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

6 May 2009
[7-09]

FIRST REVIEW REPORT

APPLICATION A577

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

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

Executive Summary

On 9 February 2009, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Application A577 - Calcium in Chewing Gum containing no more than 0.2% Residual Sugars[1]. The Ministerial Council requested that Food Standards Australia New Zealand (FSANZ) review the decision to approve the addition of calcium to chewing gum (≤0.2% residual sugars) on the grounds that it: is inconsistent with existing Ministerial Policy Guidelines; does not protect public health and safety; does not provide adequate information to enable informed choice; and is difficult to enforce or comply with in practical and resource terms.

Application A577 was 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[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.

In December 2008, FSANZ approved the inclusion of Standard 2.10.3 for chewing gum in the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve. A stand alone Standard in the Code was drafted as it recognised the unique nature of chewing gum as a food and was able to accommodate the concept of *releasable* calcium.

FSANZ has considered the issues raised by the Ministerial Council in its First Review Request in relation to the Application. These are highlighted further in the summary table of matters addressed at First Review below.

There are three options proposed for consideration under this Review:

1. re-affirm the approval of the draft Standard 2.10.3 as notified to the Ministerial Council; or
2. re-affirm the approval of the draft Standard 2.10.3 subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft Standard 2.10.3 as notified to the Ministerial Council.

[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.

Decision

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

Reasons for Decision

FSANZ reaffirms its decision to approve the draft Standard 2.10.3 permitting the addition of calcium to chewing gum (≤0.2% residual sugars) (see Attachment 1) as:

- it is consistent with FSANZ's statutory objectives including having regard to Ministerial policy guidance on voluntary vitamin and mineral fortification;
- it is not inconsistent with the nutrition policies and guidelines of Australia and New Zealand;
- chewing gum (≤0.2% residual sugars) is a unique food and is considered to be different from other foods with little nutritional value such as 'sugar free' confectionery and 'diet'soft drinks;
- it provides an additional calcium source for consumers of chewing gum (≤0.2% residual sugars) and potential dental benefits;
- it does not raise any safety concerns for consumers of calcium-fortified chewing gum (≤0.2% residual sugars) or the general population;
- consumers will be provided with adequate labelling information to make an informed choice;
- it allows for industry innovation and increased consumer choice; and
- no new evidence has emerged since Final Assessment that would support a change in FSANZ's decision to approve the draft standard.

FSANZ will notify the Ministerial Council of its decision to reaffirm the draft variations to the Code. Subject to any further request for review by the Ministerial Council of FSANZ's decision, the proposed draft variation is expected to come into effect upon gazettal.

Consultation

At First Review, FSANZ did not undertake any specific consultation apart from discussions with the Applicant in relation to the issues raised and to obtain further information where required.

Summary Table
Matters Addressed at First Review

Ministerial Council Issue	FSANZ's Response
Is inconsistent with existing Ministerial Policy Guidelines on Fortification of Food with Vitamins and Minerals (Attachment 3): • Approval of fortification of chewing gum with calcium is contrary to the intent and spirit of the Policy Guideline • chewing gum (≤0.2% residual sugars) is an inappropriate vehicle for fortification and would promote consumption patterns inconsistent with nutrition guidelines and policies in Australia and New Zealand • may establish a precedent for fortifying other foods that have little or no nutritional value • misleading as to the nutritional quality of the food.	• The FSANZ Board is not entitled to look outside the content of the Policy Guideline to ascertain intent. The Board is limited to the words in the Guideline and is not entitled to guess at what might have been intended by the drafters of the document. • The Application is not inconsistent with nutrition policies and guidelines which do not prohibit the inclusion of foods with little or no nutritional value in the diet; nor do they make any specific references to any type of chewing gum; chewing gum (≤0.2% residual sugars) is low in sugar, fat and salt; chewing gum (≤0.2% residual sugars) is recommended by dental health organisations. • Chewing gum (≤0.2% residual sugars) is different to other foods with little or no nutritional value (e.g. confectionery, soft drinks) as it provides a dental health benefit from post meal chewing. New Zealand and Australian dental associations support and recommend, respectively, chewing gum after meals. • The potential to mislead consumers is addressed below.
Does not protect public health and safety: • risk of substitution of foods with high nutrient density e.g. dairy foods • provides little nutritional or health benefit • chewing gum should not strictly be considered to be a food but more like a therapeutic • bioavailability of the released calcium • lack of evidence of a health benefit of all the permitted forms	• Consumer research shows the risk of substituting dairy foods is very low. The risk assessment indicated little overall impact on dietary intakes of other key nutrients as chewing gum (≤0.2% residual sugars) is unlikely to be a substitute for other nutrient dense calcium containing foods and dairy products. • Within the proportion of the population that chew gum, the introduction of calcium fortified chewing gum is likely to reduce the proportion of consumers with calcium intakes below the estimated average requirement. In addition, it can provide a short term dental health benefit to consumers. • Calcium fortified chewing gum does not fall within the regulation of therapeutic goods and is captured by the Food Standards Code as a food. • Fortified chewing gum provides a potential short term dental benefit in relation to tooth

Ministerial Council Issue	FSANZ's Response
	remineralisation as shown for some permitted forms. Also, the calcium from fortified chewing gum will be bioavailable, regardless of the form of calcium used. Therefore, no restriction will be placed on the number of permitted forms.
Does not provide adequate information to enable informed choice: • potential to mislead the consumer as to the nutritional value • recommendations for chewing gum consumption • reliability of self reported consumer data.	• Specific requirements for labelling and claims have been included in the draft Standard. • The consumer research available on whether consumers chew in accordance with recommendations shows that more than one third of consumers do so. • Self reported data collection is commonly used in consumer research data. Data quality has been assessed by FSANZ and the nature of the survey suggests significant over or under reporting of chewing time is unlikely.
Difficult to enforce and comply with: • no recognised method for determining releasable calcium • not enough details provided in the cost benefit analysis.	• FSANZ has provided guidance in an editorial note to the draft Standard in relation to methods for determining releasable calcium in pharmacopoeial references. FSANZ considers that discussions at forums outside of FSANZ are an appropriate means for enforcement agencies to agree upon specific implementation aspects for monitoring releasable calcium in chewing gum. • The cost benefit analysis was based on information provided to FSANZ and the Office of Best Practice Regulation advised that the analysis was adequate.

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1. Introduction

On 9 February 2009, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a Review of Application A577, which seeks to permit the voluntary addition of calcium to chewing gum containing no more than 0.2% residual sugars[3]. A response to the First Review Request (hereafter referred to as the Review Request) is due on 9 May 2009.

2. Objectives of the Review

The objective of this Review is to reconsider draft Standard 2.10.3 in light of the Ministerial Council's concerns as outlined in Section 3.

