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

7-06
4 October 2006

INITIAL ASSESSMENT REPORT

APPLICATION A577

ADDITION OF CALCIUM TO 'SUGAR-FREE' CHEWING GUM

DEADLINE FOR PUBLIC SUBMISSIONS: **6pm (Canberra time) 15 November 2006**
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 an Application from the Wrigley Company Pty Ltd (the Applicant) on 22 February 2006, seeking to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to 'sugar-free'[1] chewing gum at a maximum claim level of 100 mg (12.5 % of the Recommended Dietary Intake (RDI)[2]) per reference quantity[3]. The Applicant has requested that all forms of calcium currently permitted in the Schedule to Standard 1.1.1 – Preliminary Provisions - Application, Interpretation and General Prohibitions of the Code, be permitted.

The requested maximum claim level of 100 mg calcium per reference quantity constitutes 12.5 % of the RDI for calcium currently stated in the Code, and 10 % of the RDI as per the *Nutrient Reference Values for Australia and New Zealand*[4]. If the Application is approved, this would currently allow a nutrition content claim for calcium to be made in relation to these products.

The Applicant states the purpose of the proposed amendment is to provide an additional source of calcium for consumers. They also consider that chewing calcium-fortified 'sugar-free' gum will have benefits for both dental and bone health.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- the Application seeks approval to add calcium to 'sugar-free' chewing gum at a maximum claim level of 100 mg per reference quantity. Such an approval, if accepted, would warrant a variation to Standard 1.3.2 of the Code;
- there is currently no permission in the Code for calcium to be added to 'sugar-free' chewing gum;
- the Application is not so similar to any previous application that it should not be accepted;
- there are no other measures that would be more cost-effective than a variation to Standard 1.3.2 that could achieve the same end; and
- at this stage no other relevant matters are apparent.

[1] For the purpose of this Application, and only for this purpose, the term 'sugar-free' will be used to describe chewing gum products in which the sugar has been replaced by polyols and intense sweeteners.
[2] As stated in the Schedule to Standard 1.1.1 of the Code.
[3] The Applicant has requested a reference quantity of 'a normal serve'.
[4] NHRMC and Ministry of Health (2006). Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes. National Health and Medical Research Council: Canberra.

Regulatory Options

FSANZ is currently considering two options for addressing this Application:

Option 1 – Maintain status quo

Maintain the *status quo* by not amending the Code to allow the addition of calcium to 'sugar-free' chewing gum; and

Option 2 – Amend Standard 1.3.2 to permit the addition of calcium to 'sugar-free' chewing gum at a maximum claim level of 100 mg per reference quantity

Option 2 would allow the voluntary addition of calcium to 'sugar-free' chewing gum under Standard 1.3.2 of the Code, at a maximum claim level of 100 mg of calcium per reference quantity.

FSANZ will undertake a full impact analysis at Draft Assessment, however it has included preliminary consideration of the impacts of these two options under Section 10 of this Initial Assessment Report.

Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 1.

CONTENTS

INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report 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 Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 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 commercial-in-confidence. Section 39 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) 15 November 2006.

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 slo@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 an Application from the Wrigley Company Pty Ltd (the Applicant) on 22 February 2006 seeking to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to 'sugar-free'[5] chewing gum at a maximum claim level of 100 mg (12.5 % of the Recommended Dietary Intake (RDI)[6]) per reference quantity[7].

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comment from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

1. Nature of the Application

1.1 Basis of the Application

The Applicant has requested that the Table to clause 3 of Standard 1.3.2 of the Code be amended to permit the addition of calcium to 'sugar-free' chewing gum. The Applicant states the purpose of the proposed amendment is to provide an additional source of calcium for consumers. They also consider that chewing calcium-fortified 'sugar-free' gum will have benefits for both dental and bone health.

1.2 Scope of the Application

Chewing gum is recognised as a food under paragraph 3A(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 has requested that 'sugar-free' chewing gum be permitted to add calcium with a maximum claim level of 100 mg per reference quantity. The Applicant is seeking to allow the addition of all forms of calcium currently permitted in the Schedule to Standard 1.1.1 – Preliminary Provisions - Application, Interpretation and General Prohibitions of the Code.

The Applicant notes that 100 mg calcium constitutes 12.5 % of the RDI for calcium currently stated in the Code, and 10 % of the RDI as per the *Nutrient Reference Values for Australia and New Zealand*[8] (NRVs). If the Application is approved, this would currently allow a nutrition content claim for calcium to be made in relation to these products.

The Applicant has requested that *'a normal serving'* be prescribed as the reference quantity for 'sugar-free' chewing gum in the Table to clause 3 of Standard 1.3.2. The serving size for 'sugar-free' chewing gum has been described by the Applicant as five individual pellets of chewing gum, which equates to a 7 g net weight.

---

[5] For the purpose of this Application, and only for this purpose, the term 'sugar-free' will be used to describe chewing gum products in which the sugar has been replaced by polyols and intense sweeteners.
[6] As stated in the Schedule to Standard 1.1.1 of the Code.
[7] The Applicant has requested a reference quantity of 'a normal serve'.
[8] NHRMC and Ministry of Health (2006). Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes. National Health and Medical Research Council: Canberra.

