriate for calcium-fortified chewing gum (≤0.2% residual sugars). However, it is proposed 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.

In addition, it was considered to be potentially misleading and of no value for 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 must be located within the NIP and must be linked to the calcium declaration, for example by the use of an asterix (i.e. *). 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. The exact wording of the statement will not be prescribed.

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

Standard 1.3.2 requires that the proportion of the RDI of the claimed vitamin or mineral contributed by one serving of the food must also be declared on the label. This requirement 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.

9.4.2.1 Considerations for small packages

If a nutrition claim is made on a small package, the average quantity of the claimed nutrient must be declared. It was noted by a submitter that under the Code (paragraph 8(1)a of Standard 1.2.8), small packages would only need to refer to the calcium content per 100 g. FSANZ considers that this information would be more useful to consumers if presented on a per serve basis, particularly for foods such as chewing gum where the small package contains a number of servings that weigh much less than 100 g. 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 and the serve size of the package must be declared. Similarly, if calcium-fortified chewing gum (≤0.2% residual sugars) carries a claim about calcium and sugar content, the declaration of energy, carbohydrate, sugar and dietary fibre, which is required on a small package when a claim about sugar is made, will also be required on a per serve basis rather than per 100 g or 100 ml.

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.

9.4.3 Health claims

Health claims are currently regulated in Standard 1.1A.2 – Transitional Standard for Health Claims. This transitional Standard specifically prohibits certain health claims, such as those 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. This Standard is expected to be gazetted in mid-2008.

There were a number of comments from submitters to the Initial Assessment Report regarding health claims and the implications of Proposal P293 for this Application. Recommendations were made for the level of evidence that should be provided to support claims such as 'strengthens teeth' and those relating to tooth remineralisation that would be permitted when draft Standard 1.2.7 is gazetted.

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. Another submitter recommended that the health claims framework be finalised prior to the consideration of this Application.

The regulation of health claims is not within the scope of this Application. Under Proposal P293 it has been proposed that all health claims must be substantiated to a certain level of evidence and in accordance with certain principles. FSANZ considers that this framework will adequately address the substantiation of health claims made in regard to calcium-fortified chewing gum (≤0.2% residual sugars). FSANZ will ensure that the qualifying criteria for general level health claims for calcium-fortified chewing gum (≤0.2% residual sugars) are consistent with the criteria for nutrition claims in relation to *releasable* calcium.

9.4.4 Advisory statements

One submitter to the Initial Assessment Report suggested that an advisory statement that reflects the dietary guidelines with respect to sources of calcium should be provided on labels, so that consumers are not misled by claims which equate the nutritional benefits of calcium-fortified chewing gum (≤0.2% residual sugars) with dairy foods.

FSANZ recommends that such an advisory statement will not be prescribed. An advisory statement is only required when the general public or a sub-population are exposed to a significant potential risk to health but the risk is not life threatening, or when guidance about the use of a food is needed to protect public health and safety. As reported in the risk assessment, there is only a small risk that some consumers may replace calcium-rich foods with the proposed product, and this is unlikely to cause any dietary inadequacies of other nutrients. Also, in accordance with the wording conditions proposed under Proposal P293, all health claims must be presented in the appropriate dietary context and must make reference to a variety of foods (with the exception of small packages).

9.5 Enforcement

The proposed approach that calcium claims for calcium-fortified chewing gum (≤0.2% residual sugars) are based on the amount of calcium *released* during 20 minutes of chewing is different to that taken for other fortified foods. For this reason, a different approach to assess compliance with the Code will be required.

As the calcium content of calcium-fortified chewing gum (≤0.2% residual sugars) will differ depending on the form of calcium used, assessing the product's calcium content alone will not verify the validity of the claim(s) made. Additional information on the amount of calcium released from the chewing gum during 20 minutes will be required.

Enforcement agencies may experience difficulties gathering the addition information on the amount of calcium released from the product. For this reason, it is proposed that the manufacturer must hold information to substantiate the amount of calcium released from their product during 20 minutes of chewing, and provide this to enforcement agencies on request. It can reasonably be assumed that this requirement will not place additional burden on the manufacturer, as the relevant analytical tests should have been conducted to determine the claim stated on the food package.

9.6 Other issues raised in submissions

9.6.1 Regulation as a therapeutic good

A number of submitters to the Initial Assessment Report 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 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 rather than dental; and
- the Australian Therapeutic Goods Administration has declared that unmedicated dental chewing gums, with claims restricted to improvements to oral hygiene, are not therapeutic goods. 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.

Accordingly, permission to add calcium to chewing gum (≤0.2% residual sugars) will continue to be assessed under the FSANZ Act.

9.6.2 Use of the term 'sugar-free'

Several submitters to the Initial 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. It was noted 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.

9.6.3 Gastrointestinal/laxative effect

Several submitters expressed concern about the potential laxative effect of consuming polyols in large quantities, which may result from increased consumption of chewing gum (≤0.2% residual sugars). These concerns related to the suggested serving size of 5 pellets and if consumers increased their intake of the fortified chewing gum (≤0.2% residual sugars) to obtain more calcium.

As discussed in Section 7.11, the polyols used in chewing gum (≤0.2% residual sugars) may have a laxative effect for some individuals at high levels of intake. However, the intake of polyols in chewing gum (≤0.2% residual sugars), when consumed as suggested, is likely to be much less than the daily threshold levels for such laxative effects. For example, approximately 125 pellets of chewing gum (≤0.2 % residual sugars) would need to be consumed to exceed the daily sorbitol threshold of 50 g[42].

The likelihood that consumers will experience a laxative effect from consuming calcium-fortified chewing gum (≤0.2% residual sugars) is considered no greater than from consuming other chewing gum (≤0.2% residual sugars) products. Like other foods that contain polyols at certain levels, calcium-fortified chewing gum (≤0.2 % residual sugars) will be required to carry a label advisory statement to the effect that excess consumption of the food may have a laxative effect, as per Clause 5(2) of Standard 1.2.3.

10. Options

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

10.1 Option 1 – Maintain *status quo*

Maintaining the *status quo* would not allow the addition of calcium to chewing gum (≤0.2% residual sugars).

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

10.2 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

Option 2 would allow the voluntary addition of calcium to chewing gum (≤0.2% residual sugars) under a stand-alone Standard in Part 2.10 of the Code, at a maximum claim level of 200 mg releasable calcium per serve.

11. Impact Analysis

11.1 Affected Parties

The parties likely to be affected by this Application and preferred approach include:

- **consumers** of chewing gum (≤0.2% residual sugars);
- Australian and New Zealand manufacturers and importers of chewing gum **(industry)**; and
- **Government,** including the enforcement agencies of Australia States/Territories and New Zealand.

11.2 Benefit Cost Analysis

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

11.2.1 Option 1 – Maintain Status Quo

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).

11.2.1.1 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.

11.2.2 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.

11.2.2.1 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 Roy Morgan survey 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[43]. 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 Roy Morgan survey 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[44]. 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 through increased tooth remineralisation. An additional dental benefit may be gained through reduced consumption of sugared chewing gum products and lollies, if consumers substitute calcium-fortified chewing gum for these foods in their diet.

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 limited to specific forms of calcium.

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

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

11.2.2.2 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.

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 Roy Morgan survey 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. 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.

11.3 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 Draft Assessment suggests Option 2 provides greater net benefit to the affected parties.

COMMUNICATION AND CONSULTATION

12. Consultation

12.1 Public Consultation

The Initial Assessment Report for Application A577 was released for public comment from 4 October to 15 November 2006. In response FSANZ received 17 submissions, with nine submissions from industry, five from government, and one each from a consumer group, an academic and a public health association. A summary of these submissions is at Attachment 5.

Overall, five of the 17 submitters did not specify their preferred option at Initial Assessment, 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). Reasons provided for not supporting the proposed fortification included, a potential risk to dental health, potential for consumers to be misled, and that chewing gum (≤0.2% residual sugars) is not an appropriate food vehicle for fortification.

All the key issues raised in submissions to the Initial Assessment Report are addressed in the main body of this Report.

FSANZ is now seeking further public comment on this Draft Assessment Report to assist in undertaking a Final Assessment of this Application.

12.2 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 results of the survey conducted by Roy Morgan Research were presented to the Food Regulators' Science Network Forum. These results were used extensively to inform the assessment of this Application.

12.3 World Trade Organization

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 at Draft Assessment, FSANZ does not consider it necessary to notify WTO member nations of the proposed amendment to allow the addition of calcium to chewing gum (≤0.2% residual sugars), under either the Technical Barriers to Trade or the Sanitary and Phytosanitary Agreements.

13. Communication Strategy

At Draft Assessment, FSANZ does not intend to undertake specific communication strategies outside of the two statutory public consultation periods. Initial feedback indicates general support from the public, dental 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.

FSANZ does not anticipate any media or public criticism of the proposed amendment, or to the availability of calcium-fortified chewing gum (≤0.2 % residual sugars) on the market. However, FSANZ will monitor media activity and review the nature of feedback received from submitters to the Draft Assessment Report, and determine whether additional communication strategies are required for the Final Assessment.

CONCLUSION AT DRAFT ASSESSMENT

14. Conclusion and Preferred Approach

Preferred Approach

At Draft Assessment, the preferred regulatory approach is to prepare a draft Standard for chewing gum in Part 2.10 of 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).

FSANZ supports the preferred regulatory approach to permit the addition of calcium to chewing gum (≤0.2% residual sugars) as it:

- 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 the fortified food;

- may provide consumers with a short-term dental benefit;

- does not raise any safety concerns for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) or the general population;

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

- supports industry innovation;

- provides consumers with adequate information on the product label 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 draft Standard to permit the addition of calcium to chewing gum (≤0.2 % residual sugars) is at Attachment 1.

15. Implementation and Review

Following the consultation period for this Report, a Final Assessment of the Application will be completed and considered for approval by the FSANZ Board. The FSANZ Board's subsequent decision will then be notified to the Ministerial Council.

Following notification, the proposed draft Standard is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Dietary Intake Assessment Report
3. Risk Assessment Report
4. Consumer Research Report
5. Summary of Submissions to the Initial 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.

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 labelling requirements.

Table of Provisions

Clauses

1 Interpretation

In this Standard –

applicable chewing gum 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.

2 Permitted addition of calcium

Applicable chewing gum may contain added calcium provided that the calcium is in a permitted form specified in the Schedule to Standard 1.1.1.

3 Calcium claim

(1) A claim as to the presence of calcium ('calcium claim') in applicable chewing gum may only be made if –

(a) it contains no less than 80 mg (10% of the RDI) of releasable calcium per serve;
(b) it contains no more than 200 mg (25% of the RDI) of releasable calcium per serve;
(c) the supplier of the food has records that substantiate the matters listed in paragraphs 3(a) and (b); and
(d) the supplier makes the records available to the relevant authority upon request.

(2) Despite subclause (1), a claim to the effect that applicable chewing gum is a good source of calcium or releasable calcium may not be made.

4 Labelling requirements

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

(a) the average quantity of releasable calcium per serve;
(b) the average quantity of releasable calcium per 100 g;
(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) This clause does not apply to applicable chewing gum 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) Clause 8 of Standard 1.2.8 does not apply where a calcium claim is made in relation to applicable chewing gum contained in a small package.

(2) Where a calcium claim is made in relation to applicable chewing gum in a small package, the label must include the following information –

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

(3) For the purposes of paragraph 5(2)(a), the definitions in clause 1 of Standard 1.2.8 apply.

(4) The information required in subclause (2) 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.

Attachment 2

Dietary Intake Assessment Report

Executive 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 National Health and Medical Research Council and New Zealand Ministry of Health (NHMRC & NZMoH) Nutrient Reference Values for Australia and New Zealand (NRVs) (National Health and Medical Research Council, 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 easy comparison of the estimated calcium intakes with the relevant NRVs. For Australia, the dietary intake assessments were conducted for the following age groups: the population 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 and 70 years and above, for both males and females. For New Zealand, the following age groups were assessed: the population 15 years and above, 15-18 years, 19-29 years, 30-49 years, 50-69 years and 70 years and above, for both males and females.

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:

'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;

'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.

'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.

The 1995 Australian and 1997 New Zealand National Nutrition Surveys (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, with an even split between males and females. In order for calcium intakes to be estimated for Australian and New Zealand population groups using the 1995 and 1997 NNSs, chewing gum consumers were assumed to 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)).

These data were combined with recent survey data that were provided by the Applicant on (1) the prevalence of consumption of chewing gum (≤0.2% residual sugars) amongst the population groups; (2) the frequency of consumption of chewing gum (≤0.2% residual sugars); and (3) the number of pieces of chewing gum (≤0.2% residual sugars) consumed per eating occasion (Roy Morgan Research, 2007), to obtain the mean daily amount of chewing gum (≤0.2% residual sugars) consumed.

Results for Australia and New Zealand:

Results are presented below averaged over the whole population and for consumers alone for Australian and New Zealand population groups:

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 concentrations of either 21.3 mg releasable calcium per gram of gum ('Current technology' scenario) or 41.7 mg releasable calcium per gram of gum ('Anticipated future technology' scenario) were used. Calcium from the gum was added to the calcium intakes derived from NNS data.

Type B: A consumer-only model was generated by adding the mean daily amount of chewing gum (≤0.2% residual sugars) reported by consumers to the distribution of calcium intakes derived from the NNS data, on the assumption that dietary intakes from other foods do not vary by gum consumption choice. Calcium concentrations of either 21.3 mg releasable calcium per gram of gum ('Current technology' scenario) or 41.7 mg releasable calcium per gram of gum ('Anticipated future technology' scenario) were used.

(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.

- The increase in estimated mean calcium intakes from 'Baseline' 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.

- >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. Australian children aged 2-3 years were estimated to have adequate dietary calcium intakes.

- ≥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.

- For both the Australian and New Zealand populations, the proportion of the population sub-groups with inadequate 'Baseline' dietary calcium intakes was generally higher as age increased.

- There was little to no change in the proportions of Australian population groups (aged 9 years and above) with inadequate dietary calcium intakes under both fortification scenarios considered.

- 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%).

- There was little to no change in the proportion of New Zealand population groups (aged 15 years and above) with inadequate dietary calcium intakes under both fortification scenarios considered.

- The proportion of the Australian and New Zealand chewing gum consumers with estimated calcium intakes above the Upper Level (UL) for calcium changed minimally from 'Baseline' to the two fortification scenarios considered.

(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.

- The increase in estimated mean calcium intakes from 'Baseline', among consumers of calcium-fortified chewing gum 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.