3. Grounds for the Review requested by the Ministerial Council

A Review was requested by the Ministerial Council on the grounds that approval of the Application:

- is not consistent with existing policy guidelines set by the Ministerial Council[4];
- does not protect public health and safety;
- does not provide adequate information to enable informed choice; and
- is difficult to enforce or comply with in both practical and resource terms.

The notification of the Review Request can be found at the Food Regulation Secretariat website at http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-request-reviews.

Additional comments were provided by the Ministerial Council and are summarised by FSANZ as follows:

- The intent of the voluntary vitamin and mineral fortification Ministerial Policy Guideline was not followed.
- Chewing gum (≤0.2% residual sugars) is an inappropriate food vehicle for fortification and approving the Application would promote consumption patterns inconsistent with nutrition guidelines and policies.
- Approving the fortification of chewing gum (≤0.2% residual sugars) may establish a precedent for fortification of other foods with little or no nutritional value.
- Consumers may substitute foods high in calcium and other nutrients with calcium fortified chewing gum (≤0.2% residual sugars).
- Fortification of chewing gum (≤0.2% residual sugars) in the amount technically possible will provide insignificant amounts of calcium to consumers and no public health benefit.
- Chewing gum (≤0.2% residual sugars) should not be viewed strictly as a food, but rather as a therapeutic product.
- There is the potential to mislead consumers as to the nutritional value of the product.

[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] Policy Guideline. Fortification of Food with Vitamins and Minerals. See Attachment 3.

- Consumers may not eat the product following meals as directed.
- The bioavailability and benefit of the permitted forms are questioned.
- There is doubt over the use of self reported consumer research data.
- There are no nationally recognised methods for determining releasable calcium and not enough details are provided regarding enforcing the draft Standard.
- The cost-benefit analysis provides too little detail.

These issues are addressed under Section 6 of this report.

4. Background

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.

Specifically, the Applicant 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[5]) 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 current Standards most relevant to this Application are Standard 1.1.1 and Standard 1.3.2. Standard 1.1.1 contains the Schedule of permitted forms and the reference values of vitamins and minerals that may be added to certain foods, including the 14 forms of calcium currently permitted[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. Currently, Standard 1.3.2 permits the voluntary addition of calcium to a range of foods. 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.

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. 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.

Calcium fortified chewing gum is currently available internationally, and in Australia and New Zealand from dentists, or it can be purchased over the internet.

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

5. FSANZ Assessment of Application A577

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

FSANZ undertook a robust and extensive assessment of the public health and safety implications of this Application.

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

The Application focussed on 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. Two scenarios were considered in the risk assessment for the amount of calcium released from the product. The first related to the 'Current technology' for manufacturing the gum that results in 21.3 mg releasable calcium per gram of chewing gum. The second is for the 'Anticipated future technology' that results in 41.7 mg releasable calcium per gram of chewing gum.

Dietary intakes were estimated and were based on the amount of 'releasable calcium' from the chewing gum. Nutrient Reference Values (NRVs)[7] for calcium were used as the basis of assessing inadequate and excess intakes in the population.

A consumer research study, conducted by Roy Morgan Research (RMR) commissioned by the Applicant, was used extensively to inform the Risk Assessment, primarily the dietary intake assessment. The research looked at current consumption levels of chewing gum (≤0.2% residual sugars) and potential behavioural changes if calcium-fortified chewing gum (≤0.2% residual sugars) was permitted. FSANZ social scientists provided advice on the social research methodology and approaches required to ensure the research was robust and appropriately designed and analysed.

Two rounds of public consultation were undertaken following the release of the Initial Assessment Report (October 2006) and Draft Assessment report (December 2007). Comments from submissions were considered by FSANZ and addressed in the subsequent reports.

At Final Assessment two options were proposed; (1) reject the Application thus maintaining the *status quo*; or (2) prepare a draft Standard for chewing gum in Part 2.10 of the Code that permits the addition of calcium to chewing gum (≤0.2% residual sugars) at a maximum claim level of 200 mg releasable calcium per serve.

[7] NHMRC (2006) Nutrient Reference Values For Australia and New Zealand Including Recommended Dietary Intakes. http://www.nhmrc.gov.au/PUBLICATIONS/synopses/n35syn.htm.

In December 2008, FSANZ approved Option 2, the inclusion of a Standard for chewing gum in the Code. A stand-alone Standard in the Code was drafted as it recognises the unique nature of chewing gum as a food, was able to accommodate the concept of *releasable* calcium, set out the specific labelling requirements and provided guidance on available procedures to determine releasable calcium to assist with compliance and enforcement.

6. Issues Addressed at First Review

6.1 Not consistent with the existing Ministerial Policy Guideline for Fortification of Food with Vitamins and Minerals

6.1.1 The Application is contrary to the intent of the Policy Guideline

Concerns were raised in the Review Request that the Application was contrary to the intent of the Ministerial Policy Guideline on *Fortification of Food with Vitamins and Minerals*. For reference, the Policy Guideline can be found at Attachment 3.

In developing or reviewing any food regulatory measure, the FSANZ Board must have regard to relevant Ministerial Policy Guidelines as only one of many considerations or relevant pieces of information as specified by FSANZ's statutory responsibilities in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

In having regard to Policy Guidelines, the FSANZ Board is not entitled to look outside the content of the document to ascertain intent. In other words the Board is limited to the words in the Guideline and is not entitled to guess at what might have been intended by the drafters of the document.

When the FSANZ Board considered the Final Assessment Report in December 2008, it was sympathetic to the comments raised in submissions relating to the Policy Guideline. A rejection on grounds that chewing gum is an inappropriate food vehicle for fortification because it has little or no nutritional value was considered legally unsafe in the absence of an express Ministerial policy on fortification of foods with little or no nutritional value and the Board is unable to add in such a principle to its consideration. Therefore, a rejection by the Board would have been seriously vulnerable to legal challenge.

6.1.2 The Application would promote consumption patterns inconsistent with nutrition policies and guidelines and chewing gum (≤0.2% residual sugars) is an inappropriate vehicle for fortification

An issue raised in the Review Request was that the Application is inconsistent with policy guidance as it promotes consumption patterns inconsistent with nutrition policies and guidelines in Australia and New Zealand. Also, approval of the Application would promote consumption of confectionery or of foods with little nutritional value, and nutrition guidelines promote the consumption of dairy foods. It was stated that chewing gum (≤0.2% residual sugars) is an inappropriate vehicle for voluntary fortification as it is not part of an essential diet, is not swallowed and has no nutritional value or benefit.

The Policy Guideline states that permission to voluntarily fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand. Nutrition policies and guidelines[8] [9] [10] [11] [12] [13] do not prohibit the inclusion of foods with little or no nutritional value, in the diet. There are no specific recommendations or statements in these guidelines about chewing gum (≤0.2% residual sugars). An excerpt from the Australian Guide to Healthy Eating for Australian Adults[14] has been provided as an example in Attachment 4.