1.2.1 Use of the term 'sugar-free'

This Application pertains solely to 'sugar-free' chewing gum. The Applicant's 'sugar-free' chewing gum products contain polyols (sugar alcohols), such as sorbitol and maltitol, and intense sweeteners. These polyols technically contribute small amounts of sugar to the final product. FSANZ does not currently have a confirmed position on the use of the term 'sugar-free' for products containing polyols and intense sweeteners.

For the purpose of this Application, and only for this purpose, the term 'sugar-free' will be used to describe chewing gum products in which the sugar has been replaced by polyols and intense sweeteners.

2. Background

2.1 Sources of Calcium

The primary dietary sources of calcium in the Australian and New Zealand diet are dairy foods, with milk contributing about 30 % and cheese contributing about 10 % of calcium intake (National Nutrition Survey, 1995a; Ministry of Health, 1999). In addition to naturally occurring calcium, for example calcium present in dairy products, calcium in foods may be present as fortificant calcium such as that found in some breakfast cereals, soymilk and fruit juices, and those calcium salts permitted as food additives. Dietary supplements may also contribute to total calcium intake, although there is no detailed quantified information relating to calcium supplement intake in the Australian or New Zealand populations.

2.2 Nutritional Role of Calcium

The role of calcium in the diet involves: contributing to building and strengthening of bones in addition to contributing to bone protection by ensuring adequate circulating calcium and avoidance of bone calcium resorption (Jones, 1997); the regulation of cardiac and skeletal muscle contraction; the regulation of certain enzymes; and assistance in nerve transmission (Wylie-Rosset and Swencionis, 1990).

2.2.1 Nutrient Reference Values for Australia and New Zealand for calcium

The NRVs recently endorsed by the Australian and New Zealand governments included two reference values as measures of nutritional adequacy: Estimated Average Requirement (EAR) and RDI. 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 (NHMRC and Ministry of Health, 2006). The RDI is the value established to meet the needs of nearly all healthy individuals in a particular life stage and gender group.

The NRVs also include a measure of safety. The Upper Level of Intake (UL) is the highest intake, including potential intakes from supplements, that is likely to pose no adverse health risk for almost all individuals in the specified life stage group. The UL is not a recommended level of intake; excursions by individuals above the UL increases the risk of adverse health effects.

Table 1 provides the NRVs for calcium endorsed in 2005. These values will be utilised in the dietary intake assessment undertaken for this Application, which will be presented in the Draft Assessment Report.

Table 1: EAR, RDI and UL for calcium intake for Australia and New Zealand

Age	EAR (mg/day)	RDI (mg/day)	UL (mg/day)
1-3 years	360	500	2500
4-8 years	520	700	2500
9-11 years	800	1000	2500
12-18 years	1050	1300	2500
19-50 years	840	1000	2500
51-70 years			
male	840	1000	2500
female	1100	1300	2500
>70 years	1100	1300	2500

The UL for calcium was based on 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 of about 5 g was identified in studies and an uncertainty factor of 2 used to determine the UL. 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 calcium will interfere with absorption of other minerals such as zinc and iron in vulnerable populations (NHMRC and Ministry of Health, 2006).

FSANZ will be using the EAR and UL for calcium for dietary modelling purposes only. The reference values for vitamins and minerals in the Code[9] remain unchanged and differ from the NRVs. FSANZ will be amending the Code to reflect the Australia and New Zealand NRVs in the future. The RDI for calcium for the purposes of labelling will remain at the lower original level[10] of 800 mg until that time.

3. Description of Current Situation

The following section outlines Australian and New Zealand intakes of calcium using the best available information. The most recent national nutrition surveys undertaken were in Australia in 1995 and in New Zealand in 1997. The 2002 New Zealand Children's Nutrition Survey (Ministry of Health, 2003) is the most up to date data set from which to establish calcium intake. Since the collection of these surveys, the food supply has changed considerably and now calcium is available for consumption in a wider variety of fortified products such as juice. These recent calcium fortified foods were not taken into account in estimating the intake described and thus the estimates of intake described below may underestimate the intake of calcium.

[9] As stated in the Schedule to Standard 1.1.1 of the Code.

[10] The original RDIs for calcium, as stated in the Code, are lower than the RDIs in the NRVs recently endorsed by the NHMRC and Ministry of Health. For example, the original RDI for calcium for females aged 19-54 years was 800 mg/day compared to 1000 mg/day for women aged 19-50 years as stated in the NRVs.

3.1 Calcium Intakes

3.1.1 Estimates of consumption of calcium

Dietary modelling will be undertaken for the Draft Assessment Report to ascertain the percentage of individuals in various age/gender population groups that did not meet the EAR for calcium at the time of the national nutrition surveys. The data will be used to establish if there is need for additional sources of calcium and provide baseline values to determine the effectiveness of permitting fortification with calcium.