- The proportion of Australian population groups (aged 9 years and above) with inadequate dietary calcium intakes remained substantial (30-90% of the population group) under both fortification scenarios considered.

- 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 New Zealand population groups (aged 15 years and above) with inadequate dietary calcium intakes remained substantial (35-95% of the population group) under both fortification scenarios considered.

- 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.

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 both over the whole population and 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, with an even split between males and females. 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.

This task was undertaken by Roy Morgan Research Pty Ltd (RMR) who collected 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 survey commissioned by the Applicant

The data from 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 of 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 research undertaken by RMR 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 RMR research.

Mean daily chewing gum (≤0.2% residual sugars) consumption (grams per day) was calculated 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.

The method used to generate the mean daily consumption of chewing gum (≤0.2% residual sugars) in grams per day from RMR 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 (≤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 RMR and dividing by the number of consumers in the RMR; this was done within age-sex groups and for the total population and the calculated means are shown in Appendix 2, Table 2.2

- Mean daily chewing gum (≤0.2% residual sugars) consumption for the RMR population was calculated from the mean intake 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'.

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, with an even split between males and females. 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 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.

For each respondent in the NNS, determine:

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

2. The additional calcium that would be provided by the intake of calcium-fortified chewing gum (≤0.2% residual sugars) 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 intake in the total RMR 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 RMR. 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 weighted 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 intake of gum in the RMR 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) intake (grams) per day (intake 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.

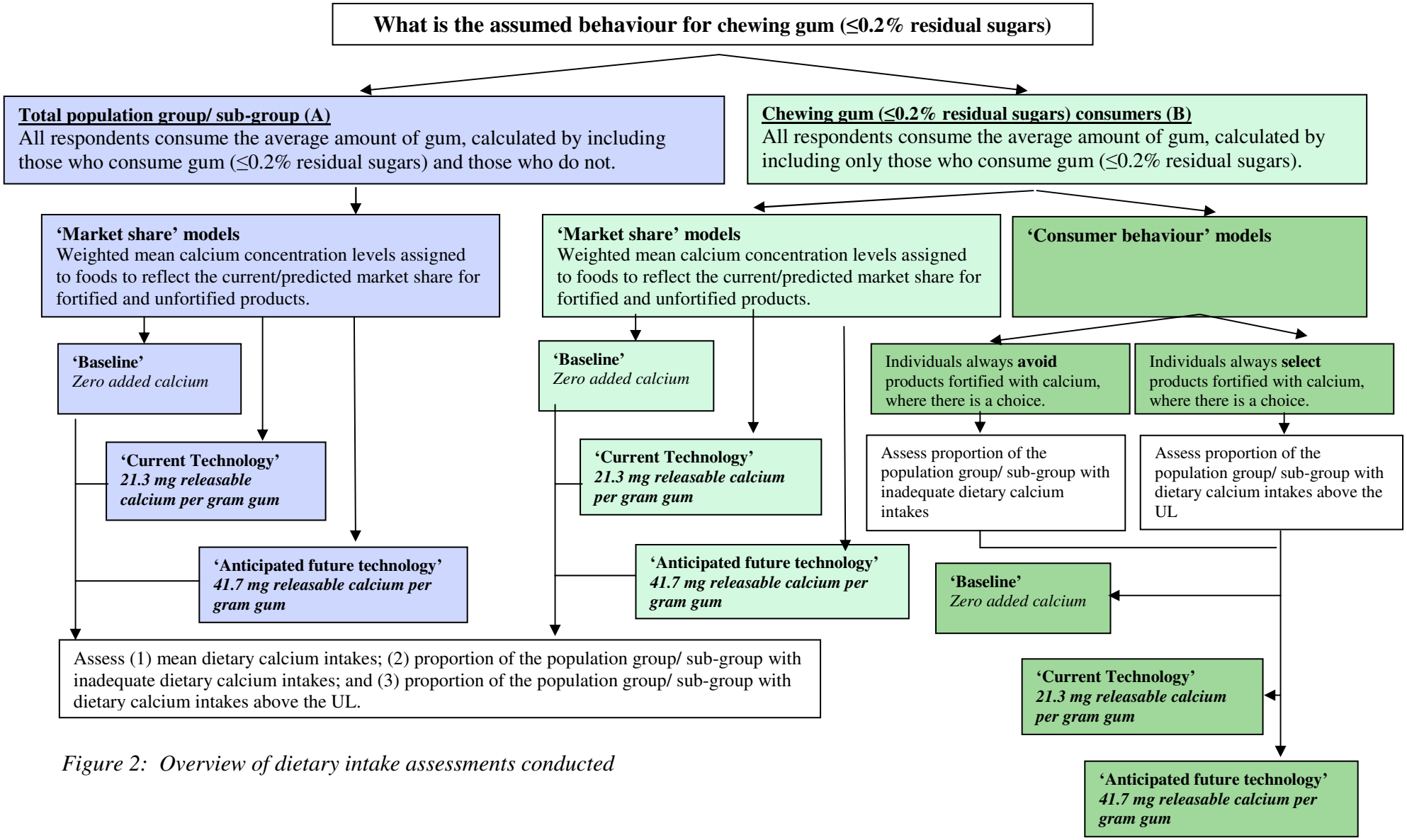

Figure 2: Overview of dietary intake assessments conducted

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 intake 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) intake (grams) per day (intake 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 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.

2.2 Market weighted and consumer behaviour models

2.2.1 Market weighted 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 conduced 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 weighted 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 weighted' 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 weighted' 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.

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 weighted' and 'consumer behaviour' models.

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 weighted' and 'consumer behaviour' model calcium concentrations

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 weighted 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 Applicants state 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 intakes 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, 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.

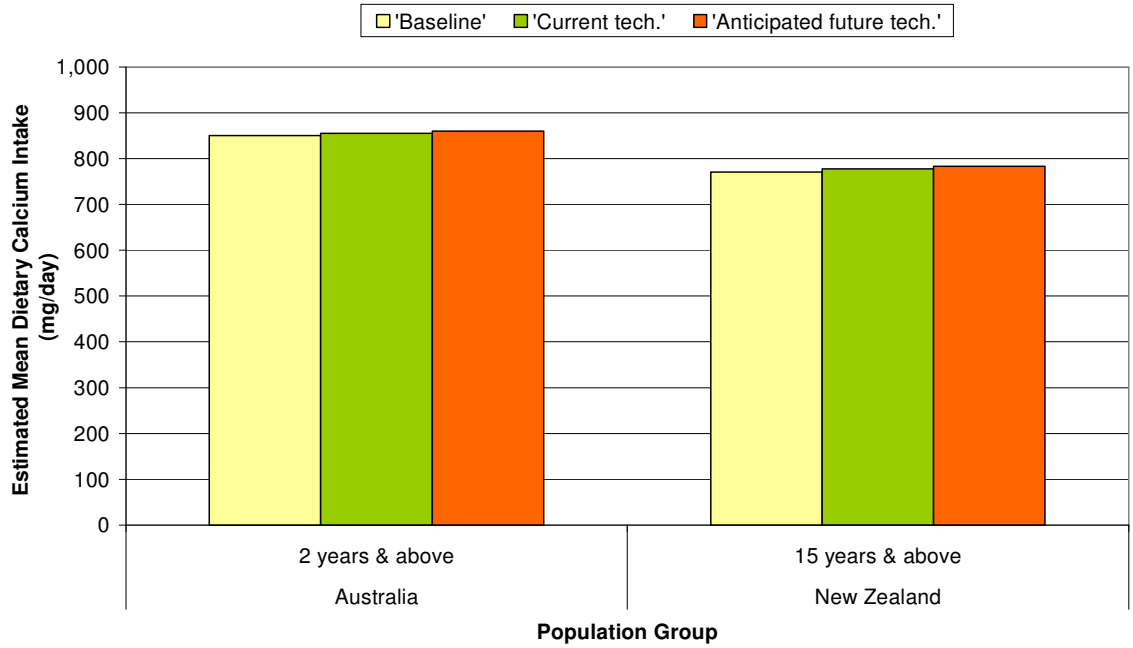

Figure 4: Estimated mean calcium intakes from food at Baseline and under the Current technology and Anticipated future technology scenarios for Australia and New Zealand (A)

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)

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'
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)
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 intakes 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)

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'
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 intakes 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).

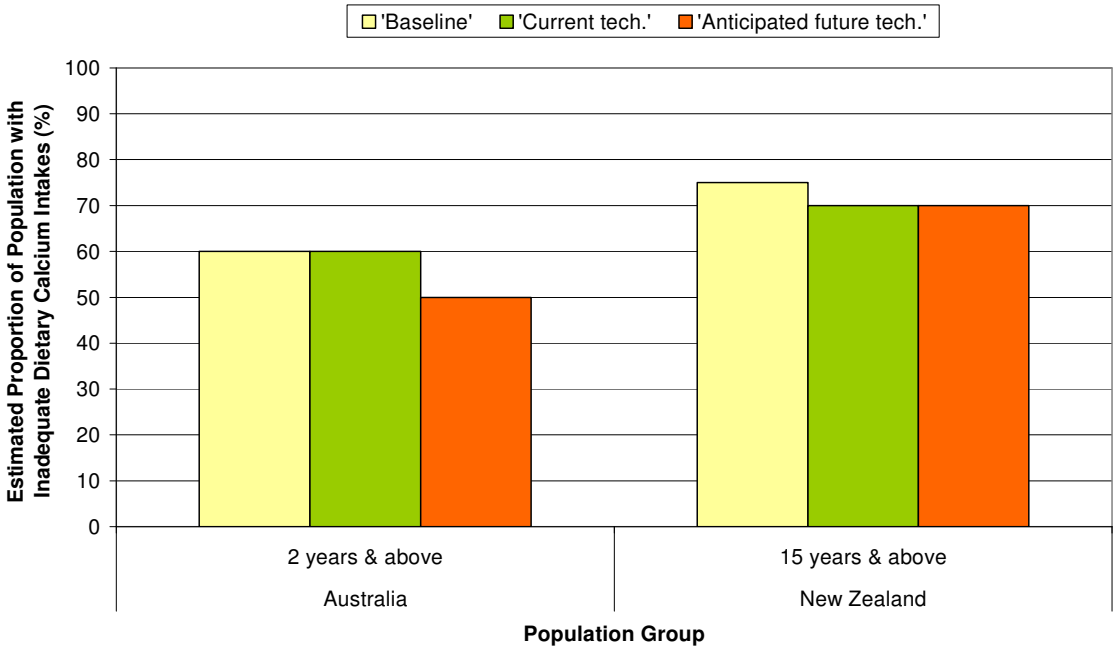

Figure 5: Estimated proportion of the population with inadequate dietary calcium intakes at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios (A)

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.

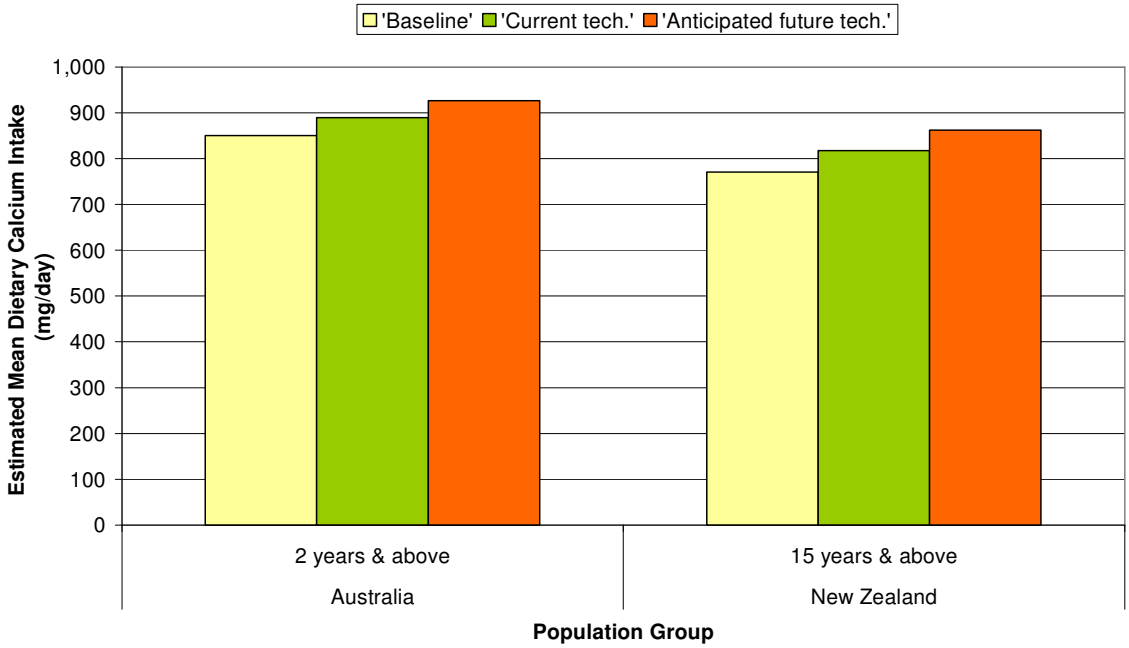

Figure 6: Estimated mean calcium intakes from food at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios, for consumers of calcium-fortified chewing gum (≤0.2 % residual sugars) (B)

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 intakes 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 intakes 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.

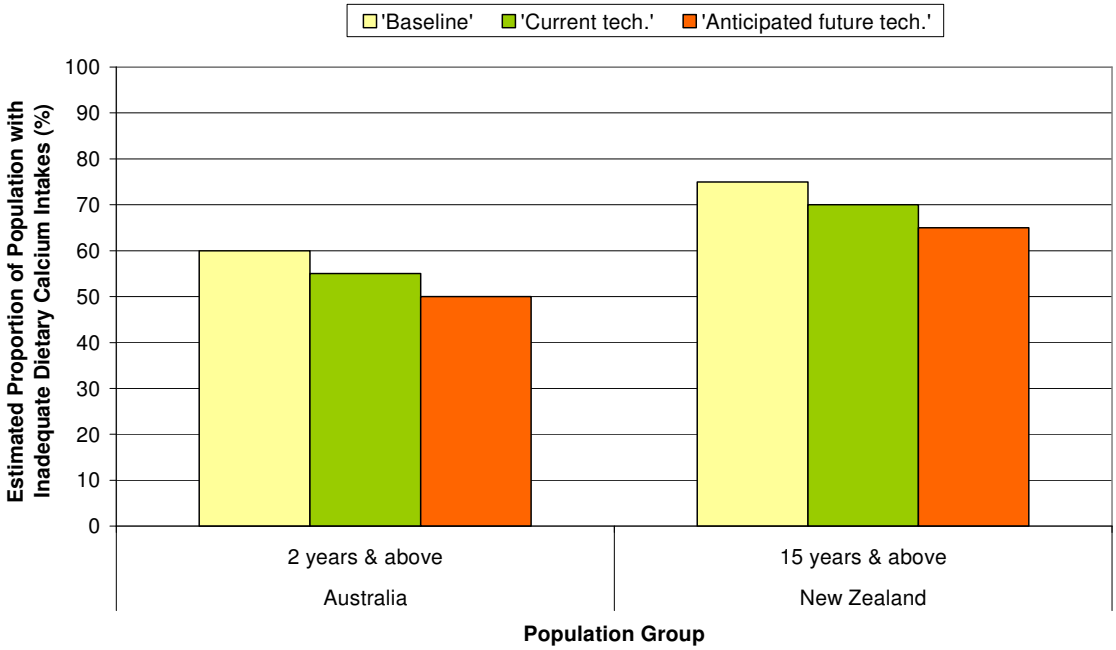

Figure 7: Estimated proportion of the population with inadequate dietary calcium intakes at 'Baseline' and under the 'Current technology' and 'Anticipated future technology' scenarios, for consumers of calcium-fortified chewing gum (≤0.2 % residual sugars) only (B)

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). T

he 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-weighted 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 weighted 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 weighted 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

Australian Bureau of Statistics. (1998) Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File 1995. Australian Bureau of Statistics, Canberra.