State and Territory nutrition policies within Australia were also reviewed. All the States and Territories either directly refer to the national nutrition guidelines (i.e. the Australian Guide to Healthy Eating or the Dietary Guidelines for Australians), or have developed their own information which is consistent with these guidelines.

Other public health policies that may be considered relevant to this Application are those relating to dental health. Chewing gum (≤0.2% residual sugars) is promoted in relation to positive health benefits to teeth. The respective national dental associations of Australia and New Zealand both promote the use of chewing gum (≤0.2 % residual sugars) for dental health, as does the World Dental Federation. The Australian Dental Association (ADA) 2008 Policy Statement 1.2.3 on Oral Hygiene[15] states that chewing gum (≤0.2% residual sugars):

> *can act as a mechanical salivary stimulant which accelerates the clearance of dietary substances and micro-organisms as well as diluting and buffering plaque acid. Chewing gum can also act as a vehicle for medicaments such as anti-plaque and re-mineralising agents.*

The Policy Guideline states that voluntary fortification should not promote increased consumption of foods high in salt, sugar and fat. In addition, both the Dietary Guidelines for Australians and New Zealand Food and Nutrition Guidelines[16] promote the consumption of foods low in fat, sugar and salt. Chewing gum (≤0.2% residual sugars) fits into this category of foods as it is low in fat, sugar and salt and therefore is not inconsistent with the Policy Guideline and nutrition guidelines in this regard.

The Policy Guideline for voluntary fortification 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. Calcium intakes for the Australian

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[8] The Australian Guide to Health Eating. http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-food-guide-index.htm

[9] NHMRC (2005) Food for Health. http://www.nhmrc.gov.au/publications/synopses/_files/n31.pdf

[10] NHMRC (2003) The Dietary Guidelines for Australians. http://www.nhmrc.gov.au/publications/synopses/dietsyn.htm

[11] Ministry of Health (1997) Food and Nutrition Guidelines for Healthy Children Aged 2-12 years. 2nd Edition. http://www.moh.govt.nz/moh.nsf/pagesmh/4019?Open

[12] Ministry of Health (2003) Food and Nutrition Guidelines for Healthy Adults: A Background Paper. http://www.moh.govt.nz/moh.nsf/pagesmh/2606

[13] Ministry of Health (1996) Food and Nutrition Guidelines for Healthy Older People: A Background Paper. 2nd Edition. http://www.moh.govt.nz/moh.nsf/pagesmh/1109?Open

[14] NHMRC (2003) The Dietary Guidelines for Australian Adults. National Health and Medical Research Council. http://www.nhmrc.gov.au/publications/synopses/_files/n33.pdf. Accessed 1 April 2009.

[15] Australian Dental Association (2008) Policy Statement 1.2.3. Oral Hygiene. http://www.ada.org.au/app_cmslib/media/lib/0805/m130856_v1_policy%20statement%201.2.3c.pdf

[16] Ministry of Health. Food and Nutrition Guidelines. http://www.moh.govt.nz/moh.nsf/indexmh/nutrition-foodandnutritionguidelines

and New Zealand populations are low in relation to the Estimated Average Requirement (EAR). The dietary intake assessment at Final Assessment showed that the majority of population groups (except very young children) have a substantial proportion below the EAR.

In addition, when the adequacy of intakes for a range of vitamins and minerals were assessed for Application A470 Formulated Beverages, calcium was identified as one of the worst nutrients in relation to the proportion of the population with intakes below the EAR[17]. This Application does have the potential to address inadequate calcium intakes (see Section 6.2.2) for consumers of fortified chewing gum (≤0.2% residual sugars).

In relation to the potential to deliver a health benefit, it was concluded in the risk assessment at Final Assessment that some evidence exists of a short-term benefit to dental health from calcium fortified chewing gum (≤0.2% residual sugars). This is through increased tooth remineralisation although this has only been shown to date when either calcium lactate, calcium carbonate or some of the more soluble forms of calcium phosphate have been added to chewing gum (≤0.2% residual sugars). This benefit is in addition to other dental benefits noted by national dental associations. The Applicant is initially proposing to add calcium lactate or calcium carbonate to chewing gum (≤0.2% residual sugars).

6.1.3 May establish a precedent for fortifying other foods with little or no nutritional value

There was concern that the Application may establish a precedent for the fortification of other foods with little or no nutritional value such as sweetened or intensely (artificially) sweetened confectionery and soft drinks.

Applications to fortify any food not currently permitted are assessed on a case by case basis by FSANZ. The existence of a precedent is considered in FSANZ's assessment but each application is assessed on its merits. However, the Board noted the concerns that there is no principle in the policy guidance that would enable it to reject an application to fortify a food which has little or no nutritional value such as, for example, a 'sugar free' confectionary and confirms that without change to the Policy Guideline to this effect, such a permission could well be granted if other factors such as safety and other Policy Guideline principles were satisfied.

In addition, chewing gum (≤0.2% residual sugars) is considered to be different to other foods with little or no nutritional value. Chewing gum (≤0.2% residual sugars) is already recommended (see ADA Policy Statement in Section 6.1.2) to be consumed in relation to its positive dental health benefits.

6.1.4 Misleading as to the nutritional quality of the food

The Policy Guideline states a product should not mislead the consumer as to the nutritional quality of the fortified food. There were concerns that the amount of additional calcium received from the chewing gum (≤0.2% residual sugars) is insignificant, however consumers may perceive it to be a good source of calcium. This issue of the potential for the product to mislead consumers is discussed further in Section 6.3.1.

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[17] FSANZ (2005) *A470 Formulated Beverages. Final Assessment Report. Attachment 5. December 2005*. http://www.foodstandards.gov.au/_srcfiles/A470%20Formulated%20Bevs%20FAR%20Attach%205%20FINAL.pdf.

An associated issue of the potential for calcium-fortified chewing gum (≤0.2% residual sugars) to change consumption patterns by substituting for dairy foods where the chewing gum is perceived to be equivalent in terms of calcium is addressed below in Section 6.2.1.

6.2 Does not protect public health and safety

6.2.1 Substitution of chewing gum for other foods

There was a concern raised that consumers will substitute other foods high in calcium and other nutrients (e.g. protein, Vitamin B_{12}, riboflavin, zinc), such as dairy foods with calcium fortified chewing gum (≤0.2% residual sugars). This concern was greatest for teenage girls and young women. Another concern raised was that in the future, if the maximum permissible level for calcium (200 mg releasable calcium/serve) is reached in the chewing gum (≤0.2% residual sugars), the risk of substitution may be greater, again for some specific population groups such as young women.

Nutrition policies and guidelines promote the consumption of dairy foods for many reasons including for their important role in contributing to calcium intakes. Both the Australian Dietary Guidelines for Adults and those for Children and Adolescents include a guideline that recommends the consumption of reduced fat varieties of 'milks, yoghurts, cheeses and/or alternatives'. The New Zealand Guidelines include specific recommends that children, adolescents and adults obtain an adequate calcium intake from milk and milk products and non-dairy sources. However, FSANZ's approval of the Application is not expected to increase the likelihood of substitution of dairy foods with calcium fortified chewing gum (≤0.2% residual sugars) that would result in appreciable decreases in calcium or other nutrient intakes.