From published information from Australian and New Zealand national nutrition surveys conducted in the 1990s, the mean consumption of calcium by the following groups did not meet their respective EARs; Australian males 65^{+} years, New Zealand males aged 11-14; 15-18; 65^{+} years, six of nine Australian female age groups (all females aged over 12 years) and seven of eight New Zealand females age groups (all females aged over 7 years). Unless there have been significant increases in dairy or calcium fortified food intake over the past decade, these results suggest that many of the age/gender population groups have inadequate calcium intakes. Modelling to be undertaken at Draft Assessment proposes to take account of new sources of dietary calcium from fortified foods if the information is available. The calcium intakes will be compared with age and gender specific EARs to provide a more accurate estimation of the percentage of the populations that have an inadequate calcium intake.

3.2 Current Regulation

3.2.1 Relevant standards

The Standards in the Code relevant to this Application are Standard 1.3.2 – Vitamins and Minerals and Standard 1.1.1 – Preliminary Provisions - Application, Interpretation and General Prohibitions.

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

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

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

3.2.2 New Zealand Dietary Supplement Regulations 1985

Under the *New Zealand Dietary Supplement Regulations 1985* (NZDSR) 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 currently being manufactured in New Zealand as a dietary supplement. 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 (TTMRA).

Proposed changes to the regulation of dietary supplements in New Zealand have been mooted by the New Zealand Food Safety Authority[12]. It is understood that the intention of the proposed changes is to align products currently regulated under the NZDSR with the Code where possible. FSANZ understands that a discussion document proposing changes to the regulation of food-type dietary supplements and therapeutic-type dietary supplements will be released for public comment before the end of 2006.

3.2.3 Therapeutics 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).

A potential avenue for the regulation of calcium-fortified 'sugar-free' chewing gum in Australia is as a complementary medicine. To date, chewing gum with added calcium has not been listed on the Australian Register of Therapeutic Goods. In future, it may also be possible to market chewing gum with added calcium as a complementary medicine, in Australia and New Zealand, under the regulations of the forthcoming Australia New Zealand Therapeutic Products Agency (ANZTPA). However, the arrangements for the ANZTPA have not yet been finalised.

3.3 Ministerial Policy Guidance

The Ministerial Council approved a Policy Guideline on *Fortification of Foods with Vitamins and Minerals* (the Policy Guideline) in May 2004. Ministers made minor amendments to the Policy Guideline in May 2006[13]. 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.

[12] New Zealand Food Safety Authority Discussion Paper No. 01/04 (July 2004) *Proposed Changes to the Dietary Supplements Regulations 1985*.

[13] 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 with reference to the Policy Guideline is discussed further in Section 8.

3.4 Overseas and International Regulations

3.4.1 Codex Alimentarius

There is no specific Codex Standard for chewing gum, although general principles exist for the addition of essential nutrients to foods[14]. 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.

[14] General Principles for the Addition of Essential Nutrients to Foods, CAC/GL 09-1987 (Amended 1989,1991). Codex Alimentarius. 1994 Volume 4, pages 9-12.

3.4.2 United States of America

At present, the United States of America Food and Drug Administration (FDA) do not have regulations permitting the fortification of 'sugar-free' chewing gum, although a *Fortification Policy* does exist[15]. This policy states that the FDA does not consider it appropriate to fortify snack foods such as candies; however it is unclear if this would include 'sugar-free' chewing gum.

3.4.3 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*. Therefore, although it is considered a 'food', chewing gum 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[16]. There would be provision for the voluntary fortification of chewing gum products in the revised policy on the addition of vitamins and minerals to foods[17].

3.4.4 Other

Overseas and international regulations for the manufacture and sale of calcium-fortified 'sugar-free' chewing gum are unclear at this stage. This will be investigated further at Draft Assessment.

3.5 Current Market

3.5.1 Australia and New Zealand

The Applicant, Wrigley Company, is the leading chewing gum manufacturer in Australia and New Zealand, with approximately 99 % market share[18]. Chewing gum can be widely purchased in grocery stores, convenience stores and other retail outlets. Total chewing gum sales are worth approximately $AUD180 million and $NZ40 million annually in Australia and New Zealand respectively[18]. Total 'sugar-free' gum sales account for approximately 70 % of units sold in Australia and New Zealand[18].

[15] Code of Federal Regulations – Fortification Policy. 2004. Title 21, Chapter 1, Subchapter B, Part 104.20. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=104&showFR=1&subpartNode=21:2.0.1.1.4.2

[16] Health Canada (2005). Addition of Vitamins and Minerals to Foods: Proposed policy and implementation plans. Found at: http://www.hc-sc.gc.ca/fn-an/nutrition/vitamin/foritfication_final_doc_1_e.html#c1

[17] Personal communication. Nutrition Evaluation Division, Health Canada (September 2006).

[18] Synovate AZTEC data: moving annual total figures for Australia (as at 16 April 2006) and New Zealand (as at 26 March 2006).

Information provided by the Applicant states that 55% of the population are chewing gum consumers, with an even split between males and females. The proportion of consumers varies across the age groups, where a higher proportion of 8-34 year olds are gum consumers compared to those aged 35 years and older. Those most likely to chew gum regularly are aged 13-17 years, with more than 60% chewing gum weekly or more often. Of those high consumers, males chew slightly greater amounts of gum than females, and average amounts remain steady at two or more packs of gum weekly for all age groups 18 years and above.