Cook, T., Rutishauser, I. and Seelig, M. (2001a) Comparable data on food and nutrient intake and physical measurements from the 1983, 1985 and 1995 national nutrition surveys.

Cook, T., Rutishauser, I. and Allsopp, R. (2001b) *The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys*. Australian Food and Nutrition Monitoring Unit, Commonwealth Department of Health and Aged Care, Commonwealth of Australia, Canberra.

Flanagan, B. (2006) Retail World's Australasian Grocery Guide 2006. 16th ed, Retail Media, North Parramatta.

National Health and Medical Research Council and New Zealand Ministry of Health (2006) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. *http://www.nhmrc.gov.au/publications/_files/n35.pdf*. Accessed on 9 June 2006.

Rutishauser, I. (2000) Getting it right:- how to use the data from the 1995 National Nutrition Survey. Commonwealth of Australia, Canberra.

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.

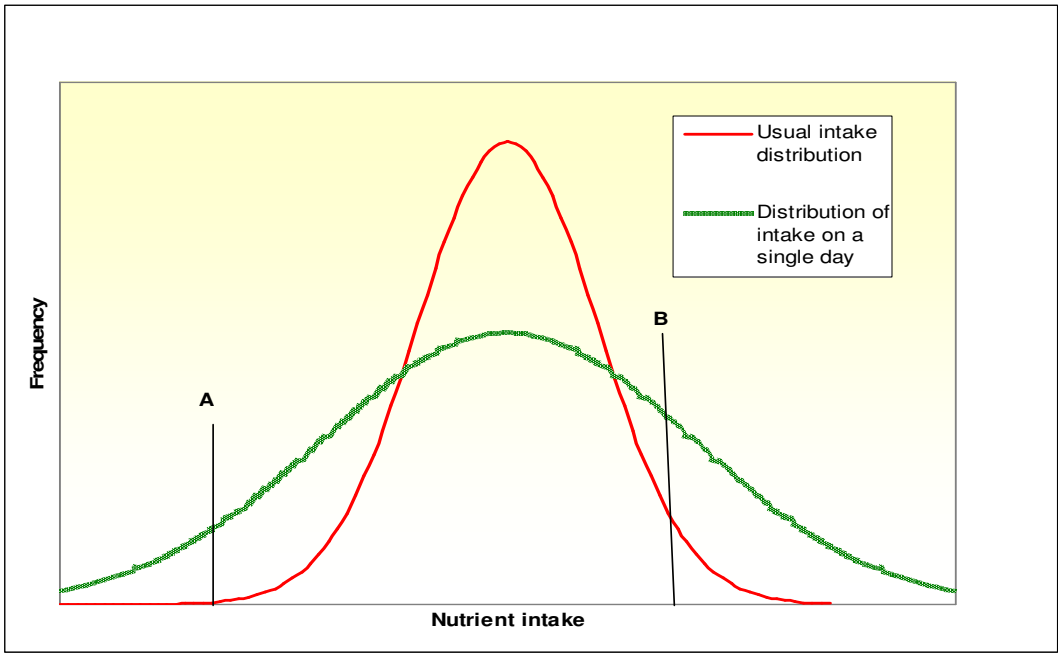

Figure A1.2: Comparison of one day and usual intake distributions

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.

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 intake 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 intakes of chewing gum (≤0.2% residual sugars) per day)

Table A2.2: Mean intake 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 intakes 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 weighted 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 intakes 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 intakes of chewing gum (≤0.2% residual sugars) for the total population (Roy Morgan Research, 2007).

Table A3.2: Market weighted 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 intakes 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 intakes 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 weighted 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 intakes 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 intakes 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 intakes 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 intakes of chewing gum (≤0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Table A4.3: Market weighted 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 intakes 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 intakes 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 intakes 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 intakes 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 intakes 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 intakes of chewing gum (containing no more than 0.2% residual sugars) for consumers of chewing gum (Roy Morgan Research, 2007).

Attachment 3

Risk Assessment Report – Potential Benefits and Risks of Calcium-Fortified Chewing Gum (≤0.2% residual sugars)

The potential benefits and risks of calcium-fortified chewing gum (≤0.2% residual sugars) have been assessed from two perspectives:

- the effect of ingested calcium on intakes in the population and its consequent impact on health; and
- a localised effect on dental health.

1. Potential nutritional/health benefits and risks from ingested calcium

1.1 Potential nutritional benefits

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, predisposing them to increased calcium resorption from bone to maintain circulating calcium levels (Institute of Medicine, 1997).

1.2 Potential health benefits

1.2.1 Bone health

In terms of the dietary contribution to bone health, the WHO/FAO (2003) reported convincing evidence that a sufficient intake of calcium and vitamin D *together* reduced the risk of osteoporosis among older people. A summary of the evidence of calcium, vitamin D and bone health published since 2003, (Heaney, 2007), highlights the accepted role of vitamin D in enhancing absorption of calcium from the diet but also emerging evidence for the role of calcium and vitamin D in reducing excessive bone remodelling. High remodelling rates increase bone fragility; both increased calcium intake and increased vitamin D status reduce bone remodelling.

1.2.2 Dental health

In terms of the dietary contribution to dental health including: dental caries, dental erosion, enamel developmental defects and periodontal disease, the WHO/FAO (2003) did not report any direct links with calcium intake. They did report that the risk of dental caries is 'probably' reduced by hard cheese and 'possibly' by milk. There is also 'possible' evidence that hard cheese may reduce the risk of dental erosion.

1.2.3 Hypertension, colorectal cancer and overweight

The potential benefit of calcium for several chronic conditions has been investigated in recent years but the evidence remains inconclusive.

The National Heart Foundation of Australia in their 2004 Information Paper on the non-drug treatment of hypertension stated that calcium appeared to have little effect on blood pressure (Beilin and Jennings, 2004). Similarly, a recent review of nutritional effects on blood pressure concluded that high intakes of calcium may reduce the risk of hypertension but the results remain inconclusive (Myers and Champagne, 2007).

Epidemiologic studies in humans to date show a moderately protective effect of total dairy products, milk and calcium on the risk of colorectal cancer (Gonzalez, 2006). However, the combined results of two randomised, double blind controlled trials involving the use of calcium supplements in doses of 1,200 mg/day for four years in one trial and 2,000 mg/day for three years in the other found a significant reduction in recurrent colorectal adenoma (OR = 0.74, CI: 0.58, 0.95) (Weingarten *et al*., 2004). There is also emerging evidence of the role of calcium and vitamin D in reducing all-cancer risk in post-menopausal women (Lappe *et al*., 2007).

Data from cross-sectional studies support an association between dairy product consumption and body weight regulation, although available data to date, do not support a causal relationship between high dairy food intake and/or high calcium intake and reduced adiposity (Barba and Russo, 2006).

1.3 Potential risks from excess calcium intake

The NHMRC and NZMoH (2006) has set an upper level of intake (UL[45]) 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.

1.4 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.

[45] 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.

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 from 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. It was noted that the modelled scenario is theoretical and very unlikely; 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 (an unlikely scenario). The results indicated that all population sub-group mean intakes would be above the 2006 RDIs for vitamin B_{12} and protein.

2. Dental health

FSANZ has investigated potential benefits and risks to dental health from a topical effect on teeth.

2.1 Potential dental health benefits 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[46].

There is considerable clinical evidence to support this recommendation. The Applicant provided a sample of the research 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). This research details the beneficial effect on dental health from chewing 'sugar-free' gum and 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.

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

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 to enable the exchange of calcium ions between the saliva and the tooth enamel. Of the permitted forms of calcium in the Code, calcium lactate is soluble in water; whereas calcium carbonate and some forms of calcium phosphate are virtually insoluble (see Box 2).

Box 2: Solubility (in water) of permitted forms of calcium

Calcium carbonate	almost insoluble
Calcium chloride	freely soluble with generation of much heat
Calcium chloride, anhydrous	–
Calcium chloride solution	–
Calcium citrate	1:1050 in cold water; more soluble in hot water
Calcium gluconate	1:30 in cold water, more soluble in boiling water
Calcium glycerophosphate	1:50; almost insoluble in boiling water
Calcium lactate	soluble
Calcium oxide	soluble in water with generation of a large quantity of heat
Calcium phosphate, dibasic	almost insoluble
Calcium phosphate, monobasic	moderately soluble
Calcium phosphate, tribasic	almost insoluble
Calcium sodium lactate	–
Calcium sulphate	0.2:100; soluble

Source: The Merck Index, 14th Ed. 2006.

2.1.1 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 various forms of calcium.

A small study (n=8; mean age=37 years) investigating more soluble forms of calcium (5% monocalcium phosphate monohydrate in one gum and 5 % TTCP + DCP 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 DCP dihydrate.

In a study (n=14; aged 25-53 years) investigating chewing gum containing 2.5% α-tricalcium phosphate[47], Vogel *et al*. (1998b) 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 between the experimental gum and the control ($p<0.01$ for each parameter). In a small study (n=10; aged 22-27 years) by Suda *et al*. (2006), a chewing gum containing xylitol[48] (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).

Despite the anticaries potential of the above forms of calcium in the short-term among adults, Lingstrom *et al*. (2003b), 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 dehydrate to chewing gums has yet to be demonstrated in either adults or children in the longer term.

There are several references identifying the dental health benefits of chewing gum with added casein phosphopeptide-amorphous calcium phosphate (CPP-ACP). For example, in a study by Shen *et al*. (2001) the authors observed a clear dose-response relationship in the level of CPP-ACP in the 'sugar-free' gum and remineralisation of sub-surface lesions on teeth. The level producing the greatest effect was 56.4 mg CPP-ACP in 1.9 g of gum. In another study investigating the acid resistance of enamel lesions remineralised *in situ* by a 'sugar-free' chewing gum containing 18.8 mg of CPP-ACP in approximately 2.5 g of gum and a control, approximately twice the level of remineralisation was observed and the treated lesions were more resistant to subsequent acid challenge (Iijima *et al*., 2004b).

Recent research involving two randomised, double blind studies compared the ability of 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. The results indicated that the CPP-ACP gum produced the highest level of subsurface lesion remineralisation, independent of chewing frequency or duration.

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.

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[47] *α-tricalcium phosphate* is easier to make than *TTCP* but its solubility in oral pH levels (7.0-7.5) is less than *DCP dihydrate.* At lower pH levels its solubility increases dramatically (Vogel *et al*., 1998c).

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

The level of enamel remineralisation across all gums correlated with the level of water-soluble calcium phosphate per piece of gum.

In contrast to the potential benefits of CPP-ACP in chewing gum described above, Schirrmeister *et al*. (2007), in a clinical trial (n=15; mean age 27.5 years), found no significant differences in tooth remineralisation in chewing gums containing either CPP-ACP (0.7%) or dicalcium phosphate (3.9%) + calcium gluconate (1.8%) + calcium lactate (0.45%) or no calcium. The authors attribute the conflicting results to study design differences as well as the location of the test specimens in the mouth and whether they came into direct contact with chewing gum – in earlier studies the gum was more likely to come into direct contact with the specimen, whereas in this study it was less likely to. A response on the quality of this paper noted that no difference in remineralisation was found between 'sugar-free' and sugar-containing gums, which contrasts the results from several long term clinical trials, hence any conclusions based on the results of this study should be made with caution (Vincent and Reynolds, 2007).

To conclude, the evidence from small but well-controlled studies investigating the immediate effects of chewing gum, fortified with predominantly soluble forms of calcium, consistently report a 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. Chewing gums containing CPP-ACP 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 containing other forms of calcium. However, 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 (Lingstrom *et al*., 2003d).

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

An issue raised in submissions to the Initial Assessment Report 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[49]. Vogel *et al*. (1998a) refer to animal studies suggesting that diets high in calcium and phosphorus could promote calculus formation. However, a small clinical trial by Schirrmeister *et al*. (2007) reported no surface mineral deposits after chewing calcium-fortified chewing gums, four times a day for 14 days over five different time periods.

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 other forms of calcium.

[49] Periodontal disease has been associated with several detrimental health outcomes including preterm low birth weight and cardiovascular disease (Fowler *et al*., 2001).

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*. (2004a) 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 commissioned Dr Peter Shellis[50] to provide additional advice 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). 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, however, 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 (DCPD) (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 *DCPD*, 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 *DCPD* 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 *DCPD* 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[51] and Professor Domenick T. Zero[52,53] – 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.

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[50] Division of Restorative Dentistry, University of Bristol Dental School, Bristol, United Kingdom and Editor of *Dental Caries*.
[51] Department of Oral Biology, Faculty of Dentistry, The University of Manitoba, Canada.
[52] Oral Health Research Institute, Indiana University School of Dentistry, United States.
[53] Both of these experts have undertaken consultancy work for The Wrigley Co.

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. Summary

3.1 Ingested calcium

In terms of the contribution of ingested calcium to bone health, the WHO/FAO (2003) reported convincing evidence that a sufficient intake of calcium and vitamin D *together* reduced the risk of osteoporosis among older people.

There is some evidence that calcium-rich foods may reduce the risk of dental caries and dental erosion.

To date, there is limited evidence for a beneficial effect of calcium on hypertension and weight regulation, although there is emerging evidence that calcium may be beneficial in reducing the risk of colorectal cancer.