The evidence for this comes from several sources. Firstly, consumer research was undertaken across the Australian and New Zealand populations by Roy Morgan Research[18] on behalf of the Applicant. The research indicated that substitution of calcium fortified chewing gum (≤0.2% residual sugars) for other calcium risk foods, such as dairy foods, is unlikely. The results showed:

- The proportion of chewing gum consumers (≤0.2% residual sugars) is highest among 14-19 year olds.
- Females (40% Australian; 44% New Zealand) were more likely than males (25% Australian, 31% New Zealand) to express 'interest' in purchasing a calcium-fortified product.
- Forty per cent of Australians (n=170) and 38% of New Zealanders (n=164) interested in purchasing the calcium-fortified chewing gum (≤0.2% residual sugars), reported that they would replace a food in their diet with the calcium-fortified chewing gum. This translates to 13% of all Australian respondents and 14% of all New Zealand respondents.
- A very small proportion of survey respondents (nine in Australia; 11 in New Zealand) indicated they would replace foods such as milk, cheese or yoghurt with this calcium-

[18] FSANZ (2008) A577 Calcium in Chewing Gum containing no more than 0.2% residual sugars. Final Assessment Report. Attachment 4. http://www.foodstandards.gov.au/_srcfiles/FAR_A577_%20Addition%20_Calciu_%20to%20Sugar_free_Chewing_Gum.pdf

fortified chewing gum.[19]

- In the majority of cases the foods listed to be substituted for the calcium-fortified chewing gum (≤0.2% residual sugars) were 'other chewing gum' (41-44% respondents), 'mints', or 'lollies/confectionery' (21-27% respondents).

This shows only a very small proportion of those interested in buying calcium fortified chewing gum (≤0.2% residual sugars) reported they would seek to substitute dairy foods.

In addition, the majority of respondents who reported they would substitute any food, eat chewing gum up to twice a week (62-64% varying for tab or pellet gum Australia; 61-70% for New Zealanders), with very small numbers consuming it more frequently. Therefore, any substitution with other foods is not likely to occur frequently therefore reducing the risk that there would be an impact on usual nutrient intakes.

Other consumer research commissioned by FSANZ in 2005 for Application A424 – Fortification of Foods with Calcium (i.e. fruit- and vegetable- juices and drinks, soups and savoury biscuits) also indicates that significant substitution of dairy foods with calcium fortified foods is unlikely to occur[20]. The main findings of the research were that there was likely to be relatively little impact of calcium fortified drinks on the purchase of milk products for the population and less than 2% of the population stated that they would shift from a milk product to a calcium fortified juice product.

Teenage girls and young women were thought to be particularly vulnerable to substituting dairy foods assuming that the weight conscious among these groups may perceive them to be fattening. The consumer research was evaluated in more detail and broken down by age and gender in order to determine whether it was the teenage or young women that are more likely to substitute dairy foods. The results are shown in Table 1 which shows that teenage girls in Australia did not indicate they would substitute dairy foods, however a small number did in New Zealand. A single young female respondent (20-29 years) in both Australia and New Zealand indicated she would substitute dairy foods. Substitution of dairy foods is not isolated to these two population groups. There are also differences between males and females and between countries.

In addition to the consumer research, FSANZ undertook a worst case dietary modelling scenario by assuming a 50% reduction in milk consumption due to substitution with calcium-fortified beverages as part of Application A424. For riboflavin and zinc, micronutrients that are abundant in milk, the results showed a small decrease in dietary intakes and a small increase in the proportion of the population with dietary intakes below the EAR. Similarly, mean vitamin B_{12} and protein intakes would decrease slightly but still remain above the current Recommended Dietary Intake (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 expected increases in calcium intake from fortified chewing gum (≤0.2% residual sugars).

[19] These numbers are too small to calculate percentages of the total populations of Australia and New Zealand respondents. A total of 1311 Australians and 1084 New Zealanders were surveyed.

[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

Table 1: Number of people in Australia and New Zealand who reported they would substitute calcium rich foods like milk, cheese or yoghurt for calcium-fortified chewing gum (≤0.2% residual sugars), by age and gender[21]

	Australia		New Zealand	
	Male	**Female**	**Male**	**Female**
14-19 years	2	0	0	4
20-29 years	2	1	0	1
30-39 years	0	0	1	3
50 years and over	2	2	0	2

Note: total number surveyed = 1311 Australia; 1084 New Zealand. Sampling was undertaken to obtain a representative sample from each population. The samples were stratified by area, with quotas controlled by gender and age.

Chewing gum (≤0.2% residual sugars) is also promoted to be consumed following meals[22], therefore this is in addition to the normal diet, not replacing foods.

Any effects of substitution behaviours on nutrient intakes, for calcium or other nutrients, resulting from new fortified products coming onto the market would be identified in future monitoring activities. Such activities would cover both foods that are a natural source of the nutrient and those that have been fortified. Food composition programs produce data on the nutrient content of the food supply, including data on fortified foods, and are regularly updated. This monitoring could determine the uptake of this voluntary permission, changes to technology used by gum manufacturers and amounts of calcium added to and available from the gum. National nutrition surveys (NNSs) monitor food consumption patterns, including for fortified foods, and usually report chewing gum consumption. NNSs also estimate dietary intakes of a range of nutrients including calcium, protein, zinc, iron, and many other vitamins and minerals. Therefore, any impacts on changes to the food supply, as well as food consumption patterns and dietary intakes for relevant foods and nutrients, would be assessed and evaluated as part of these monitoring activities.

6.2.2 Little nutritional or health benefit provided

A concern raised in the Review Request was that the amount of additional calcium ingested from the fortified chewing gum, especially with the current technology, will not provide a significant public health benefit and will not address inadequate calcium intakes.

The Policy Guideline states that fortification is appropriate where it has the potential to address the deficient or deliver a benefit to consumers of the fortified food according to its reasonable intended use. At the population level, the dietary intake assessment at Final Assessment indicated that in Australia and New Zealand, calcium-fortified chewing gum (≤0.2 % residual sugars) was likely to have little impact on reducing the proportion of the population with inadequate calcium intakes. However, among chewing gum consumers, fortification is likely to provide a benefit to those consumers with calcium intakes below that of the estimated average requirement. This benefit is expected to increase with future improvements in technology, which could provide a greater amount of calcium per serve, within the maximum permitted levels. This nutrition benefit would also exist for people who

[21] Respondent numbers are too small to report as proportions.
[22] http://www.wrigley.com.au/HealthyTeeth/QuickFacts.asp

have a low consumption of calcium containing foods (e.g. those with lactose intolerance or vegans).