FSANZ is not aware of 'sugar-free' chewing gum products with added calcium being manufactured and/or sold in Australia or New Zealand through grocery or convenience stores, nor being sold by dentists or pharmacies. However, these products are available for sale over the Internet. One product available includes a variety for children, and describes the calcium containing ingredient as a 'remineralising ingredient that helps strengthen teeth'.

3.5.2 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[19]. A wide range of chewing gum products are available worldwide, and the availability of calcium-fortified 'sugar-free' chewing gum internationally will be investigated at Draft Assessment.

3.5.3 Future market share predictions

The Applicant predicts that a calcium-fortified 'sugar-free' chewing gum 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 the 'sugar-free' chewing gum in Australia to 73 % market share. Similarly in New Zealand, an increase of approximately 2 % in market share of 'sugar-free' gum sales is predicted. In the absence of a calcium-fortified chewing gum, they predict the market share of sugar verses 'sugar-free' gum and the overall size of the gum market would remain stable.

Additional consumer research conducted by the Applicant indicates that calcium-fortified chewing gum would substitute for other gums (58 %), mints and lollies (25 %) and other foods (7 %), with the remaining 10 % coming from uptake by new consumers.

The Applicant has not indicated a specific target group for the proposed calcium-fortified 'sugar-free' chewing gum, and considers all age groups could be reached by this product. They identify a potential target group as post-menopausal women who require additional calcium, noting that 25 % of the 45-64 year age group consume gum at least weekly.

4. The Issue

The Applicant is seeking permission for the voluntary addition of calcium to 'sugar-free' chewing gum. The Applicant states the purpose of their request is to provide an additional source of calcium for consumers. 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.

[19] Source: www.wrigley.com. Accessed 7 September 2006.

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 'sugar-free' chewing gum.

5. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

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

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

RISK ASSESSMENT

6. Key Risk Assessment Questions

The key risk assessment questions at Initial Assessment are:

- What is the nutritional and/or health benefit of permitting the addition of calcium to 'sugar-free' chewing gum?
- What is the bioavailability of calcium in a 'sugar-free' chewing gum product that contains added calcium?
- What are the public health and safety risks to consumers of calcium-fortified 'sugar-free' chewing gum?

7. Potential Health Benefits and Risks of an Increased Intake of Calcium from the use of Calcium-Fortified 'Sugar-Free' Chewing Gum

The Applicant has requested this voluntary fortification permission on the basis that additional calcium intake can deliver a health benefit to the population by way of improved bone health and reduction in the risk of osteoporosis. In addition to bone health, the Applicant suggests that the chewing of calcium-fortified 'sugar-free' gum after a meal should increase the potential benefits of tooth remineralisation already observed with chewing 'sugar-free' gum without added calcium.

The Applicant has described two health benefits, firstly as a result of calcium absorbed and used in the body for the replenishment of circulating calcium to aid in bone structure and reduction of bone loss; the second is the result of calcium in the mouth which is not swallowed but has surface contact with teeth aiding in their remineralisation.

7.1 Issues associated with Potential Health Benefits of Increased Calcium Intake from Calcium-Fortified 'Sugar-Free' Chewing Gum

7.1.1 Bioavailability of calcium

Calcium bioavailability refers to the fraction of dietary calcium that can be absorbed by the intestine and used for physiological functions, particularly bone mineralisation, or to limit bone loss. The actual bioavailability will vary somewhat between individuals and may be influenced by both dietary and non-dietary factors including: the source and solubility of the calcium, an adequate intake of vitamin D, physiological adaptation, level of physical activity, hormones, drugs and physiological status.

Calcium absorption and intake are inversely related, declining from 45 % at intakes of 200 mg/day to 15 % at intakes above 2000 mg/day. In women, absorptive efficiency falls with age, declining 2.2 % at the time of the menopause onset 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 (United States Institute of Medicine, 1997). Changes in calcium intake lead to up- or down-regulation of absorption (O'Brien *et al.*, 1996).

7.1.1.1 Bioavailability of calcium in 'sugar-free' chewing gum

Issues related to bioavailability will be investigated at Draft Assessment. It will be important to establish the proportion of calcium taken into the mouth that is used for tooth mineralisation, that is swallowed and the proportion remaining in the spent gum. Information is also sought on the differential absorption from the intestine of permitted forms of added calcium released during chewing of gum, as well as the impact of various other factors on calcium absorption and metabolism. The Applicant suggests that similar to 'sugar-free' chewing gum without added calcium, calcium-fortified 'sugar-free' gum will be marketed with the recommendation that the gum be chewed immediately after food, thus improving the absorption of any calcium from the chewing gum that reaches the gut.