The NHMRC and NZMoH have set a UL for calcium intake of 2,500 mg/day, thus, there is a potential risk of excess intakes from additional calcium in the food supply.

There is also 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 Application to add calcium to a range of foods indicated that this was unlikely to cause inadequacy of other nutrients as a result of nutrient interactions.

3.2 Topical calcium

There is considerable clinical evidence to support using chewing gum (≤0.2% residual sugars) as part of a daily dental health care plan but not in place of regular daily brushing. There is some evidence that chewing gum (≤0.2% residual sugars) with added calcium may offer an additional benefit.

The evidence from 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. There is insufficient evidence to date, however, that calcium-fortified chewing gum reduces the risk of dental caries in the long term (Lingstrom *et al*., 2003a)

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.

References

Australian Bureau of Statistics (1997) *National Nutrition Survey: Selected Highlights Australia*. ABS, Canberra.

Australian Bureau of Statistics (1998) *National nutrition survey: nutrient intakes and physical measurements. Australia. 1995*. Report No. catalogue No 4805.0, ABS, Canberra.

Australian Bureau of Statistics (1999) *National nutrition survey: foods eaten. Australia. 1995*. ABS, Canberra.

Barba, G. and Russo, P. (2006) Dairy foods, dietary calcium and obesity: a short review of the evidence. *Nutr.Metab Cardiovasc.Dis.* 16(6):445-451.

Beilin, L.J. and Jennings, G.L. (2004) *Non-drug management of hypertension*. National Heart Foundation of Australia.

Chevalley, T., Rizzoli, R., Nydegger, V., Slosman, D., Rapin, C.H., Michel, J.P., Vasey, H. and Bonjour, J.P. (1994) Effects of calcium supplements on femoral bone mineral density and vertebral fracture rate in vitamin-D-replete elderly patients. *Osteoporos.Int* 4(5):245-252.

Chow, L.C., Takagi, S., Shern, R.J., Chow, T.H., Takagi, K.K. and Sieck, B.A. (1994) Effects on whole saliva of chewing gums containing calcium phosphates. *J.Dent.Res.* 73(1):26-32.

Dawes, C. and Macpherson, L.M. (1992) Effects of nine different chewing-gums and lozenges on salivary flow rate and pH. *Caries Res.* 26(3):176-182.

Dawson-Hughes, B., Dallal, G.E., Krall, E.A., Sadowski, L., Sahyoun, N. and Tannenbaum, S. (1990) A controlled trial of the effect of calcium supplementation on bone density in postmenopausal women. *N Engl J Med* 323(13):878-883.

Fowler, E.B., Breault, L.G. and Cuenin, M.F. (2001) Periodontal disease and its association with systemic disease. *Mil.Med.* 166(1):85-89.

Gonzalez, C.A. (2006) Nutrition and cancer: the current epidemiological evidence. *Br.J.Nutr.* 96 Suppl 1:S42-S45.

Hayes, C. (2001) The effect of non-cariogenic sweeteners on the prevention of dental caries: a review of the evidence. *J Dent.Educ* 65(10):1106-1109.

Heaney, R.P. (2007) Bone health. *Am.J Clin.Nutr* 85(1):300S-303S.

Heaney, R.P., Recker, R.R. and Hinders, S.M. (1988) Variability of calcium absorption. *Am.J.Clin.Nutr.* 47(2):262-264.

Iijima, Y., Cai, F., Shen, P., Walker, G., Reynolds, C. and Reynolds, E.C. (2004b) Acid resistance of enamel subsurface lesions remineralized by a sugar-free chewing gum containing casein phosphopeptide-amorphous calcium phosphate. *Caries Res.* 38(6):551-556.

Iijima, Y., Cai, F., Shen, P., Walker, G., Reynolds, C. and Reynolds, E.C. (2004a) Acid resistance of enamel subsurface lesions remineralized by a sugar-free chewing gum containing casein phosphopeptide-amorphous calcium phosphate. *Caries Res.* 38(6):551-556.

Institute of Medicine (1997) *Dietary Reference Intakes for calcium, phosphorous, magnesium, vitamin D and fluoride*. National Academy Press, Washington.

Institute of Medicine. (2006) Dietary Reference Intakes: The essential guide to nutrient requirements. National Academy Press, Washington D.C.

Lappe, J.M., Travers-Gustafson, D., Davies, K.M., Recker, R.R. and Heaney, R.P. (2007) Vitamin D and calcium supplementation reduces cancer risk: results of a randomized trial. *Am.J Clin.Nutr* 85(6):1586-1591.

Lau, E.M., Lynn, H., Chan, Y.H. and Woo, J. (2002) Milk supplementation prevents bone loss in postmenopausal Chinese women over 3 years. *Bone* 31(4):536-540.

Leach, S.A., Lee, G.T. and Edgar, W.M. (1989) Remineralization of artificial caries-like lesions in human enamel in situ by chewing sorbitol gum. *J.Dent.Res.* 68(6):1064-1068.

Lingstrom, P., Holm, A.K., Mejare, I., Twetman, S., Soder, B., Norlund, A., Axelsson, S., Lagerlof, F., Nordenram, G., Petersson, L.G., Dahlgren, H. and Kallestal, C. (2003d) Dietary factors in the prevention of dental caries: a systematic review. *Acta Odontol.Scand.* 61(6):331-340.

Lingstrom, P., Holm, A.K., Mejare, I., Twetman, S., Soder, B., Norlund, A., Axelsson, S., Lagerlof, F., Nordenram, G., Petersson, L.G., Dahlgren, H. and Kallestal, C. (2003a) Dietary factors in the prevention of dental caries: a systematic review. *Acta Odontol.Scand.* 61(6):331-340.

Lingstrom, P., Holm, A.K., Mejare, I., Twetman, S., Soder, B., Norlund, A., Axelsson, S., Lagerlof, F., Nordenram, G., Petersson, L.G., Dahlgren, H. and Kallestal, C. (2003b) Dietary factors in the prevention of dental caries: a systematic review. *Acta Odontol.Scand.* 61(6):331-340.

Lingstrom, P., Holm, A.K., Mejare, I., Twetman, S., Soder, B., Norlund, A., Axelsson, S., Lagerlof, F., Nordenram, G., Petersson, L.G., Dahlgren, H. and Kallestal, C. (2003c) Dietary factors in the prevention of dental caries: a systematic review. *Acta Odontol.Scand.* 61(6):331-340.

Manning, R.H. and Edgar, W.M. (1993) pH changes in plaque after eating snacks and meals, and their modification by chewing sugared- or sugar-free gum. *Br.Dent.J.* 174(7):241-244.

Myers, V.H. and Champagne, C.M. (2007) Nutritional effects on blood pressure. *Curr.Opin.Lipidol.* 18(1):20-24.

National Health and Medical Research Council (2003a) *Food for health: Dietary guidelines for Australian adults*. NHMRC, Canberra.

National Health and Medical Research Council (2003b) *Food for health: Dietary guidelines for Children and Adolescents in Australia*. NHMRC, Canberra.

National Health and Medical Research Council and New Zealand Ministry of Health (2006) *Nutrient reference values for Australia and New Zealand including recommended dietary intakes*. NHMRC, Canberra.

New Zealand Ministry of Health (1997) Food and nutrition guidelines for healthy childrens aged 2-12 years - a backgound paper. 2nd Edition ed, Ministry of Health, Wellington.

New Zealand Ministry of Health (1998) *Food and nutrition guidelines for healthy adolescents - a backgound paper*. Ministry of Health, Wellington.

New Zealand Ministry of Health (2003) *Food and nutrition guidelines for healthy adults: a backgound paper*. Ministry of Health, Wellington.

Park, K.K., Schemehorn, B.R., Bolton, J.W. and Stookey, G.K. (1990) Effect of sorbitol gum chewing on plaque pH response after ingesting snacks containing predominantly sucrose or starch. *Am.J.Dent.* 3(5):185-191.

Pasco, J.A., Sanders, K.M., Henry, M.J., Nicholson, G.C., Seeman, E. and Kotowicz, M.A. (2000) Calcium intakes among Australian women: Geelong Osteoporosis Study. *Aust.N.Z.J.Med.* 30(1):21-27.

Prince, R., Devine, A., Dick, I., Criddle, A., Kerr, D., Kent, N., Price, R. and Randell, A. (1995) The effects of calcium supplementation (milk powder or tablets) and exercise on bone density in postmenopausal women. *J Bone Miner.Res* 10(7):1068-1075.

Reid, I.R. (2005) *Calcium in the prevention and treatment of osteoporosis*. Proceedings of the Vitamin D and Calcium Forum. Osteoporosis Australia, Sydney, 28-43.

Reynolds, E.C., Cai, F., Shen, P. and Walker, G.D. (2003) Retention in plaque and remineralization of enamel lesions by various forms of calcium in a mouthrinse or sugar-free chewing gum. *J.Dent.Res.* 82(3):206-211.

Ruegsegger, P., Keller, A. and Dambacher, M.A. (1995) Comparison of the treatment effects of ossein-hydroxyapatite compound and calcium carbonate in osteoporotic females. *Osteoporos.Int* 5(1):30-34.

Russell, D., Parnell, W. and Wilson, N. (1999) *NZ food: NZ people: key results of the 1997 national nutrition survey*. Ministry of Health, Wellington.

Schirrmeister, J.F., Seger, R.K., Altenburger, M.J., Lussi, A. and Hellwig, E. (2007) Effects of various forms of calcium added to chewing gum on initial enamel carious lesions in situ. *Caries Res.* 41(2):108-114.

Selwitz, R.H., Ismail, A.I. and Pitts, N.B. (2007) Dental caries. *Lancet* 369(9555):51-59.

Shen, P., Cai, F., Nowicki, A., Vincent, J. and Reynolds, E.C. (2001) Remineralization of enamel subsurface lesions by sugar-free chewing gum containing casein phosphopeptide-amorphous calcium phosphate. *J.Dent.Res.* 80(12):2066-2070.

Suda, R., Suzuki, T., Takiguchi, R., Egawa, K., Sano, T. and Hasegawa, K. (2006) The effect of adding calcium lactate to xylitol chewing gum on remineralization of enamel lesions. *Caries Res.* 40(1):43-46.

Szoke, J., Banoczy, J. and Proskin, H.M. (2001) Effect of after-meal sucrose-free gum-chewing on clinical caries. *J.Dent.Res.* 80(8):1725-1729.

Therapeutic Goods Administration (2006) *Substances that may be used in Listed medicines in Australia*. 23 January 2007.

Vincent, J. and Reynolds, E.C. (2007) Effects of various forms of calcium added to chewing gum on initial enamel carious lesions in situ. *Caries Res.* 41(5):336.

Vogel, G.L., Zhang, Z., Carey, C.M., Ly, A., Chow, L.C. and Proskin, H.M. (1998c) Composition of plaque and saliva following a sucrose challenge and use of an alpha-tricalcium-phosphate-containing chewing gum. *J.Dent.Res.* 77(3):518-524.

Vogel, G.L., Zhang, Z., Carey, C.M., Ly, A., Chow, L.C. and Proskin, H.M. (1998b) Composition of plaque and saliva following a sucrose challenge and use of an alpha-tricalcium-phosphate-containing chewing gum. *J.Dent.Res.* 77(3):518-524.

Vogel, G.L., Zhang, Z., Carey, C.M., Ly, A., Chow, L.C. and Proskin, H.M. (1998a) Composition of plaque and saliva following a sucrose challenge and use of an alpha-tricalcium-phosphate-containing chewing gum. *J.Dent.Res.* 77(3):518-524.

Vogel, G.L., Zhang, Z., Carey, C.M., Ly, A., Chow, L.C. and Proskin, H.M. (2000) Composition of plaque and saliva following use of an alpha-tricalcium-phosphate-containing chewing gum and a subsequent sucrose challenge. *J.Dent.Res.* 79(1):58-62.

Weingarten, M.A., Zalmanovici, A. and Yaphe, J. (2004) Dietary calcium supplementation for preventing colorectal cancer and adenomatous polyps. *Cochrane.Database.Syst.Rev.* (1):CD003548.

WHO/FAO (2003) *Diet, Nutrition and the Prevention of Chronic Disease*. Report No. WHO Technical report Series 916, World Health Organization, Geneva.

Winston, A.E. and Bhaskar, S.N. (1998) Caries prevention in the 21st century. *J Am.Dent.Assoc.* 129(11):1579-1587.

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 survey 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 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[54] age group of Australian survey respondents and New Zealand survey respondents was 40-44 years. Table 2 presents a breakdown of the sample by age groups that were collected in the survey.

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[55] were used for each country.

[54] 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.

[55] Quartiles are divisions of data into four equal parts, so that each quartile represents 1/4th of the sample or population.

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+

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.