While the 1995 Australian and 1997 New Zealand NNSs reported very low numbers of chewing gum consumers (<1% of the population), results from the more recent consumer research 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)[23].

The difference in the proportion of chewing gum consumers reported in the NNS compared to the consumer research can be explained by the different methodologies used to collect the data and the year that the surveys were conducted in relation to the popularity of consuming chewing gum at those times. The recent consumer research indicated 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). Therefore, additional dietary calcium could be provided to a third or more of the Australian and New Zealand populations.

The dietary intake assessment showed the proportion of chewing gum (≤0.2% residual sugars) consumers with inadequate calcium intakes at baseline, (i.e. with intakes below the EAR before any fortification of chewing gum with calcium), ranged from 35% to 95% of each population group, dependent on age and gender. Further to this, the dietary intake assessment showed that for chewing gum consumers there could be up to a 15% reduction in the proportion of the population whose intakes are below the EAR were the Application to be approved.

An additional source of calcium in the diet from chewing gum provides an additive effect to calcium from many other dietary sources.

Some ingredients and some of the calcium contained in the gum will not be released during chewing. The manufacturers will have product formulations that take this into account including the form of calcium they choose to add. FSANZ's dietary intake assessments were conducted on the amount of calcium *released* from the gum. Claims can only be made in relation to the amount of calcium *released* from the gum.

The Review Request does acknowledge that based on current evidence, chewing gum does provide a dental health benefit. The respective national dental associations of Australia and New Zealand both promote the use of chewing gum (≤0.2 % residual sugars) for dental health, as does the World Dental Federation. At Final Assessment, the risk assessment concluded that based on the available evidence, there is a short term dental benefit of increasing tooth remineralisation from chewing calcium fortified chewing gum (≤0.2% residual sugars).

6.2.3 Chewing gum should not strictly be viewed as a food

It was noted in the Review Request that chewing gum should not strictly be viewed as a food even though it is acknowledged as such in food legislation, as it is not recommended to be swallowed, and therefore the perception that it will contribute to nutrient intake is

[23] FSANZ (2008) A577 Calcium in Chewing Gum containing no more than 0.2% residual sugars. Final Assessment Report. Attachment 4. http://www.foodstandards.gov.au/_srcfiles/FAR_A577_%20Addition%20_Calciu_%20to%20Sugar_free_Chewing_Gum.pdf

unreasonable. It was felt that recommendations in relation to use of the gum (e.g. stipulated serve size, chew time, proximity to a meal) make it fall more in line with a therapeutic product.

As outlined in the Final Assessment Report, and in the Review Request, chewing gum (≤0.2% residual sugars) is considered to be a food according to food legislation. The Final Assessment Report also outlined why the product would not be a therapeutic good. The Australian Therapeutic Goods Administration has declared that oral hygiene products (including unmedicated dental 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 2008)[24]. Therefore, this product is excluded from therapeutic goods legislation.

Calcium-fortified chewing gum (≤0.2% residual sugars) could only be regulated as a therapeutic good if therapeutic claims were made in association with the use of the product.

6.2.4 Bioavailability of the released calcium

A further issue raised in the Review Request related to bioavailability; that the amount of calcium released from the gum will not necessarily equate to the amount absorbed and metabolised.

FSANZ reviewed the bioavailability of calcium as part of Application A424[25]. 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).

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

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

6.2.5 Evidence of health benefit of the permitted forms

Another issue raised was that there is evidence to support some of the permitted forms in relation to absorption and having a health benefit (i.e. the soluble forms), however, no evidence for other forms.

The Applicant had requested permission to use all 14 of the currently permitted forms of calcium in the Code for chewing gum (≤0.2% residual sugars).

At Final Assessment, a number of forms of calcium were noted as providing a dental health benefit, including calcium lactate (permitted form of calcium), calcium carbonate (permitted

[24] TGA (2008) Therapeutic Goods (Excluded Goods) Order No. 1 of 2008. www.tga.gov.au/legis/tgeg0801.htm.
[25] The Application A424 Second Review Report is located at http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa424calciuminjuices/index.cfm

form of calcium), tetracalcium phosphate/dicalcium phosphate (equivalent to the permitted form calcium phosphate dibasic), monocalcium phosphate monohydrate (equivalent to the permitted form calcium phosphate monobasic); and α-tricalcium phosphate (equivalent to the permitted form calcium phosphate tribasic). The Applicant is initially proposing to add calcium lactate or calcium carbonate to chewing gum (≤0.2% residual sugars).

The 14 forms of calcium permitted in the Code for use in many other foods provide additional sources of calcium in the diet. The bioavailability of calcium was described in the previous FSANZ Applications, Application A424 and Application A470 – Formulated Beverages, both of which permitted the voluntary addition of each of the 14 forms of calcium.

As there is no appreciable difference in bioavailability when calcium is released from the chewing gum and swallowed, each of the 14 permitted forms of calcium has the potential to deliver a nutritional benefit. Therefore, FSANZ does not believe that there is a need to restrict the number of forms of calcium permitted to be added to chewing gum (≤0.2% residual sugars).

6.3 Does not provide adequate information to enable informed choice

6.3.1 Potential to mislead the consumer as to the nutritional value of the product

The Review Request raised a concern that there is the potential to mislead consumers as to the nutritional value of the product as they may perceive it to be a good source of calcium. As a result, consumers may choose fortified chewing gum as a substitute for good sources of calcium such as dairy foods. It was also noted in the Review Request that chewing gum (≤0.2% residual sugars) will not be able to make a nutrition claim unless the technology improves to increase the amount of releasable calcium.

The product will be labelled accordingly in order to provide adequate information to enable informed choice. Under the proposed Standard, a claim such as 'with calcium' or 'source of calcium' would only be permitted on the label of calcium-fortified chewing gum (≤0.2% residual sugars) if at least 10% of the regulatory RDI for calcium is released from one serve of the chewing gum during 20 minutes of chewing (i.e. 80 mg releasable calcium per serve). The 10% of the RDI is consistent with the amount of calcium required in other foods under Standard 1.3.2 for nutrition claims to be made about calcium, though the concepts of the amount of calcium *contained* in the produce and *released* from the product are different. While chewing gum (≤0.2% residual sugars) manufactured using the current technology and currently used serve sizes will not be eligible to make a nutrition claim (80 mg releasable calcium/serve), within the context of the future anticipated technology, it is likely that the product will be eligible to make a claim.

Claims such as 'good source' of calcium or releasable calcium are not permitted on calcium-fortified chewing gum (≤0.2% residual sugars). The draft Standard provides an explicit prohibition of such claims.

In addition, the average amount of calcium per 100 g and per serving (per serving only on small packages) and a statement to the effect that the average amount of calcium is released during 20 minutes of chewing, must be declared on the label of chewing gum that carries a nutrition claim about calcium. The label must also include a declaration of the percentage of

the RDI for calcium released from one serving of chewing gum during 20 minutes of chewing.