Question:

1. **What proportion of calcium from calcium-fortified 'sugar-free' chewing gum is swallowed and reaches the gut?**
2. **What proportion of the calcium in fortified 'sugar-free' chewing gum is left in the spent (unswallowed) chewing gum?**
3. **What is the evidence for bioavailability of various permitted forms of calcium ingested from calcium-fortified 'sugar-free' chewing gum?**

7.1.2 Calcium-fortified 'sugar-free' chewing gum and enhanced bone health

The skeleton contains 99 % of the calcium in the body, while the remaining 1 % exists as serum calcium. In the case of negative calcium balance, where losses of calcium in the urine, faeces or skin are greater than the intake and the fraction of the intake absorbed by the intestine; skeletal reserves will be used to maintain serum ionised calcium (Seeman, 1995). Serum ionised calcium is maintained and closely guarded within a well-defined narrow normal range by the interaction of calcium regulating hormones. These hormonal mechanisms result in bone resorption to bring the serum calcium back to within the normal range, but at the price of bone loss. Negative calcium balance over a prolonged period places the individual at a greatly increased risk of osteoporosis.

A dietary intake assessment will be undertaken at Draft Assessment to ascertain the potential effect of calcium-fortified 'sugar-free' chewing gum on the calcium intakes of the general population and population subgroups. This assessment, combined with more information on the bioavailability of calcium from chewing gum, and any effects resulting from recommended gum chewing practice, will then be used to determine more clearly the potential health benefits of calcium-fortified 'sugar-free' chewing gum.

7.1.3 Calcium-fortified 'sugar-free' chewing gum and tooth remineralisation

The Applicant has provided several references to the effect that chewing 'sugar-free' gum results in dental benefits including tooth strengthening by aiding the remineralisation of teeth. Chewing 'sugar-free' gum stimulates the production of saliva to help wash away food debris and neutralise plaque acid in the mouth (Manning and Edgar, 1993). Stimulated saliva can have a remineralising effect on previously demineralised tooth enamel (Leach *et al.,* 1989) as it contains the same types of calcium, phosphate and hydroxyl ions that occur naturally in the teeth. The demonstrated result is that chewing 'sugar-free' gum after eating or drinking for a period of 20 minutes helps reduce the incidence of tooth decay by up to 40 % (Szóke *et al.,* 1999). The Applicant states that the marketing of 'sugar-free' chewing gum already recommends chewing gum immediately after meals and snacks.

The Applicant suggests that the addition of calcium to 'sugar-free' chewing gum will further increase the remineralisation benefits observed with 'sugar-free' chewing gum without added calcium and provided evidence in support of their position. The Applicant has also provided three unpublished studies, all of which are commercial-in-confidence, showing a remineralising and strengthening effect of calcium-fortified 'sugar-free' chewing gum on tooth enamel that exhibited the very early stages of the dental caries process. These studies and other evidence will be further examined at Draft Assessment.

Questions:

4. **What proportion of the calcium in fortified 'sugar-free' chewing gum would potentially be utilised in the remineralisation of teeth compared to what is swallowed?**
5. **At what stage of tooth decay (i.e. small cavity or progressed cavity) would calcium-fortified 'sugar-free' chewing gum provide a protective effect?**
6. **What forms of calcium permitted in Standard 1.1.1 are likely to have a beneficial effect on tooth remineralisation?**

Question:

7. What forms of calcium are technically able to be added to 'sugar-free' chewing gum?

7.2 Potential Health Risks of an Increased Calcium Intake via 'Sugar-Free' Chewing Gum

7.2.1 Risk of excess calcium intake

On ascertaining the amount of calcium in calcium-fortified 'sugar-free' chewing gum that is swallowed, a dietary intake assessment will be undertaken. This assessment will determine if there are any risks to consumers of exceeding the UL as a result of using calcium-fortified 'sugar-free' chewing gum and if calcium-fortified 'sugar-free' chewing gum would be an effective method of increasing calcium intakes. An assessment based on the amount of calcium proposed to be added to 'sugar-free' chewing gum, and the amount of 'sugar-free' chewing gum consumed by the population will be made available in the Draft Assessment Report.

7.2.2 Inappropriate substitution of other calcium rich foods

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. In this case, consumers could replace milk and dairy products with calcium-fortified 'sugar-free' chewing gum. However, available research[20] indicates that this is unlikely to occur. 'Sugar-free' chewing gum is considered to be sufficiently different in nutrient profile, taste and use from milk and similar dairy products not to be considered a substitute food for these products.

The Applicant has stated that calcium-fortified 'sugar-free' chewing gum is not intended for promotion as a substitute for dairy foods, but is intended to provide an additional source of calcium, in addition to calcium supplements or other calcium fortified foods, for those already not consuming sufficient dairy products for whatever reason.

Due to the nutrition profile of 'sugar-free' chewing gum, additional consumption of this product is likely to make no difference to the nutrient intake of consumers. It contains small amounts of energy and so is unlikely to add to overall energy intakes. The polyols used to sweeten the chewing gum can produce a laxative effect if consumed in high amounts. Because of this, 'sugar-free' gums carry a statement warning against over consumption.

Question:

8. Is calcium-fortified 'sugar-free' chewing gum likely to be used as a replacement for other calcium rich foods, or as an additional food in the diet?

[20] 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

7.3 Risk Assessment Summary

The Applicant has requested permission for the addition of calcium forms to 'sugar-free' chewing gum based on evidence of an inadequate calcium intake in many age groups in the population. They suggest that increased calcium intakes via calcium-fortified 'sugar-free' chewing gum will result in two potential health benefits: the first being improved bone health for those individuals who have an inadequate calcium intake, the second being the potential for calcium-fortified 'sugar-free' chewing gum to increase the protective effect on teeth that has already been observed in chewing 'sugar-free' gum without added calcium.