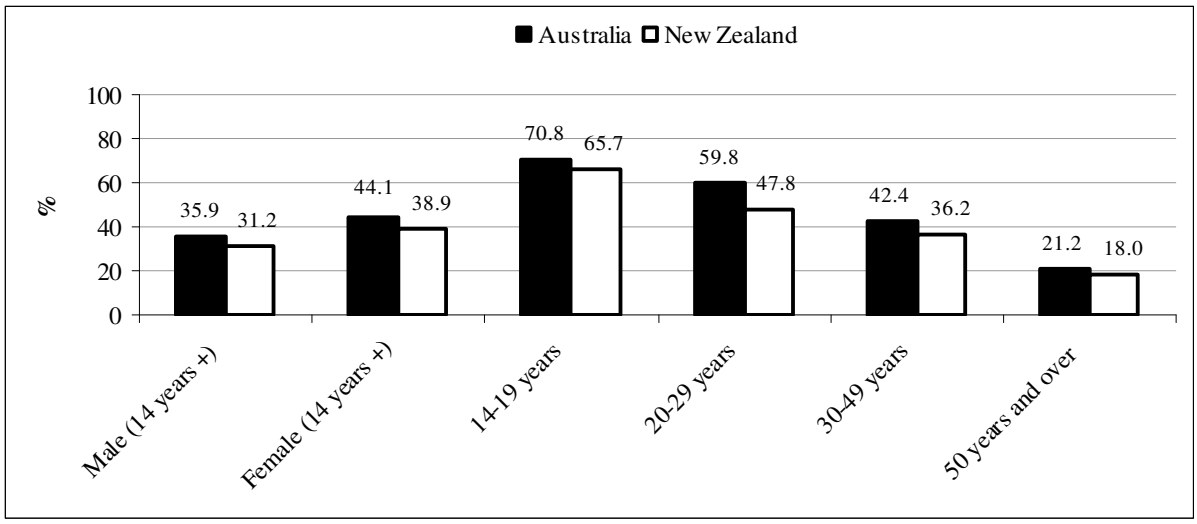
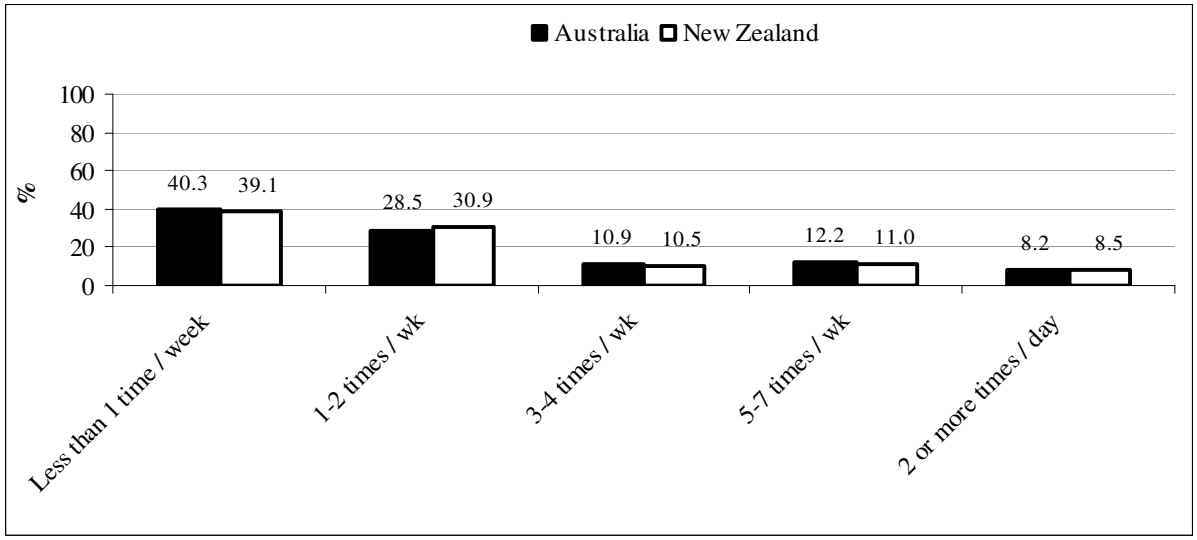


Figure 1: Proportion of Australians and New Zealanders who consume gum (≤0.2% residual sugars), by gender and age group

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).

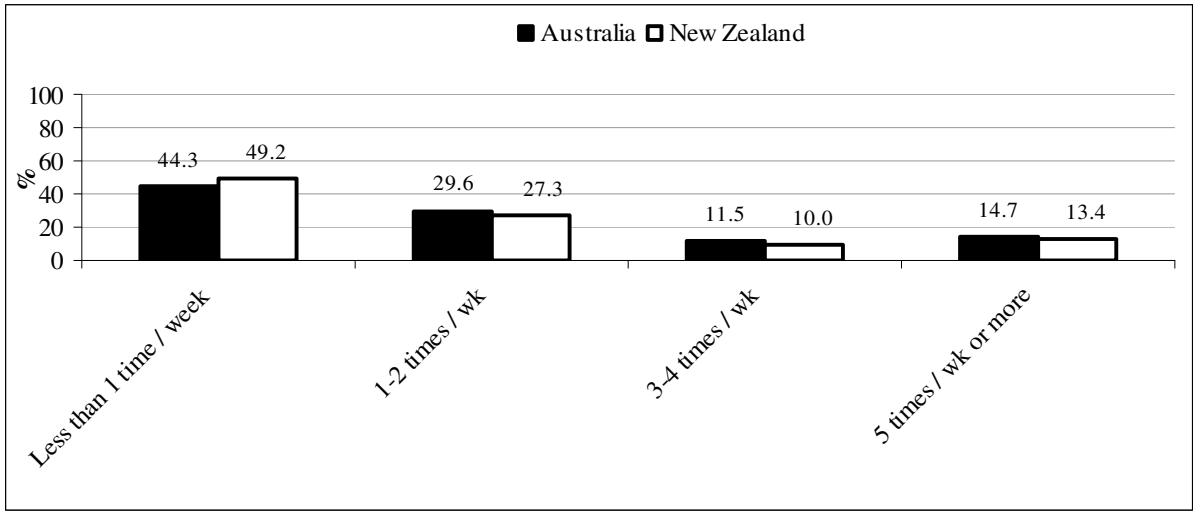
Figure 2 shows that of Australians and New Zealanders who are self-reported consumers of pellet chewing gum (≤0.2% residual sugars), around 40% consume this chewing gum less than one time per week. Around 30% consume pellets between one and two times per week. There is an observed decline in consumers of pellets of this chewing gum with increasing consumption frequency.



Note: Data has 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.

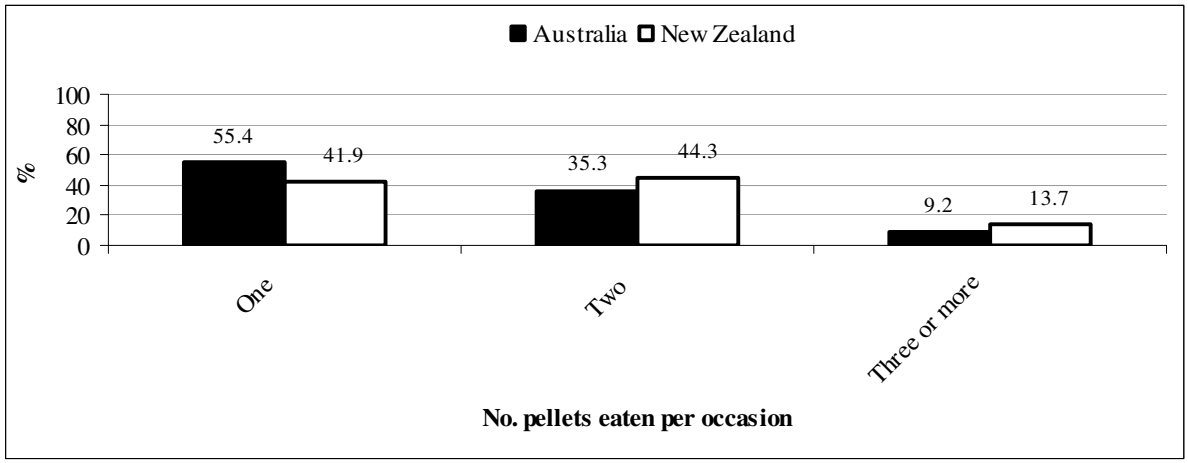


Note: Data has been combined into larger groups were cell sizes were less than 30 (as specified in Section 3.3). Responses of tab consumption 5-6 times per week, once per day, 2-3 times per day, 4-5 times per day and more than 5 times per day were combined.

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?

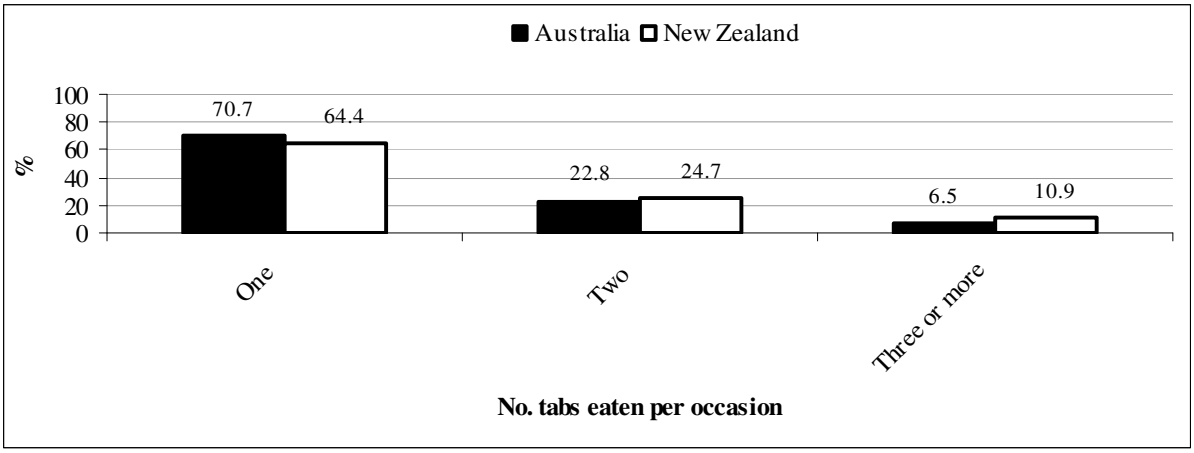
Figure 4 indicates that for self-reported consumers of pellet chewing gum (≤0.2% residual sugars), the highest proportion of people consume one or two pellets per eating occasion. The mean consumption of pellet chewing gum (≤0.2% residual sugars) per eating occasion was around one and a half pellets per eating occasion for both Australians and New Zealanders.



Note: Data has 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 has 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.

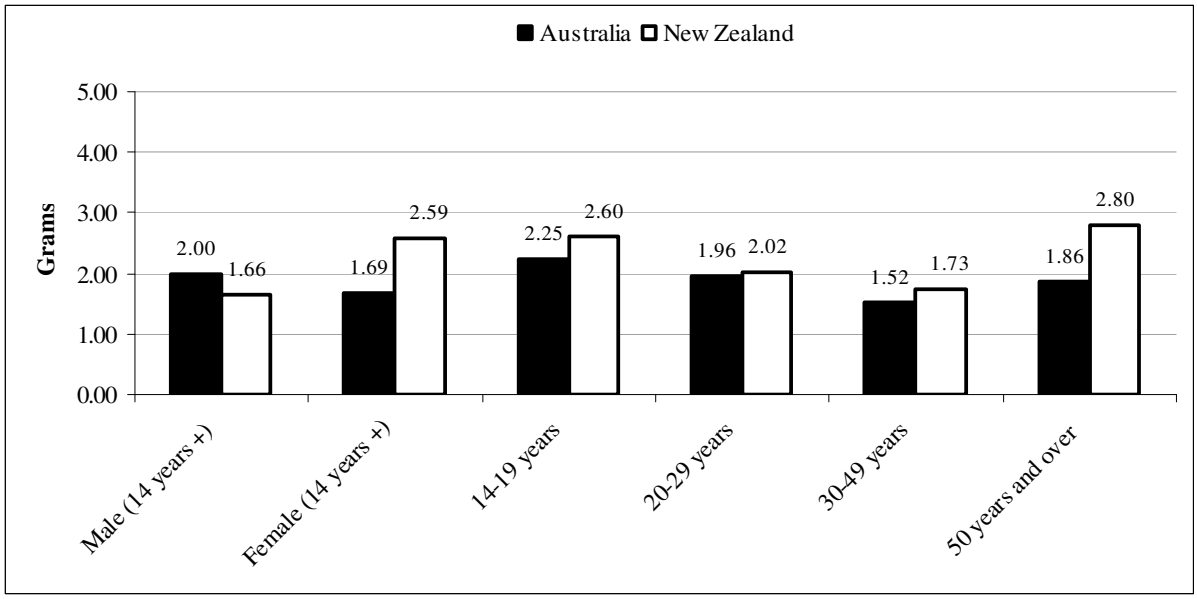


Figure 6: Mean daily consumption of chewing gum (≤0.2% residual sugars), ***chewing gum consumers only****, by gender and age group*

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).

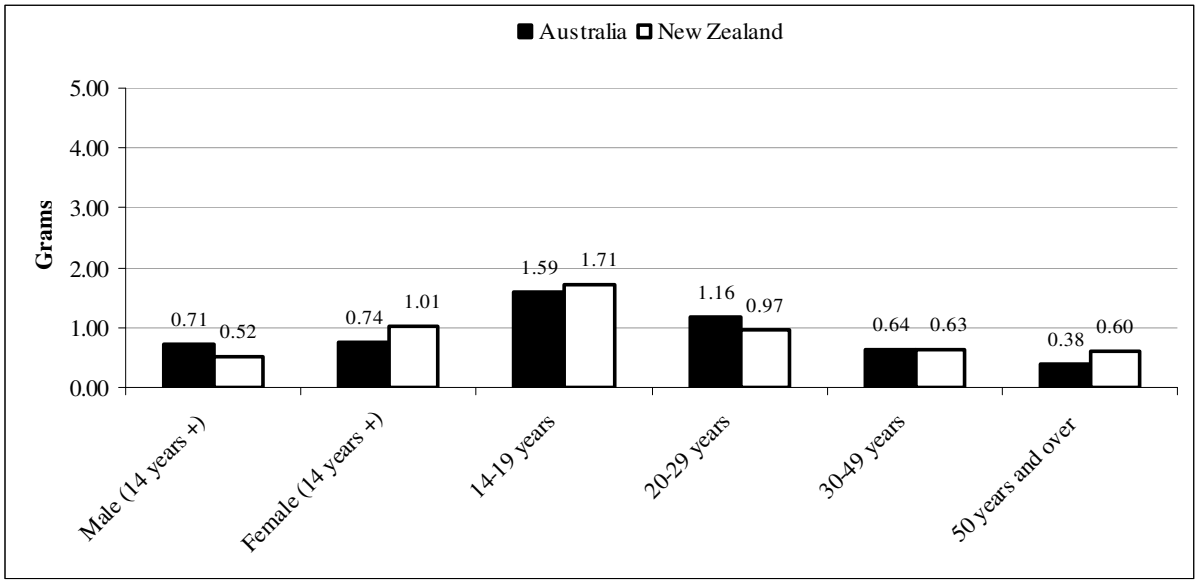


Figure 7: Mean daily consumption of chewing gum (≤0.2% residual sugars), ***overall population****, by gender and age group*

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.