The consumer research showed that for those respondents interested in purchasing calcium fortified chewing gum (≤0.2% residual sugars), only a very small proportion would substitute dairy foods (see Section 6.2.1). This is an indication that consumers would not be mislead by the nutritional value of the product.

This issue was also raised in relation to consistency with the Policy Guideline as indicated in Section 6.1.4.

6.3.2 Recommendations for chewing gum (≤0.2% residual sugars) consumption

The associated marketing for chewing gum (≤0.2% residual sugars) recommends that the product be consumed after eating meals[26]. It is questioned whether this will occur in reality and at the recommended serve size.

The consumer research conducted by Roy Morgan Research on behalf of the Applicant did not assess chewing of gum after meals. FSANZ also evaluated all information provided previously by the applicant and conducted a literature search, and did not find any consumer research that has been done in this area. FSANZ also asked the Applicant if they were aware of any information on this issue. They provided some information from a study conducted for them by TNS Social Research[27] which showed that for 13-65 year olds, on the last occasion when chewing gum was consumed, 36% of respondents reported they consumed the gum following a meal. Given this was only for one eating occasion, it would be expected that the proportion of the population consuming following a meal averaged across a longer period of time would be higher.

The recommendation to chew chewing gum (≤0.2% residual sugars) after meals is in relation to dental benefits such as plaque reduction. However, whether the gum is chewed following meals or not should not have an impact on the amount of calcium released from the gum during 20 minutes of chewing.

The chewing gum serve size according to product labels is around two grams[28]. The consumer research showed that consumers aged 14 years and over in Australia consumed a mean of 1.8 g/day and in New Zealand, a mean of 2.2 g/day. This indicates that consumers do chew gum in line with serve sizes specified on product labels.

6.3.3 Reliability of self reported data for chewing gum consumption patterns

The Review Request noted that the Applicant provided data to support that consumers do chew chewing gum for 20 minutes. However, there is a concern that these are self reported data and therefore there are doubts about the reliability of this data and therefore the accuracy of this claim.

FSANZ acknowledges that self-reported data have limitations. However, the quality of data is determined by many factors including how the data were collected, the survey

[26] http://www.wrigley.com.au/HealthyTeeth/QuickFacts.asp
[27] TNS Social Research (2008) Gum Chewers.
[28] One tab = 1.9g; one pellet = 1.4g.

methodology, the validity of the questions used, and whether the data provided are correct based on comparison with benchmarks and expected ranges. FSANZ routinely undertakes these quality checks on data sets used in its assessments.

Self-report mechanisms of data collection are commonly used in psychology and other social sciences, and underlying processes of self-reports have been well understood for at least two decades of research into survey methodologies[29] [30] [31]. The main issues affecting accuracy of self-reported data are when questions about past behaviour are asked, for example when respondents are required to remember frequencies of behaviours. Attitudinal measures and predicted/future behaviour are affected by context, and can be subject to biases such as social desirability[32] [33] where the respondent may give an answer they feel would portray them in a certain light. However, in the case of measuring the length of time gum is chewed, there is no apparent social norm which would prompt respondents to over or under report their answer.

The data used to determine whether consumers chew gum for 20 minutes was provided by the Applicant. Based on the two documents provided, the majority of respondents reported that they chew gum for 20 minutes or more. The results of the information provided were not described in detail in the Final Assessment Report. Therefore, a summary of the findings is included below. Data quality has been assessed by FSANZ and the nature of the survey suggests that over or under reporting of chewing time is unlikely.

The first of the two documents was a published paper[34] that investigated self-reported chewing time. This was achieved by asking each respondent (n=4064) to think about how long they would normally chew gum and were given a number of options of minutes to select from for their answer (i.e. 5, 10, 15, 20, 25, 30, 35, 40, 45, 55 or over 55 minutes). The mean chewing time of all respondents was 36 minutes. Over 80% of respondents chewed for 20 minutes or more. Twenty-eight percent of respondents chewed for longer than 55 minutes. A statistical analysis of the results of all respondents shows that the chewing time was significantly longer for females, for those aged 12-17 years and for sorbitol-type chewing gum (compared to sucrose-containing gum). All of the sub-group analyses (gender, age and type of gums) showed a chewing time of over 30 minutes. It should also be noted that the type of gums used for the study is biased towards gum with sucrose with 74% of respondents consuming sucrose-containing gum. However, the sub-group analysis showed the sorbitol gum chewers chew significantly longer than sucrose gum chewers; mean of 36.4 minutes and 34.0 minutes respectively ($p>0.0001$).

The second of the two documents was provided in confidence, however, it does support the published study described above.

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[29] Schwarz, N. (1999) Self-reports: How the questions shape the answers. *American Psychologist, 54*: 93-105.
[30] Sudman, S., Bradburn, N.M. and Schwarz, N. (1996) *Thinking about answers: The application of cognitive processes to survey methodology.* Jossey-Bass, San Francisco, CA.
[31] Tourangeau, R., Rips, L.J. and Rasinski, K. (2000) *The psychology of survey response*. Cambridge University Press, Cambridge.
[32] Describes the tendency of respondents to reply in a manner that will be viewed favorably by others. This will generally take the form of overreporting "good/positive" behaviours, or underreporting "bad/negative" behaviours.
[33] Weaver, K. and Schwarz, N. (2008) Self-reports in consumer research. In Haugtvedt, C.P., Herr, P.M. and Kardes, F.R., eds. *Handbook of Consumer Psychology*. Psychology Press, New York.
[34] Baragolak, R., Hoerman, K., Kroll, B. and Record D. (1991) Gum chewing profiles in the U.S. population. *Community Dentistry and Oral Epidemiology*, 19: 126-126.

FSANZ is not aware of any more recent or further evidence to support or refute that consumers do chew gum for around or more than 20 minutes.

6.4 Difficult to enforce or comply with in both practical and resource terms

6.4.1 No recognised method for determining releasable calcium

The issues raised in the Review Request included there being no standard proven process available, or nationally recognised method, for determining releasable calcium. It was also suggested that, in the absence of validated methodology, neither the regulator nor the manufacturer could be confident that the composition of the product meets the requirements of the draft Standard. It has been further suggested that it is considered 'totally unacceptable' for a standard to be developed without an appropriate scientifically validated methodology.

FSANZ is unaware of any 'current nationally recognised methodology' for any specific chemical substance in food and therefore does not consider that it would be appropriate to apply such a requirement for this particular Application. In addition, FSANZ cannot develop 'methodology' because method development and validation must be undertaken by appointed analysts to reflect their individual capability, their available analytical facilities and their commercial priorities. For this reason, data provided by the Applicant on methods can be of assistance in developing food regulatory measures.