Issues associated with calcium bioavailability, dietary intake, and consumption practice will be explored to inform assessment of a potential impact on bone health.

The chewing of 'sugar-free' gum directly after meals has been shown to increase the remineralisation of teeth and aid in preventing tooth decay. Studies have been undertaken to establish the localised effect of chewing gum with added calcium. The Applicant has provided published and unpublished commercial-in-confidence studies that show an additional protective effect on teeth from chewing 'sugar-free' gum with calcium added in particular forms over and above the protective effects observed from chewing gum with no added calcium.

RISK MANAGEMENT

8. Risk Management Issues

8.1 Efficacy and Safety of Calcium-Fortified 'Sugar-Free' Chewing Gum

At Initial Assessment, FSANZ notes there is evidence of calcium inadequacy within the Australian and New Zealand population. It also notes that adequate calcium is required for optimal bone health and that studies are available that have shown the beneficial effect of chewing 'sugar-free' gum on dental health.

However, uncertainty exists about the bioavailability of calcium in 'sugar-free' chewing gum in relation to the amount of calcium released from the chewing gum into the mouth, the proportion of the added calcium that reaches the gut for absorption, and the proportion of calcium that remains in the unswallowed gum. In addition, there is uncertainty about the bioavailability of the various forms of calcium permitted in the Schedule to Standard 1.1.1 of the Code. The Applicant suggests that similar to 'sugar-free' chewing gum without added calcium, calcium-fortified 'sugar-free' gum will be marketed with the recommendation that the gum be chewed immediately after food, thus improving the absorption of any calcium from the chewing gum that reaches the gut.

Ascertaining information on the amount of calcium in 'sugar-free' chewing gum that is swallowed will also be important in order to determine the potential for the voluntary fortification of 'sugar-free' chewing gum with calcium to result in detrimental excesses or imbalances of calcium across the general population.

The efficacy and safety of permitting the addition of calcium to 'sugar-free' chewing gum will be more thoroughly investigated and reported at Draft Assessment.

8.2 Appropriateness of the Food Vehicle

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

The Applicant considers that 'sugar-free' chewing gum is the *perfect food vehicle for calcium fortification*, stating that it has low energy content and contains no sugar, salt or fat, and considers it does not have an impact on eating patterns.

The introduction of a newly fortified food or food category into the market can result in four possible scenarios[21]. In this case for example, calcium-fortified 'sugar-free' chewing gum might:

- 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 suggests that other gum and confectionary products would be substituted with calcium-fortified 'sugar-free' chewing gum. 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.

Another important consideration is whether the proposed fortification will deliver the nutrient to the target group. The Applicant has not specified a particular target group, and instead notes the benefits of increased calcium intake across the general population. Their research indicates that 50 % of the population are chewing gum consumers, with gum being used equally between genders and spread across the different age groups of the population. In addition, as the proposed fortification would be on a voluntary basis, this would allow consumers to choose whether they consume a fortified gum or not.

Questions:

9. Is 'sugar-free' chewing gum an appropriate food for the voluntarily addition of calcium?

10. Is there any further evidence to support the Applicant's consumer research as to the likely impact of 'sugar-free' chewing gum on consumption patterns?

11. Who are the likely target group(s) for calcium-fortified 'sugar-free' chewing gum?

[21] FSANZ (2005). *Fortification Implementation Framework, June 2005.*

8.3 Potential to Mislead Consumers

As stated in the Policy Guideline in relation to voluntary fortification, *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.*

8.3.1 Nutritional quality of calcium-fortified 'sugar-free' chewing gum

There is a potential risk that consumers could be misled as to the nutritional quality of calcium-fortified 'sugar-free' chewing gum. Firstly, consumers may be misled if they assume that the form of calcium in the product is completely bioavailable and therefore able to be used in the body. Secondly, consumers may not realise that some calcium may remain in the unswallowed chewing gum. In addition, it is not known how much calcium would be absorbed and used by the body to replenish circulating calcium stores compared to the amount that would be used through the direct surface contact with teeth. Therefore, depending on the consumer's desired benefit from consuming the product, they may be misled as to the actual amount of calcium that is available for use by their bones and/or to remineralise teeth.

In addition, some may argue that this proposed fortification may displace other foods or beverages that are traditional sources of calcium in the diet, e.g. dairy products, where consumers may be misled that they can meet their calcium requirements by chewing calcium-fortified gum alone.

8.3.2 Reference quantity and serving size

The Applicant has requested that 'sugar-free' chewing gum be permitted to contain calcium at a level to allow a 'source' claim (10 % RDI per reference quantity). They have requested that the reference quantity be stated as *a normal serving* in the Table to clause 3 of Standard 1.3.2. This unquantified reference quantity could create some difficulties, as it would allow the manufacturer to determine the weight of the reference quantity, in addition to the weight of the serving size.