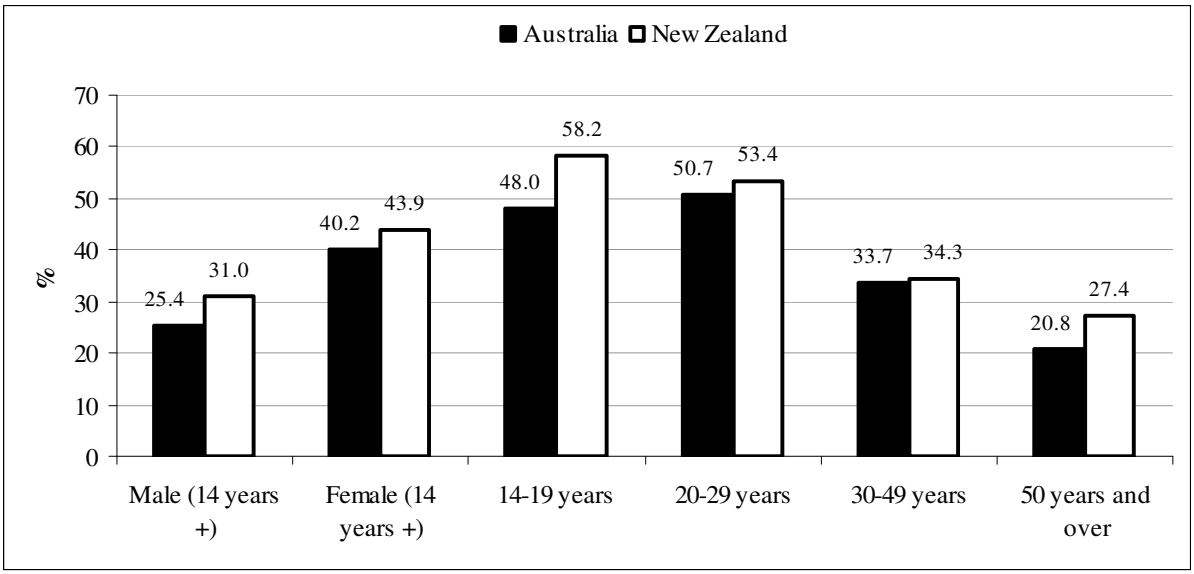


Figure 8: Proportion of those interested in buying calcium-fortified chewing gum (≤0.2% residual sugars)

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[56]. 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[57].

Results below are unweighted numbers of responses as cell sizes are predominantly less than 30 (see Section 3.3).

One hundred and seventy Australian respondents and 164 New Zealand respondents indicated they would replace foods in their diet with calcium-fortified chewing gum (≤0.2% residual sugars). Seventy-five 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 has been used to:

[56] Weighted quantities presented here.
[57] A single respondent was able to select more than one food.

- Calculate the additional calcium intake per population sub-group through the addition of calcium to chewing gum (≤0.2% residual sugars) (see Attachment 2 – 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 – Risk Assessment Report).

- 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 3 – Risk Assessment Report).

- Determine the potential for substitution of other calcium-rich foods in the diet (see Attachment 3 – Risk Assessment Report).

Attachment 5

Summary of Submissions

FSANZ received 17 submissions in response to the Initial Assessment Report on Application A577 – Calcium in Chewing Gum Containing No More Than 0.2% Sugars, during the 6-week public consultation period of 4 October to 15 November 2006. A summary of submitter comments is provided in the table below.

Two regulatory options were presented in the Initial Assessment Report:

Option 1 – Maintain the *status quo*; or

Option 2 – Amend Standard 1.3.2 to permit the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 100 mg per reference quantity.

No.	Submitter	Submission Comments
Consumer		
1	**CHOICE (formerly the Australian Consumers' Association)** *Ms Clare Hughes*	**Preferred Option Not Specified** Agrees with the principle of fortifying certain foods with vitamins and minerals in order to address significant deficiencies in those nutrients. However, considers food vehicles should be carefully selected to ensure that fortification delivers appropriate amounts of these nutrients to the target populations without causing excessive consumption among other consumers. ***Potential health benefits*** Considers the Initial Assessment Report (IAR) did not provide sufficient evidence for the health benefits of calcium-fortified chewing gum. Believes there may be some dental health benefit, but is not convinced that the product should be presented as an appropriate source of calcium, especially as 5 pellets provides only 10% of the Recommended Dietary Intake (RDI). ***Bioavailability and forms of calcium*** Notes there are unanswered questions about bioavailability of calcium in chewing gum, the amount of calcium that reaches the gut for absorption, how long the chewing gum needs to be chewed to ensure maximum intake of calcium, and the amount of calcium that remains in the unswallowed chewing gum. ***Food vehicle*** Considers the FSANZ application process does not allow for selection of the 'most appropriate' food vehicle(s) to deliver a particular nutrient to the target group, and instead manufacturers decide and apply to have the Code amended accordingly. Therefore, considers that voluntary fortification is more successful in promoting industry innovation than addressing nutrient deficiencies.

No.	Submitter	Submission Comments
		Serving size Concerned that a serving size of 5 pellets of gum is not consistent with normal consumer use of the product. Considers that few consumers are likely to eat 5 pellets in one day, and therefore are unlikely to consume a sufficient amount of calcium-fortified chewing gum to achieve the stated health benefit. Considers the IAR did not provide adequate justification for this serving size. Notes that if consumers increase their consumption of calcium-fortified chewing gum to 5 pellets per day their intake of intense sweeteners will also increase, which can have adverse effects on the gastrointestinal system when consumed in excess quantities. ***Potential to mislead consumers*** Unsure whether consumers will substitute chewing gum for other dietary sources of calcium as chewing gum is not consumed as a food for the purpose of nutrition or satiety. Considers there is a risk that consumers may believe that the product is contributing more calcium than it actually is and may not seek out other calcium rich foods. Considers consumers may also be misled if they do not understand that they need to eat 5 pellets of chewing gum per day to obtain sufficient calcium from the chewing gum to have the stated health or nutritional benefit.
Academic		
2	**Professor Eric C. Reynolds** *Head of the School of Dental Science, The University of Melbourne*	**Supports Option 1** ***Potential health benefits*** *Dental health* States the suggestion that calcium-fortified chewing gum (≤0.2% residual sugars) should increase the potential benefits of tooth remineralisation is not consistent with peer-reviewed published studies that suggest that fortification with calcium (of the types permitted in Standard 1.1.1) of chewing gum (≤0.2% residual sugars) and other foods does not result in the reduction of dental caries experience. Describes the pathological process of tooth destruction, which results in dental caries, and lists the factors influencing whether a lesion will progress to a frank cavity that requires restoration (filling). Comments that remineralisation *per se* does not mean that the lesion will not finally progress to a frank cavity, as remineralisation can vary in quality. Therefore, considers that a non-fluoride product that is claiming 'remineralisation' needs to demonstrate that the remineralisation produced by normal use of the product will result in the formation of a structured mineral and a significant slowing of caries progression relative to a control used in an identical matter.

No.	Submitter	Submission Comments
		This would need to be demonstrated in a randomised, controlled, double-blind caries clinical trial. Is only aware of one form of calcium, casein phosphopeptide stabilised amorphous calcium phosphate (CCP-ACP) or Recaldent™ that has been demonstrated to slow caries progression in such a trial (Morgan *et al*, 2006). States that to effect substantial remineralisation the calcium ions must be released from the chewing gum while chewing, the released calcium ions must be stabilised from complexing with salivary phosphate and fluoride ions, and must be localised at the tooth surface in an ionic form to produce an effective concentration gradient into the subsurface lesion. States that calcium carbonate and the calcium phosphates in chewing gum (≤0.2 % residual sugars), even at high concentrations, are poorly released from the chewing gum while chewing and poorly remineralise enamel subsurface lesions relative to CPP-ACP (Morgan *et al*, 2006; Reynolds *et al*, 2003). Reference a review by Lingstrom *et al, 2003* who concluded that 'no caries-preventative effect was found from adding calcium phosphate to chewing gums'. Describes a potential risk associated with the addition of unstabilised calcium to chewing gum (≤0.2% residual sugars). This may place the consumer at risk of developing dental calculus (tartar) and periodontal disease. This risk is high in individuals with poorly stabilised calcium phosphate in their saliva and dental plaque. Therefore, it is essential to include molecules in the gum with the calcium that stabilise calcium, phosphate and fluoride ions and do not allow transformation into the insoluble phases to promote dental calculus. Notes that remineralisation is only effective when caries are at an early stage. States there is no evidence that dietary calcium supplementation reduces caries experience (Lingstrom *et al*, 2003) and it has been shown that only highly structured remineralisation with acid-resistant mineral will translate into a lowering of caries risk, as shown by fluoride and/or casein phosphopeptide stabilised amorphous calcium phosphate (CCP-ACP) (Iijima *et al*, 2004). ***Bioavailability and forms of calcium*** Notes the proportion of calcium left in the unswallowed chewing gum would depend on the form of calcium used. Notes that a very small proportion of calcium in chewing gum (≤0.2% residual sugars) is available to remineralise subsurface tooth enamel. States the permitted forms of calcium listed in Standard 1.1.1 are poorly bioavailable in terms of providing calcium ions that are capable of diffusing into subsurface tooth enamel. Comments that many chewing gums (≤0.2% residual sugars) already contain calcium carbonate and/or calcium phosphates as fillers in the gum base.

No.	Submitter	Submission Comments
		States that calcium in the form of calcium carbonate and calcium phosphate has low bioavailability from chewing gum (≤0.2% residual sugars) (Reynolds *et al*, 2003). Here bioavailability is defined as the ability of the calcium to be released from the chewing gum in saliva and deposited in crystallite voids in subsurface enamel to produce structured, acid-resistant mineral (Iijima *et al*, 2004). Comments that some forms of calcium permitted in Standard 1.1.1 may have a slight effect on tooth remineralisation though this would be minor and unlikely to translate into a caries benefit. Comments that only the very soluble forms of calcium listed are likely to significantly contribute to salivary calcium concentrations, however this increase in salivary calcium concentration will not necessarily result in increased remineralisation unless the calcium ions are localised at the tooth surface in high concentration. ***Potential to mislead consumers*** Considers it likely that a claim related to the added calcium will be made, e.g. 'calcium is good for strong bones and teeth'. Believe this claim misleads the consumer to assume that the calcium in the chewing gum can directly strengthen teeth and make them more resistant to tooth decay. Considers consumers may be misled to believe that the added calcium, through remineralisation, will lower the risk of dental caries (tooth decay). ***Labelling and claims*** Considers a 'strengthens teeth' claim should only be allowed for products that have been demonstrated to slow caries progression in a randomised, controlled, caries clinical trial (e.g. fluoride and CPP-ACP). ***Impact analysis*** Considers Option 2 would encourage chewing gum manufacturers to incorporate a cheap form of calcium in their chewing gum and then make a claim, which will mislead consumers. ***References*** Provides a number of references.
Public Health		
3	**Dietitians Association of Australia** *Ms Kate Poyner*	**Supports Option 2 (in relation to dental health only)** Supports Option 2, however does not support the use of any claims for a source of calcium in this product. Support is based on the improved dental health proposition not on making a significant nutritional contribution to calcium intake in the population.

No.	Submitter	Submission Comments
		Potential health benefits *Dental health* Supports the role of calcium-fortified chewing gum in promoting improved dental health, as shown by available evidence. *Addressing calcium deficiency and/or inadequacy* Considers there is insufficient evidence to support the role of calcium-fortified chewing gum (≤0.2% residual sugars) in improving nutritional status, specifically increasing the dietary calcium intake of Australians, for the following reasons: • the suggested serve size of 5 pellets is unrealistic; • the sweetening agents used in chewing gums (≤0.2% residual sugars) may have adverse gastrointestinal effects when consumed in large quantities; • there is no information on the degree of absorption of calcium from fortified gum; and • some consumers may believe that they can replace food sources of calcium. Notes that calcium is only one of several nutrients required for strong healthy bones throughout life. ***Bioavailability and forms of calcium*** Considers more information on the bioavailability of calcium from chewing gum (≤0.2% residual sugars) is needed to support any nutritional benefit. ***Food vehicle*** Considers calcium-fortified chewing gum (≤0.2% residual sugars) is an appropriate food vehicle to deliver a dental health benefit, however its use as a dietary source of calcium is limited. ***Serving size*** Considers a serving size of 5 pellets is unrealistic and would not constitute a single serve for most consumers. Notes the Applicant uses a 1 pellet serve in all other nutrition information, and that the requested serving size of 5 pellets appears to be based solely on making a source claim for calcium. Considers a claim based on 5 pellets is potentially misleading to consumers who do not note the number of pellets that need to be consumed to achieve the amount of calcium required to support a source claim. Notes that if eaten in large amounts chewing gum (≤0.2% residual sugars) can produce adverse gastrointestinal symptoms.

No.	Submitter	Submission Comments
		Target group(s) Considers the target groups appear to be current consumers of chewing gum (≤0.2% residual sugars) who are concerned with dental health, and those who believe that they are not consuming sufficient calcium. ***Potential to mislead consumers*** Concern that consumers may believe that calcium-fortified chewing gum (≤0.2 % residual sugars) will make a significant contribution to their daily calcium requirement. Considers there is a risk that consumers will be misled as to the nutritional quality of calcium-fortified chewing gum (≤0.2% residual sugars), due to the large serving size and uncertainty regarding the bioavailability of calcium in the chewing gum. Considers it would be useful to investigate the likelihood of calcium-fortified chewing gum being used as a replacement for other calcium rich foods, or as an additional food in the diet. ***Impact analysis*** *Option 1* Considers there may be a marginally reduced dental health role from chewing gum (≤0.2% residual sugars) without calcium. Notes that as the bioavailability of calcium in a fortified product is not known it is not possible to quantify the nutritional impact of maintaining the status quo. *Option 2* Considers the dental benefits of allowing calcium-fortified chewing gum (≤0.2% residual sugars) may over time lead to a reduction in dental caries and demand on dental health services, and thus benefit consumers and government, though the amount of this benefit is difficult to predict. The market for chewing gum (≤0.2% residual sugars) may increase through the introduction of a calcium-fortified product. ***Regulation as a therapeutic good*** Considers it may be more appropriate for calcium-fortified chewing gum (≤0.2% residual sugars) to be listed as a therapeutic good, as the proposed product contains no other nutrients and is similar to a vitamin/mineral supplement.

No.	Submitter	Submission Comments
Industry		
4	**Australian Food and Grocery Council** *Mr Kim Leighton*	**Supports Option 2** Supports the permission to add calcium in the various forms to chewing gum (≤0.2% residual sugars). Considers the fortification of chewing gum (≤0.2% residual sugars) meets the requirements of the Policy Guideline for voluntary fortification and that, subject to a safety assessment, Option 2 should be supported. ***Potential health benefits*** *Dental health* Considers the principle benefit of permitting calcium-fortified chewing gum (≤0.2% residual sugars) is the remineralisation of teeth and dental hygiene. *Addressing calcium deficiency and/or inadequacy* Considers that while the amount of available calcium from chewing gum may, on its own, be insufficient to address nutritional deficiency, in combination with other fortified products it would contribute in addressing the nutritional requirement of a subsection of the population. ***Policy Guideline on voluntary fortification*** Considers evidence of the increasing incidence of osteoporosis and the dental health crisis clearly demonstrates a need for increasing calcium intakes. Considers the data provided by the Applicant demonstrates the bioavailability and benefits of calcium-fortified chewing gum (≤0.2% residual sugars), and therefore that there is a health benefit. Considers chewing gum (≤0.2% residual sugars) is an appropriate food vehicle for calcium fortification, is consistent with the nutrition policy guidelines, and has no impact on eating patterns.
5	**Cadbury Schweppes Pty Ltd** *Mr Neil Smith*	**Supports Option 2 (in relation to increasing dietary calcium only)** In-principle support Option 2, however, only as another means of increasing dietary calcium intake. Concern about the references to dental benefits, such as tooth strengthening and remineralisation. ***Potential health benefits*** Considers increasing dietary calcium intake and dental benefits are two distinct issues and they should be treated separately. *Dental health* Concern if only some of the 14 sources of calcium exhibit the additional protective effect (dental) over and above the protective effects observed from chewing gum with no added calcium.