There are forums where agencies can collaborate or develop agreements as to which methods or processes they consider suitable for implementing food regulatory measures or monitoring compliance. FSANZ considers that discussions at these forums are an appropriate means for enforcement agencies to agree upon specific implementation aspects for monitoring releasable calcium in chewing gum. Application A577 has a statutory timeframe under the FSANZ Act and therefore FSANZ is unable to indefinitely delay progress on the Application pending advice from an external body on implementation aspects, other than the Applicant.

Chewing gum (sweetened by polyols and intense sweeteners) fortified with calcium is available in a number of developed countries. For example, 'Cow Power Calcium Chewing Gum', a calcium-fortified chewing gum (sweetened by polyols and intense sweeteners) made in the United States by Ford Gum & Machine Company. The Adams confectionery business was the first company to use Recaldent™ (calcium phosphopeptide-amorphous calcium phosphate or CPP-ACP) in chewing gum (sweetened by polyols and intense sweeteners) that was marketed in the United States, Japan and four European countries. On this basis, FSANZ is of the view that any implementation aspects should be able to be resolved in a similar manner as would appear to have occurred in other countries.

It has been suggested that FSANZ is advocating methods from pharmaceutical references for determining releasable calcium that are used for ingredients in medicated chewing gums. Pharmacopoeial references were provided in an editorial note to the proposed draft Standard 2.10.3 as guidance only. This was included because submissions to the Draft Assessment Report (DAR) requested further guidance in relation to enforcement. Pharmacopoeial references are widely used around the world and are referenced in the Code

for specifications for substances that may be added to food. Kvisti *et al* (1999)[35] refer to guidelines that recommend that mechanical equipment used to determine in vitro substance release from chewing gum should mimic an in vivo situation as closely as possible.

Available apparatus have controls on parameters such as temperature (usually set at 37^{o}C), stroke frequency, distance between chewing surfaces and twisting between surfaces in order to achieve this. In vitro apparatus have been shown to replicate in vivo chew out results[36] [37]. FSANZ therefore considers that pharmacopoeial references are appropriate guidance for inclusion in the Code.

6.4.2 Not enough details provided in the Cost Benefit Analysis

One issue raised in the Review Request was that the cost benefit section provided too little detail and was more qualitative than quantitative. More information was requested in relation to how the costs were determined and agreed upon, the negligible health care expenditure of government and expected small government enforcement costs.

The Office of Best Practice Regulation reviews FSANZ's assessments in accordance with the Council of Australian Governments (COAG) *Best Practice Regulation Guidelines*. The OBPR have advised that the analysis for this Application including the cost benefit section is adequate.

It should be noted that the cost benefit analysis is based on data provided in submissions and by the Applicant. Some quantitative information was provided in the cost benefit analysis that was obtained from the Applicant. Therefore, the cost benefit analysis is primarily qualitative to reflect the data provided, including data in submissions from food regulatory agencies.

No public health and safety concerns were raised as part of the risk assessment for this Application, therefore this results in no changes to current health care costs.

The benefits from approving this Application go beyond nutritional benefits related to calcium intake. Other benefits include an increase in consumer choice in chewing gum products, increased scope for industry innovation and potential short term dental benefits.

[35] Kvist, C., Andersson, S.B., Fors, S., Wennergren, B. and Berglund, J. (1999) Apparatus for studying in vitro drug release from medicated chewing gums. *International Journal of Pharmaceutics*, 189: 57-65.
[36] Kvist, C., Andersson, S.B., Fors, S., Wennergren, B. and Berglund, J. (1999) Apparatus for studying in vitro drug release from medicated chewing gums. *International Journal of Pharmaceutics*, 189: 57-65.
[37] Gajendran, J., Kraemer, J. and Knudsen, S.R. (2008) Stimuli to the Revision Process. Product Performance Test for Medicated Chewing Gums. *Pharmacopeial Forum*, 34 (3) May-June 2008: 843-847.

7. Review Options

There are three options proposed for consideration under this review:

1. re-affirm the approval of the draft Standard 2.10.3 as notified to the Ministerial Council; or

2. re-affirm the approval of the draft Standard 2.10.3 subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft Standard 2.10.3 as notified to the Ministerial Council.

8. Decision

FSANZ has considered the issues raised by the Ministerial Council in relation to Application A577 – Calcium in Chewing Gum containing no more than 0.2% Residual Sugars.

At First Review it is concluded that the preferred option is Option 1. FSANZ has decided to reaffirm, without amendment, the approval of the draft Standard 2.10.3 to permit the voluntary fortification of chewing gum (≤0.2% residual sugars) with calcium.

Decision

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

8.1 Reasons for the Decision

FSANZ reaffirms its decision to approve the draft Standard 2.10.3 permitting the addition of calcium to chewing gum (≤0.2% residual sugars) as:

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

- it is not inconsistent with the nutrition policies and guidelines of Australia and New Zealand;

- chewing gum (≤0.2% residual sugars) is a unique food and is considered to be different from other foods with little nutritional value such as confectionery and soft drinks;

- it provides an additional calcium source for consumers of chewing gum (≤0.2% residual sugars) and potential dental benefits;

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

- consumers will be provided with adequate labelling information to make an informed choice;

- it allows for industry innovation and increased consumer choice; and

- no new evidence has emerged since Final Assessment that would support a change in FSANZ's decision to approve the draft standard.

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

9. Implementation and Review

FSANZ will notify the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) of its decision to re-affirm the draft variations to the Code.

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

ATTACHMENTS

1. Draft Standard for the *Australia New Zealand Food Standards Code*
2. Executive Summary from the Final Assessment Report
3. Ministerial Policy Guideline: *Fortification of Foods with Vitamins and Minerals*
4. The Dietary Guidelines for Australian Adults

Attachment 1

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

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

To commence: on gazettal

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

STANDARD 2.10.3

CHEWING GUM

Purpose

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

Table of Provisions

Clauses

1 Interpretation

In this Standard –

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

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

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

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

Where –

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

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

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

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

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

Editorial note:

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

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

2 Permitted addition of calcium

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

3 Calcium claims

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

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

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

4 Labelling requirements

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

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

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

Editorial note:

EXAMPLE

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

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

5 Small packages

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

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

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

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

Editorial note:

For the purposes of labelling, Standard 1.2.1 defines a 'small package' as a package with a surface area of less than 100 cm^2.
See clause 8 of Standard 1.2.8 for labelling requirements where nutrition claims, other than calcium claims, are made on small packages of chewing gum suitable for added calcium.

Attachment 2

Executive summary from the Final Assessment Report

Regulatory Approach

Food Standards Australia New Zealand (FSANZ) received a paid Application from the Wrigley Company Pty Ltd (the Applicant) on 22 February 2006 seeking to amend the *Australia New Zealand Food Standards Code* (the Code), to permit the addition of calcium to chewing gum containing no more than 0.2% residual sugars[38].

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[39]) releasable calcium per serve;
- add each of the 14 forms of calcium currently permitted in the Schedule to Standard 1.1.1; and
- base claims on the amount of calcium released from calcium-fortified chewing gum (≤0.2% residual sugars) during 20 minutes of chewing.