The Applicant has described a serving size of 'sugar-free' chewing gum to be five individual pellets of chewing gum. This quantity may or may not constitute a normal serving size of chewing gum from the perspective of a consumer. The potential for consumers to be misled may be further compounded if the product label states a claim in relation to the calcium content per serving of the product.

Questions:

12. Are consumers likely to be misled as to the nutritional quality of the calcium-fortified 'sugar-free' chewing gum? If so, what evidence supports this?

8.4 Labelling

Generic labelling provisions are included within the Code as a means of achieving three main objectives: to protect public health through the management of risk, to provide adequate information to the consumer to facilitate informed choice, and to prevent misleading conduct.

Under current labelling requirements in Standard 1.2.4 – Labelling of Ingredients, an added vitamin or mineral must be listed in the ingredient list of most packaged foods. Under Standard 1.2.8 – Nutrition Information Requirements, if a nutrition claim is made in relation to the food, the average quantity of the claimed nutrient on a per serving and per 100 g or 100 ml basis is required to be listed in the nutrition information panel (NIP) on the label. The NIP must also contain information on the number of servings of the food in the package. 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.

An exception to these requirements is provided for small packages. Small packages are defined in the Code as having a surface area of less than 100 cm^2. The packets of most currently available pellet chewing gum products meet the definition of a small package. The labels on small packages are exempt from the requirement to include an ingredient list. If a nutrition claim is made on a small package, the average quantity of the claimed nutrient must be declared. This information must be declared on a per 100 g or 100 ml basis, however it is not required to be presented as a percentage RDI per serving, on a per serving basis or in the prescribed NIP format.

The Applicant noted that 100 mg of calcium per serving constitutes a claimable amount (i.e. 10 % or more of the RDI for calcium per reference quantity), in respect to both the RDI for calcium currently stated in the Code and for the corresponding RDI recently adopted by the Australian and New Zealand Governments. If permission to add calcium to 'sugar-free' chewing gum were permitted under Standard 1.3.2 of the Code, this would allow chewing gum to meet the definition of a 'claimable food', and therefore a claim could be made in accordance with this Standard. Proposal P293 – Nutrition, Health and Related Claims is currently in progress, and is considering conditions for making nutrition and health claims.

9. Options

FSANZ is currently considering two options for addressing this Application:

Option 1 – Maintain status quo

Maintain the *status quo* by not amending the Code to allow the addition of calcium to 'sugar-free' chewing gum; and

Option 2 – Amend Standard 1.3.2 to permit the addition of calcium to 'sugar-free' chewing gum at a maximum claim level of 100 mg per reference quantity

Option 2 would allow the voluntary addition of calcium to 'sugar-free' chewing gum under Standard 1.3.2 of the Code, at a maximum claim level of 100 mg of calcium per reference quantity.

10. Impact Analysis

10.1 Affected Parties

The parties likely to be affected by this Application are: **consumers** of chewing gum; Australian and New Zealand manufacturers and importers of chewing gum **(industry)**; and the **government enforcement agencies** of Australia States/Territories and New Zealand.

10.2 Benefit Cost Analysis

This analysis provides a preliminary assessment of the potential impacts of the regulatory options on the affected parties. A full benefit cost analysis will be undertaken at Draft Assessment.

10.2.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers of chewing gum, as chewing gum will continue to be available for consumers to purchase. Option 2 would provide consumers with an additional food source of calcium, and a greater choice of chewing gum products to purchase. There is also the potential that calcium-fortified 'sugar-free' chewing gum may provide additional benefits for dental health, compared to non-fortified 'sugar-free' chewing gum. It also has the potential to contribute to the overall calcium intake of the consumer, which may or may not have beneficial effects on bone health. A potential cost for consumers may arise if they are mislead as to the nutritional quality of the calcium fortified product.

10.2.2 Industry

A permission to allow the addition of calcium to 'sugar-free' chewing gum allows industry to be innovative and produce new products for the market place. The Applicant predicts that a calcium-fortified 'sugar-free' chewing gum would achieve a 12 % market share in the first year, and generate a 5 % growth in the chewing gum market. While there would be a cost to manufacturers to fortify these products, this cost would be passed on to consumers at the point of sale. Permission to voluntarily fortify 'sugar-free' chewing gum with calcium would enable manufacturers to export their product to countries where the same fortification permissions exist, and allow similar products manufactured overseas to be sold in Australia and/or New Zealand. It would also remove the possible inconsistency with the NZDSR that currently allow the manufacture of fortified chewing gum products in New Zealand, which can then be sold in Australia.

10.2.3 Government

There is no particular benefit to Government of maintaining the *status quo*. However, under Option 2 there may be the potential to reduce the public health costs associated with poor dental health, osteoporosis, fractures and other conditions associated with inadequate calcium intake.

Questions:

13. **What is the likely impact on consumers, industry and government if the *status quo* was maintained?**
14. **What is the likely impact on consumers, industry and government if 'sugar-free' chewing gum was permitted to contain calcium?**

10.3 Comparison of Options

At this Initial Assessment stage, no comparison of the identified regulatory options can be undertaken. Further information on the risk assessment and risk management aspects of this Application is required before such a comparison can be made. A comparison will therefore be provided at Draft Assessment.