No.	Submitter	Submission Comments
		Considers the Applicant should provide appropriate peer-reviewed published studies to show which of the 14 forms of calcium provide the additional protective effect (dental) so that these can be differentiated from those forms of calcium that are being added to provide a dietary source of calcium only. ***Bioavailability and forms of calcium*** Notes that calcium is often used as a filler in the gum base of chewing gum, however the form of calcium used is not always readily bioavailable. Notes the presence of 100 mg of calcium alone does not guarantee that 100 % of the calcium in that source is bioavailable and readily absorbed. Considers the Applicant should provide appropriate evidence of peer reviewed studies where all 14 potential sources of calcium have been trialled to identify the percentage and quantity of calcium that is released from the chewing gum, and the bioavailability and absorption rate of each source of calcium. Considers the calcium release studies should be conducted on the specific product that the Applicant proposes to make available in Australia and New Zealand. ***Food vehicle*** Questions the suitability of chewing gum (≤0.2% residual sugars) as a food vehicle for calcium, noting that approximately 30% of a chewing gum is not swallowed and is discarded. Questions why this Application should not be expanded to include other products containing polyols and intense sweeteners, such as hard confectionery candy and beverages. ***Policy Guideline on voluntary fortification*** Supports the voluntary fortification of a wide range of foods with specific nutrients where there is a deficiency of that nutrient in the general population. Considers the Application satisfies the 'Specific Order' Policy Principles, including that it will not promote consumption patterns inconsistent with nutrition policies and will not promote increased consumption of foods high in salt, sugar and fat. ***Impact on consumption patterns*** Believes it is unlikely that chewing gum (≤0.2% residual sugars) will be substituted for traditional sources of calcium, such as dairy products, as the main source of dietary calcium intake. ***Labelling and claims*** Seeks clarification on whether chewing gum (≤0.2% residual sugars) fortified with calcium to a level of 10% RDI would be eligible to make a general level health claim in accordance with the draft health claims Standard released with the Proposal P293 – Nutrition, Health & Related Claims Draft Assessment Report.

No.	Submitter	Submission Comments
		AFGC understanding is that a general level claim such as 'calcium is good for strong bones and teeth' would be permitted. Notes that claims relating to tooth remineralisation are currently not permitted on a food product. Expresses concern that, in the future, under the proposed health claims Standard, dental benefit claims may be approved in confidence as a high level health claim to provide the Applicant some market advantage once the claim has been approved and gazetted. For this reason the AFGC provided the following comments: • the 3 commercially confidential studies provided by the Applicant should be peer-reviewed by cariology experts to determine the appropriateness of the design, and the methods used to measure remineralisation be validated by demonstrating that the same results would be found in a conventional, long-term clinical caries trial conducted with the identical product; and • the Applicant should demonstrate that the deposition of calcium in the early caries lesion is in the form of hydroxyapatite crystals of enamel and not just an accumulation of calcium salts that would later be lost. ***Use of the term 'sugar-free'*** Considers that the term 'sugar-free' needs to be clarified, noting the proposed alignment with ACCC under Proposal P293 that 'free' means zero, even though these products contain residual amounts of sugars. Supports the inclusion of a quantified definition for 'sugar-free' in the proposed health claims standard, in line with those limits previously allowed in the CoPoNC.
6	**Complementary Healthcare Council of Australia** *Mr Allan Crosthwaite*	**Supports Option 1** Does not support the progress of this Application as considers 'remineralisation' to be a therapeutic claim and in principle does not support the fortification of a food which otherwise has no nutritional value making nutritional claims. Expresses concern about the appropriateness of the Australian Dental Association promoting chewing gum (≤0.2% residual sugars) with added calcium for therapeutic effect – 'help repair and strengthen tooth structure', when such claims are currently not substantiated or allowed in the Code and according to FSANZ, the product is unlikely to be generally available in Australia. ***Bioavailability and forms of calcium*** Considers the Applicant should provide clinical trial data to answer questions 1, 2, 4 & 5 outlined in the IAR, as this would be specific to the product formulation and should be answered by an evaluation of the product.

No.	Submitter	Submission Comments
		Notes there is publicly available research on calcium-fortified chewing gum (≤0.2% residual sugars) and remineralisation, however these studies relate to specific forms of calcium and therefore cannot be considered supportive of the specific product formulation for which the claims are being requested. ***Dietary assessment*** Recommends that the Draft Assessment addresses supplement intake, although acknowledges there is no detailed quantified information relating to calcium supplement intake, as a significant proportion of the population (across all demographics) consume these products. ***Potential to mislead consumers*** Considers consumers may be misled to believe that their nutritional or healthcare needs are being catered for by eating certain foods, particularly chewing gum as it is not ingested. ***Impact analysis*** Notes it is not only the food industry that is potentially affected by this Application but also complementary medicines currently regulated as therapeutic goods. Considers consumers do not necessarily differentiate between the different sources of calcium, especially when chewing gum can be compared with similar complementary medicine dosage forms including chewing gum and chewable multi-vitamin/mineral and calcium tablets. ***Regulation as a therapeutic good*** Recommends that consideration be given to the food/therapeutic interface issues related to this Application. Notes chewing gum is an acceptable dosage form for therapeutic supplements, and considers a non-nutritional food used as a dosage form for mineral supplementation and therapeutic action should be regulated as a therapeutic good. Considers its regulation as a therapeutic good would ensure content, stability and bioavailability claims in relation to calcium supplementation and teeth remineralisation. Does not consider it appropriate for FSANZ to consider the remineralisation properties of this food. Consider 'remineralisation' is a high level claim and more appropriately regulated as a therapeutic good. Does not consider dental decay to be a serious disease. Notes the Australian Public Register of Therapeutic Goods contains a listing for a chewing gum product that delivers vitamin C. Comments that a calcium-fortified chewing gum could be listed under the current *Therapeutic Goods Act 1989* and does not have to wait until the Australia New Zealand Therapeutic Products Agency arrangements have been finalised, as indicated in the IAR.

No.	Submitter	Submission Comments
7	**Confectionery Manufacturers of Australasia Ltd** *Ms Jennifer Thompson*	**Supports Option 2** Supports the Application as it will: • provide additional sources of calcium for consumers; • increase the scope for product innovation; and • provide increased consumer choice. ***Potential health benefits*** Considers calcium-fortified chewing gum (≤0.2% residual sugars) will provide existing benefits such as oral hygiene, and would serve to further enhance these benefits. Considers it has the potential to positively impact on consumers in relation to dental and bone heath benefits, and these benefits may reduce public health costs associated with inadequate calcium intake. ***Food vehicle*** Considers chewing gum (≤0.2% residual sugars) is an appropriate food vehicle for voluntary calcium fortification. Considers it will provide an additional source of calcium for consumers, thereby assisting to meet consumers' needs for increased calcium intakes. Considers it will increase the scope for product innovation. ***Policy Guideline on voluntary fortification*** Considers the Application meets the Policy Guideline principles for voluntary fortification. Considers it is unlikely to promote consumption patterns inconsistent with nutrition policy. Considers it will not promote increased consumption of foods high in sugar, fat or salt. Considers it will provide increased consumer choice, as consumers will still have option to choose chewing gum (≤0.2% residual sugars) without added calcium. ***Potential to mislead consumers*** Considers consumers should not be misled by the fortification. ***Use of the term 'sugar-free'*** Notes the residual sugars in the finished product, by virtue of the manufacturing practice, enables manufacturers in Australia and New Zealand to comply with the requirements of the CoPoNC which states that 'sugar-free' means no more than 0.2 g sugars per 100 g food. Considers domestic producers would be able to comply with the Codex requirement of no more than 0.5 g sugars per 100 g food.

No.	Submitter	Submission Comments
		Considers the above international practice recognises the limitations of technology, and the nutritional insignificance associated with minute traces of sugars in 'sugar-free' products.
8	**Dairy Australia** *Ms Jacinta Orr*	**Supports Option 1** ***Bioavailability and forms of calcium*** Comments that the bioavailability of calcium in chewing gum is not clear, including information as to the length of time that the chewing gum must be chewed for calcium to be extracted and digested, and how much is thrown out with the spent gum. Considers questions 1-6 asked in the IAR need to be answered. Comments on the importance of a broad range of vitamins and minerals found in dairy products for bone health and dental health, which is different to the effect of calcium salts in isolation. Provides references to studies that demonstrate that components in dairy food over and above calcium have been shown to be vital for dental health (Moynihan and Peterson, 2004 and Merritt *et al*, 2006). ***Food vehicle*** Considers chewing gum is not an appropriate food for fortification for use by the general population, as it is sold as a confectionery product and provides little nutrition. ***Serving size*** Does not consider 5 pellets is a reasonable serving size, instead believes 1 or 2 pellets is reasonable. Suggests that the Applicant may be manipulating the serving size in order to make a nutrient content claim. ***Policy Guideline on voluntary fortification*** Notes that chewing gum does not have a food group classification and therefore does not fit the 'Specific Order' Policy Principle that *permission to fortify should not promote consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand*. ***Potential to mislead consumers*** Considers that if the product is marketed as a source of dietary calcium, an individual obtaining some of their calcium from the product may be less concerned with ensuring an adequate intake of calcium from more nutritious sources, such as dairy foods.

No.	Submitter	Submission Comments
		Labelling and claims Considers it is not appropriate that calcium-fortified chewing gum (≤0.2% residual sugars) be linked to dental or bone health benefits in the future through a general level health claim, as this could mislead consumers if statements seek to equate the nutritional benefits of chewing gum to dairy foods (implied or direct). Recommends consideration of an advisory statement that reflects dietary guideline recommendations, for example 'dairy foods are the best source of calcium and other nutrients for bone and dental health'. ***References*** Provides some references.
9	**Food Technology Association of Australia** *Mr David Gill*	**Supports Option 2** ***Bioavailability and forms of calcium*** Question, in relation to the bioavailability of calcium to humans, what proof is available to support the claims?
10	**Fonterra Co-operative Group Ltd** *Ms Mara Fisher*	**Supports Option 1** Considers the addition of a nutrient to an otherwise completely non-nutritious substance should not be permitted. ***Potential health benefits*** Does not agree that 3 unpublished and unreviewed studies provide an appropriate level of evidence to support benefits attributed to chewing gum. Until there is sufficient evidence, does not agree that there are benefits that would outweigh the substantial risks to the population from substitution away from nutritional dense, bioavailable sources of nutrients. ***Bioavailability and forms of calcium*** Considers there is insufficient evidence demonstrating the extent to which calcium in chewing gum is bioavailable. Notes that chewing gum does not contain vitamin D, which can assist in the absorption of calcium by between 30 and 80%. Notes there has been no evidence provided as to the length of time that the chewing gum must be chewed for calcium to be extracted and digested, nor as to the perception of consumers as to this length of time. ***Food vehicle*** Does not support chewing gum as a vehicle for fortification, however does support a review of the fortification permissions for nutritious products, such as dairy.

No.	Submitter	Submission Comments
		Serving size Considers that 5 pellets is an inappropriate serving size of chewing gum from the perspective of a consumer. Notes that current chewing gum packages do not state 5 pellets as one serving. Notes that without consumer research it is difficult to know if 5 pellets would be perceived as the serving size. ***Impact on consumption patterns*** Considers there is a strong risk that chewing gum containing calcium will result in substitution away from dairy foods, which will have a detrimental impact on health. ***Potential to mislead consumers*** Comments that chewing gum is not part of a balance diet, and permitting it to be marketed as containing an important nutrient creates a risk that it will be perceived as a nutritious food. Considers permitting the addition of calcium to chewing gum risks a focus on calcium at the expense of other nutrients such as magnesium, vitamin D and iron, which are found in other traditional calcium sources such as dairy. Notes these other nutrients contribute to body and bone health, and considers a focus on calcium alone will detract from the understanding of their roles by consumers. ***Regulation as a therapeutic good*** Considers the addition of calcium to a non-nutritional substance such as chewing gum should be regulated under the *Therapeutic Goods Act 1989*. Considers chewing gum is not a food in terms of its nutritional value. Considers that adding calcium to chewing gum permits it to be marketed as a form of a nutrient supplement, and therefore it should have to comply with the requirements for marketing such supplements. These requirements include warnings, advice on when to consume such chewing gum, and appropriate levels for calcium supplementation.
11	**Nestlé Australia Ltd** *Ms Janet Macdonald*	**Supports Option 1** Supports the addition of vitamins and minerals to food products, however believe that any addition should be appropriate and in the best interest of the consumer. Considers chewing gum is not an appropriate food vehicle for nutrient fortification, and therefore supports maintaining the *status quo*. ***Level of fortification*** Notes the proposed product will contain minimal calcium – 20 mg or 2.5% of the RDI per pellet.

No.	Submitter	Submission Comments
		Comments that if a consumer tried to achieve the RDI for calcium from calcium-fortified chewing gum alone, this would equate to 42 pellets and they could suffer from the laxative effects of the 58 g of polyols contained in the product. ***Bioavailability and forms of calcium*** Notes there has been no evidence provided to show that the calcium will be absorbed as available calcium. Notes that some forms of calcium requested are not water soluble, for example calcium carbonate. If insoluble forms of calcium are used this calcium will be discarded after chewing as chewing gum is usually not swallowed. This raises the concern as to how much calcium can be absorbed. ***Food vehicle*** Considers chewing gum is not an appropriate food vehicle for nutrient fortification. ***Serving size*** States consumer research indicates that most people will eat only one pellet at a time, with heavy users eating up to 5 or 6 pellets in a day. ***Potential to mislead consumers*** Consider a calcium content claim could be misleading to consumers who do not understand the meaning of 'reference quantity'. Considers consumers could be persuaded to use such a product as a substitute to dairy products, fruit juices or cereals, for their calcium intake, particularly those that are weight conscious. As the amount of calcium in the proposed product is small and the bioavailability unknown, this could lead to a negative shift in calcium intake. ***Labelling and claims*** Notes that under existing legislation small packages only need to refer to the calcium content per 100 g, which equates to 5-11 packs of chewing gum (using current products). ***Regulation as a therapeutic good*** Consider calcium-fortified chewing gum (≤0.2% residual sugars) should be regulated under the *Therapeutic Goods Act 1989*, due to the potential for these products to carry therapeutic claims in the future.
12	**The Wrigley Company** *Ms Catherine Pemberton*	**Supports Option 2** ***Level of fortification*** States intent is to *deliver* at least 100 mg of calcium per serve (approximately 5 pellets or pieces of gum), but the product will actually *contain* significantly more calcium as a large proportion of calcium will remain in the cud (unswallowed gum).