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

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

Risk Assessment

The risk assessment approach has considered Ministerial policy guidance (*Fortification of Food with Vitamins and Minerals*)[40]. The Application was assessed on the basis of inadequate calcium intakes and whether the proposed addition of calcium to chewing gum (≤0.2% residual sugars) has the potential to assist in addressing calcium inadequacy among consumers of the product.

[38] 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)'.
[39] The current RDI for calcium is 800 mg, as stated in the Schedule to Standard 1.1.1.
[40] http://www.foodstandards.gov.au/_srcfiles/Mandatory_Fortification_June_2006.pdf.

In addition, the Application has been assessed on the ability to deliver a health benefit; in this case, the potential for a dental health benefit arising from a topical application of calcium from chewing gum (≤0.2% residual sugars) with added calcium[41].

Dietary intakes were estimated and were based on the amount of 'releasable calcium' from the chewing gum. The recently endorsed Nutrient Reference Values (NRVs)[42] for calcium (described in Section 2.5) have been used as the basis of assessing inadequate and excess intakes in the population.

At Final Assessment, the key risk assessment findings are:

- the majority of males and females in Australia and New Zealand have inadequate calcium intakes[43];

- calcium-fortified chewing gum (≤0.2% residual sugars) could have a modest impact on reducing the proportion of chewing gum consumers who have inadequate calcium intakes;

- each of the 14 permitted forms of calcium has the potential to deliver a nutritional benefit as there is no appreciable difference in bioavailability;

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

- there is a small risk that some consumers may replace calcium-rich foods with calcium-fortified chewing gum (≤0.2% residual sugars), but this is unlikely to cause any dietary inadequacies of other nutrients;

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

- some evidence exists of a short-term benefit to dental health through increased tooth remineralisation although this has only been shown to date when either calcium lactate, calcium carbonate or some of the more soluble forms of calcium phosphate have been added to chewing gum (≤0.2% residual sugars).

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

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[41] FSANZ notes in the Policy Guideline that 'can deliver a health benefit' is in the context of increased intake of a vitamin or mineral, but has extended the application of the Specific Order Policy Principle in this case to include dental benefit from a topical application of the vitamin or mineral.

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

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

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

Risk Management

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

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

Decision

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

Reasons for Decision

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

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

- supports industry innovation;

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

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

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

Consultation

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

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

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

Implementation and Review

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

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

Attachment 3

Policy Guideline Fortification[44] of Food with Vitamins and Minerals

This Policy Guideline provides guidance on development of permissions for the addition of vitamins and minerals to food.

The Policy Guideline does not apply to special purpose foods the formulation and presentation of which are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code).

The policy should only apply to new applications and proposals. There is no intention to review the current permissions.

The policy does not apply to products that should be or are regulated as therapeutic goods. This should not lead to a situation were generally recognised foods, through fortification, become like or are taken to be therapeutic goods.

The policy assumes the continuation of a requirement for an explicit permission for the addition of a particular vitamin or mineral to particular categories of foods to be included within the Food Standards Code. Currently the majority of permissions are contained in Standard 1.3.2 – Vitamins and Minerals.

Regard should be had to the policy in development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.

The policy for regulation of health and nutrition claims on fortified food is covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims should be permitted on fortified foods, providing that all conditions for the claim are met in accordance with the relevant Standard.

'High Order' Policy Principles

The Food Standards Australia New Zealand Act 1991 (the Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
   (a) the protection of public health and safety;

[44] Within the context of this policy Fortification is to be taken to mean all additions of vitamins and minerals to food including for reasons of equivalence or restoration.

(b) the provision of adequate information relating to food to enable consumers to make informed choices; and

(c) the prevention of misleading or deceptive conduct.

2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;

(b) the promotion of consistency between domestic and international food standards;

(c) the desirability of an efficient and internationally competitive food industry;

(d) the promotion of fair trading in food; and

(e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating the addition of vitamins and minerals to food.

A number of other policies are also relevant to the development of food standards including the Council Of Australian Governments document 'Principles and Guidelines for national Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies(1995, amended 1997)(Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System and relevant World Trade Organisation agreements.

Specific Order Policy Principles - Mandatory Fortification

The mandatory addition of vitamins and minerals to food should:

1. Be required only in response to demonstrated significant population health need taking into account both the severity and the prevalence of the health problem to be addressed.
2. Be required only if it is assessed as the most effective public health strategy to address the health problem.
3. Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
4. Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
5. Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

The specified health objective of any mandatory fortification must be clearly articulated prior to any consideration of amendments to the Food Standards Code to require such mandatory fortification.

The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia New Zealand raise a proposal to consider mandatory fortification.

The assessment of public health strategies to address the stated health problem must be comprehensive and include an assessment of alternative strategies, such as voluntary fortification and education programs.

Consideration should be given, on a case by case basis, to a requirement to label foods that have been mandatorily fortified by including the information in the Nutrition Information Panel of the food label.

An agreement to require mandatory fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Specific order policy principles – Voluntary fortification

- 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 data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits.

  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.

  or
  - To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration[45]).

  or
  - To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).
- 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.

[45] The principle of Modified Restoration as derived from The FSANZ document *Regulatory principles for the addition of vitamins and minerals to foods*. (Canberra, 2002) is as follows:
Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

- 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.
- Fortification will not be permitted in alcoholic beverages.
- 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.

Additional Policy Guidance - Voluntary Fortification

Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements.

Monitoring/Review - A permission to voluntary fortify should require that it be monitored and formally reviewed in terms of adoption by industry and the impact on the general intake of the vitamin/mineral.

Attachment 4

The Dietary Guidelines for Australian Adults

Enjoy a wide variety of nutritious foods

- Eat plenty of vegetables, legumes and fruits
- Eat plenty of cereals (including breads, rice, pasta and noodles), preferably wholegrain
- Include lean meat, fish, poultry and/or alternatives
- Include milks, yoghurts, cheeses and/or alternatives. Reduced-fat varieties should be chosen, where possible
- Drink plenty of water.

and take care to

- Limit saturated fat and moderate total fat intake
- Choose foods low in salt
- Limit your alcohol intake if you choose to drink
- Consume only moderate amounts of sugars and foods containing added sugars.

Prevent weight gain: be physically active and eat according to your energy needs

Care for your food: prepare and store it safely

Encourage and support breastfeeding

These guidelines are not in order of importance.

Each one deals with an issue that is key to optimal health.

Two relate to the quantity and quality of the food we eat—getting the right types of foods in the right amounts to meet the body's nutrient needs and to reduce the risk of chronic disease. Given the epidemic of obesity we are currently experiencing in Australia, one of these guidelines specifically relates to the need to be active and to avoid overeating.

Another guideline stresses the need to be vigilant about food safety, and, in view of the increasing awareness of the importance of early nutrition, there is a further guideline that encourages everyone to support and promote breastfeeding.