COMMUNICATION AND CONSULTATION

11. Consultation

11.1 Public Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this Report, which are also presented at Attachment 1.

The first public consultations period will remain open for six weeks. Comments made by submitters during this period will be reviewed and reported in the Draft Assessment Report.

11.2 Targeted Consultation

FSANZ intends to conduct targeted consultation with experts in the field of dental and medical health on the benefits and risks associated with this Application. FSANZ will conduct other targeted consultation as necessary.

11.3 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.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade or Sanitary and Phytosanitary Measure Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION AT INITIAL ASSESSMENT

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- the Application seeks approval to add calcium to 'sugar-free' chewing gum at a maximum claim level of 100 mg per reference quantity. Such an approval, if accepted, would warrant a variation to Standard 1.3.2 – Vitamins and Minerals of the Code;
- there is currently no permission in the Code for calcium to be added to 'sugar-free' chewing gum;
- the Application is not so similar to any previous application that it should not be accepted;
- there are no other measures that would be more cost-effective than a variation to Standard 1.3.2 that could achieve the same end; and
- at this stage no other relevant matters are apparent.

REFERENCES

Heaney, R.P., Recker, R.R., Stegman, M.R. and Moy, A.J. (1989a) Calcium absorption in women: relationships to calcium intake, estrogen status and age. *J Bone Miner. Res.* 4: 469-475.

Jones, G.P. (1997) 'Minerals', Wahlqvist, M.L., Editor: 'Food and Nutrition', Chapter 25: p20

Leach, S.A., Lee, G.T.R. and Edgar, W.M. (1989) Remineralisation of artificial caries-like lesions in human enamel in situ by chewing sorbitol gum. *J Dent Res.* 69: 1064-1068

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

Ministry of Health (1999) NZ Food: NZ People: Key Results of the 1997 National Nutrition Survey, Ministry of Health, Wellington.

Ministry of Health (2003) NZ Food: NZ Children: Key Results of the 2002 National Children's Nutrition Survey. Ministry of Health, Wellington.

NHMRC and Ministry of Health (2006) Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes. National Health and Medical Research Council, Canberra.

National Nutrition Survey (1995a) 'Foods Eaten'. Available at http://www.abs.gov.au/Ausstats/abs@.nsf/0/9a125034802f94ceca2568a9001393ce?OpenDocument

National Nutrition Survey (1995b) Selected Highlights Australia. Available at http://www.abs.gov.au/AUSSTATS/abs@.nsf/ProductsbyTopic/1173B761B1662AE9CA2568A900139371?OpenDocument

O'Brien, K.O., Abrams, S.A., Liang, L.K., Ellis, K.J. and Gagel, R.F. (1996) Increased efficiency of calcium absorption during short periods of calcium intake in girls. *Am. J. Clin. Nutr.* 63: 579-583.

Seeman, E. (1995) Eat Foods Containing Calcium. National Health and Medical Research Council (extract) 'Dietary Guidelines for Adults'. p97ff.

Szóke, J., Proskin, H.M. and Banoczy, J. (1999). Effect of after-meal sugar free chewing gum on dental caries. *J Dent Res.* 80(8): 1725-29

Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. (1997) Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes. National Academy Press, Washington DC.

Wylie-Rosset, J. and Swencionis, C. (1990) 'Nutritional Approaches to Hypertension'. Langford L and Langford E (ed) 'Nutritional Factors in Hypertension', Chapter 6: p83.

ATTACHMENTS

1. Initial Assessment Questions for Public Comment

Attachment 1

Initial Assessment Questions for Public Comment

1. What proportion of calcium from calcium-fortified 'sugar-free' chewing gum is swallowed and reaches the gut?

2. What proportion of the calcium in fortified 'sugar-free' chewing gum is left in the spent (unswallowed) chewing gum?

3. What is the evidence for bioavailability of various permitted forms of calcium ingested from calcium-fortified 'sugar-free' chewing gum?

4. What proportion of the calcium in fortified 'sugar-free' chewing gum would potentially be utilised in the remineralisation of teeth compared to what is swallowed?

5. At what stage of tooth decay (i.e. small cavity or progressed cavity) would calcium-fortified 'sugar-free' chewing gum provide a protective effect?

6. What forms of calcium permitted in Standard 1.1.1 are likely to have an effect on tooth remineralisation?

7. What forms of calcium are technically able to be added to 'sugar-free' chewing gum?

8. Is calcium-fortified 'sugar-free' chewing gum likely to be used as a replacement for other calcium rich foods, or as an additional food in the diet?

9. Is 'sugar-free' chewing gum an appropriate food for the voluntarily addition of calcium?

10. Is there any further evidence to support the Applicant's consumer research as to the likely impact of 'sugar-free' chewing gum on consumption patterns?

11. Who are the likely target group(s) for calcium-fortified 'sugar-free' chewing gum?

12. Are consumers likely to be misled as to the nutritional quality of the calcium-fortified 'sugar-free' chewing gum? If so, what evidence supports this?

13. What is the likely impact on consumers, industry and government if the *status quo* was maintained?

14. What is the likely impact on consumers, industry and government if 'sugar-free' chewing gum was permitted to contain calcium?