No.	Submitter	Submission Comments
		Provides 'chew out' test results (in confidence) that show approximately 25 % of calcium carbonate in fortified chewing gum (≤0.2% residual sugars) is released during 20 minutes of chewing, with approximately 75 % remaining in the chewing gum cud. (Note: the Applicant has since provided updated data). States that to ensure accuracy of expression, they intend to express on the package the amount of calcium in terms of how much is *delivered* to the consumer rather than how much is *contained* in the food, which differs from the usual expression in Standard 1.3.2. ***Potential health benefits*** *Dental health* Notes that if the calcium used in the chewing gum is a calcium compound that is soluble in saliva, such as calcium lactate, this will be dissolved in the saliva and available for the remineralisation of teeth. Any remaining in the saliva when is it swallowed will contribute to dietary calcium. The exact proportion of each is unknown. Notes that if the form of calcium used is an insoluble form, such as calcium carbonate, it will be extracted at a rate of approximately 25% during chewing, but will not be available for tooth remineralisation. This calcium will be swallowed, absorbed and available for distribution in the body. Notes that chewing gum (≤0.2% residual sugars) can help with the remineralisation of teeth because of its stimulating effect on saliva production, and this helps shift the equilibrium to tooth remineralisation. Comments that regardless of whether a soluble form of calcium is used or not, chewing calcium-fortified chewing gum (≤0.2% residual sugars) will be beneficial to dental health. The protective action is enhanced with the addition of a soluble form of calcium to the chewing gum. Provides information and references in relation to standard chewing gum (≤0.2% residual sugars) including, the mechanism for the protection of teeth, how it helps prevent dental lesions, and how it enhances remineralisation. States literature reports clearly show that consuming chewing gum (≤0.2% residual sugars) with calcium helps to enhance the natural remineralisation process that takes place with the stimulation of saliva. In addition, adding calcium in a variety of forms, particularly soluble forms, has a positive effect on teeth in terms of further assisting the process of enamel remineralisation, which results in tooth strengthening. Provides information (in confidence) relating to the effect of calcium-fortified chewing gum (≤0.2% residual sugars) on tooth remineralisation. ***Bioavailability and forms of calcium*** Notes that recommendations from the Vitamin D and Calcium Forum (2005) and Heaney *et al* (1989) both indicate that consuming calcium with food increases its bioavailability.

No.	Submitter	Submission Comments
		Considers that as it is already recommended that chewing gum (≤0.2% residual sugars) should be consumed immediately after meals, drinks and snacks to maximise dental benefits, this is also the most beneficial time for bioavailability of calcium. Considers the issue of bioavailability to be difficult. Notes that FSANZ reported in the Second Review Report for Application A424 – Addition of Calcium to Foods that *studies have shown that age plays the most significant role in determining how much of a nutrient is absorbed, including calcium, rather than its source or chemical form*. Quotes relevant sections from the Application A424 Report and provide supporting references. Comments that any form of calcium that is soluble in saliva will provide calcium ions to the saliva for tooth remineralisation and additional calcium to the body when the saliva is swallowed. ***Technical issues*** States that technically the calcium compound can comprise up to 3-4% of the mass of the chewing gum. Notes some sources of calcium have higher molecular weights than others, therefore the forms with lower molecular weights will provide proportionately more calcium than forms with higher molecular weights. Notes that a more soluble form of calcium is likely to be more bioavailable than a less soluble form. Provides information on 11 forms of calcium relating to their solubility in water and molecular weight. Notes the most likely forms of calcium to be added to chewing gum (≤0.2% residual sugars) to achieve a nutrient function claim will be lower molecular weight forms of calcium like calcium carbonate and calcium phosphates. Notes that technically calcium lactate can be incorporated into chewing gum (≤0.2% residual sugars), but due to its heavy molecular weight it is not possible to achieve 10% RDI in a serve using calcium lactate alone. ***Food vehicle*** Considers chewing gum (≤0.2% residual sugars) is 'highly appropriate' as a food vehicle for the voluntary addition of calcium as: • provides an additional source of supplementary calcium without displacing other calcium rich foods; • most segments of the population have an inadequate calcium intake and the reach of chewing gum (≤0.2% residual sugars) is broad; • the calcium in chewing gum (≤0.2% residual sugars) is as bioavailable as any other source, dietary or supplemental; • consumers can increase their calcium intake with the addition of a very low amount of energy into the diet, and no additional sugar, salt or fat; • one 10 pellet pack of chewing gum (≤0.2% residual sugars) will deliver 20% of the RDI for calcium;

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		• consumers will accrue both the benefit of additional calcium and the additional dental health benefit of tooth remineralisation, which has the potential to cheaply improve the dental health of an ageing population; and • it is a convenient and portable form of calcium fortification which is appealing to consumers. ***Target group(s)*** States the primary target group is women over 35 years of age. The product has been specifically developed to meet the needs of this consumer group, and consumer research indicates that it has appeal and is likely to be consumed by this group. In addition, notes there is broad consumption of chewing gum (≤0.2% residual sugars) across the population, so the dietary supplementation and dental health benefit of this product may be accrued more widely than its primary target. ***Impact on consumption patterns*** Comments there is no evidence to suggest that calcium-fortified chewing gum (≤0.2% residual sugars) would be used as a substitute for other calcium rich foods. Wrigley research indicates that calcium-fortified chewing gum may replace other gum purchases or other confectionery purchases, which are not significant sources of calcium nor may they be fortified with calcium. Considers consumers use chewing gum as an add-on to the normal diet rather than as a replacement for a part of the diet. Considers it highly unlikely that chewing gum would displace any sort of food as it is unlike any other food and unlike any dairy product. It cannot be consumed as a beverage like milk, and is unlike other solid foods in that it is not swallowed. Notes that Wrigley's calcium-fortified chewing gum (≤0.2% residual sugars) has been recently launched in Ireland, but consumption data is not yet available. ***Potential to mislead consumers*** Considers consumers will not be misled as calcium-fortified chewing gum (≤0.2% residual sugars) will comply with all labelling requirements. Considers a consumer who chooses to read the information on the label will not be misled as to the content of the product, or its nutritional value. ***Labelling and claims*** In addition to the regulatory labelling requirements, intends to state the amount of calcium delivered by the product via a product statement and voluntary supplementary information in the Nutrition Information Panel about the percentage daily intake delivered. Comments that the claims currently allowable for a calcium-fortified

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		chewing gum (≤0.2% residual sugars) are limited to nutrient function claims. However, while peer-reviewed clinical evidence exists that consumers accrue the benefit of tooth remineralisation through chewing standard and calcium-fortified chewing gum (≤0.2% residual sugars), this high order claim is not allowable under current food standards. Provides a packaging mock up for the proposed product (in confidence). ***Impact analysis*** *Option 1* Consumer: many consumers are calcium-deficient and will be denied an additional source of calcium in the diet, and will also be denied the additional protection to teeth. Industry: will be denied the opportunity for a new category of products and potential increased sales to the target audience. Government: continued large health costs relating to osteoporosis and dental health. *Option 2* Consumer: will provide consumers with an additional source of calcium in their diet, and thus assist some consumers to achieve more adequate intake of calcium and over the long-term deliver improved bone density and overall improved health outcomes. In addition, it will provide an additional benefit for teeth. Industry: will be given the opportunity for a new category of products and potential increased sales to the target audience, and will renew the incentive for industry to develop novel products that meet a real consumer need. Government: reduced health costs relating to osteoporosis and dental health. ***Use of the term 'sugar-free'*** Considers the issue of 'sugar-free' to be integral to this Application, and to the future of marketing of any calcium-fortified chewing gum, should the Application be approved. Comments that consumers understand that the term 'sugar-free' describes a product where sugars have been replaced by 'other' (non-sugar) sweeteners. Notes that 'sugar-free' claims on food packaging are currently not regulated in the Code, and thus are ultimately regulated by the ACCC and New Zealand Commerce Commission. These bodies maintain that 'free' means zero, however, have determined that claims of 'sugar-free' may continue to be made under the industry code of practice in the absence of any consumer complaints. States that for business, maintaining this system does not deliver certainty or compliance moving forward, and hence does not deliver business confidence. Notes the maximum tolerance level for sugars for 'sugar-free' products set under the CoPoNC is 0.2% compared to 0.5% permitted by Codex.

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		Considers these trace levels of sugar are physiologically, nutritionally and clinically irrelevant. Lists consumer benefits of 'sugar-free' products, including as a choice of sweet treats for those with diabetes or who are obese, and that consuming chewing gum (≤0.2% residual sugars) can reduce the incidence of dental caries by up to 40%. Does not support the use of a '% sugar-free' claim in place of 'sugar-free' as considers this would mislead consumers. Comments that a significant investment has been made in the development of a 'sugar-free' category within the confectionery industry in Australia and New Zealand, with the Wrigley Company investing in excess of approximately $125 million over the past 19 years. The 'sugar-free' segment of the market will require ongoing investment, including new product development. Comments that the 'sugar-free' market is worth over $235 million in retail sales per annum in Australia and New Zealand. Sales from the Wrigley Company make up about 80%, with the majority of these sales being 'sugar-free' chewing gum. Supports the adoption of the 0.2% tolerance currently permitted for 'sugar-free' products under the CoPoNC into the Code to ensure compliance by all manufacturers. ***References*** Provides a number of references relating to bioavailability and dental health benefits.
Government		
13	**Department of Human Services, Victoria** *Mr Victor Di Paola*	**Supports Option 1** Does not support the progression of this Application. ***Bioavailability and forms of calcium*** Considers the calcium present must be in a form to allow effective absorption. ***Food vehicle*** Considers approval of this Application would be 'out of step' with the rest of the world and would set a precedent that would potentially allow the fortification of other confectionery products. ***Serving size*** Considers the serving size of 5 pellets is unrealistic. ***Labelling and claims*** Considers the health claims framework should be finalised prior to considering this and other similar applications.

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		Regulation as a therapeutic good Considers calcium-fortified chewing gum (≤0.2% residual sugars) should be treated as a therapeutic good.
14	**Environmental Health Unit, Queensland Health (with input from the Oral Health Unit)** *Mr Chris Wold*	**Preferred Option Not Specified** ***Potential health benefits*** *Dental health* Considers further evidence is required to support any claims of dental benefits from use of the product. Notes that conventional sugarless chewing gum products only have a small impact on reducing dental decay and studies of the addition of dicalcium phosphate dehydrate to chewing gum has not produced very promising results. Comments that studies published by the University of Melbourne (J Dent Res, 2001) have reportedly shown that certain chewing gums available on the market provide less remineralisation of enamel loss (dental benefit) than a calcium releasing gum which uses CPP technology to regulate the behaviour of the calcium in the chewing gum for dental benefits. Recommends, at the request of their stakeholders, that FSANZ contact Professor Eric Reynolds at the University of Melbourne, who is an internationally recognised expert on calcium bioavailability of chewing gums. ***Bioavailability and forms of calcium*** Notes that the IAR did not identify any concerns regarding the toxicity level of the calcium. Considers further information should be obtained on what types of calcium are proposed to be used in the chewing gum (≤0.2% residual sugars), particularly in relation to the bioavailability and the remineralisation effects of the proposed forms. Notes that literature states that different forms of calcium have varying levels of solubility (Winston *et al*, 1998). Considers there is a lack of information on the release of calcium from the chewing gum (by serving size) and how this will impact bioavailability.

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15	**NSW Food Authority** *Ms Jenine Ryle*	**Preferred Option Not Specified** Does not object to further consideration of this Application as oral health is a large public health issue. Considers answering the questions included in the IAR is imperative as part of the assessment, however is unable to assist with information to answer these questions. ***Policy Guideline on voluntary fortification*** Believes that in assessing this Application consideration of the wider public health effects is warranted, including concerns about fortifying foods which may encourage consumption patterns inconsistent with nutrition policies and guidelines.
16	**New Zealand Food Safety Authority** *Ms Carole Inkster*	**Preferred Option Not Specified** Recognises the public health benefit of additional calcium for certain sectors of the population. Supports FSANZ undertaking the dietary modelling, bioavailability and risk assessment studies as proposed in the IAR. ***Serving size*** Questions the proposed reference quantity of 5 pellets and if there is any consumer research on what consumers consider to be a 'normal serve'. ***Policy Guideline on voluntary fortification*** Supports the assessment of the Application in line with the Policy Guideline for voluntary fortification. ***Use of the term 'sugar-free'*** Notes that adding 'sugar-free chewing gum' to the claimable foods in the Table to clause 3 of Standard 1.3.2 could require a definition of this term in the Code.
17	**South Australia Department of Health** *Ms Joanne Cammans*	**Preferred Option Not Specified** Cannot categorically dismiss consideration of this Application, however, has some concerns over the protocol set by permitting fortification of confectionery, albeit sweetened with polyols and intense sweeteners. ***Potential health benefits*** *Dental health* Notes that as much of the benefits relate to dental health, they intend to consult with the South Australian Dental Association and public health nutritionists at Draft Assessment. Recommends that specific input from dental associations be sought at Draft Assessment.

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		Serving size Considers a serving size of 5 pellets may be misleading if consumer research indicates that 5 pellets would not be normally consumed per day. Questions if the serving size of 5 pellets will be clearly stated on the package. Notes that since the purported benefit of the calcium is only when the gum is consumed immediately following food consumption, the recommendation to chew 5 pellets is not feasible. ***Target group(s)*** Disagrees that a potential target group for this product may be post-menopausal women, as women in this age group are unlikely to consume chewing gum at a level that will convey any benefit. Considers the most likely target group for this product will be teenagers and young adults. ***Impact on consumption patterns*** Agrees that fortified gum is unlikely to replace other foods containing calcium, however recommend more research on this matter. ***Potential to mislead consumers*** Considers consumers may be misled by the use of a calcium content claim on the label, especially if the serving size is 5 pellets. Considers there is also some risk that consumers may be misled as to the nutritional quality of the fortified food.