EXPLANATORY STATEMENT

APPLICATION A424

FORTIFICATION OF FOODS WITH CALCIUM

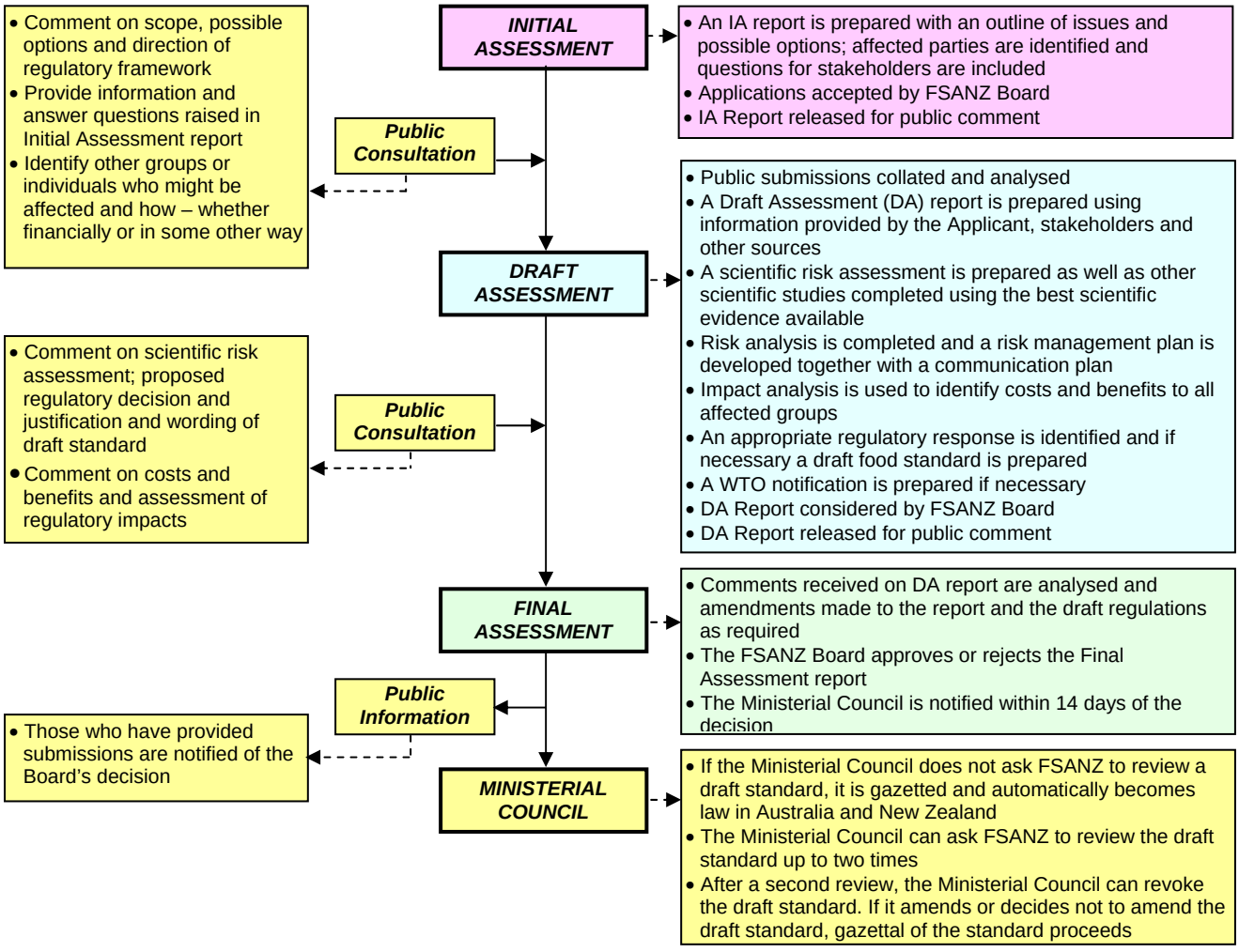
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage

The Authority has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and are now being reviewed by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC).

If accepted by ANZFRMC, a change to the *Australia New Zealand Food Standards Code* is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the Standards Liaison Officer at Food Standards Australia New Zealand at one of the following addresses:

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

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

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

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from Food Liaison Pty Ltd on behalf of Arnott's Biscuits Limited and Nutrinova Pty Ltd 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 fruit- and vegetable juices, fruit- and vegetable drinks, fruit cordial, soups and savoury biscuits. Following Draft Assessment the Applicant notified FSANZ that fruit cordials has been withdrawn from the requested list of foods. Consequently the scope of this Application has narrowed to fruit- and vegetable- juices and drinks, soups and savoury biscuits. Further reference to the Applicant's requested list of foods in this Report now omits fruit cordials.

Regulatory Problem

Vitamins or minerals are not permitted to be added to general-purpose foods unless the addition of the vitamin or mineral is specifically permitted in Standard 1.3.2 – Vitamins and Minerals and the vitamin or mineral is in a permitted form as specified in the Schedule to Standard 1.1.1 of the Code.

Objective

Protect the health and safety of the community in their consumption of calcium-fortified fruit juices, fruit drinks, soups and savoury biscuits.

Background

This Application has been assessed against Regulatory Principles for the voluntary vitamin and mineral addition to general purpose foods that were previously clarified and elaborated by FSANZ in 2002 from a previous version developed during the 1990s based on the Codex *General Principles for the Addition of Essential Nutrients to Foods* (Codex General Principles).

Issues

Issues considered in this Final Assessment include (with consideration of the dietary intake assessment):

- the eligibility of the nutrient for voluntary fortification;
- the eligibility of the foods proposed for fortification;
- an assessment of the risk of excess calcium intake;
- a consideration of potential effectiveness;
- an assessment of the risk of nutrient deficits or imbalances; and
- consideration of risk management strategies in relation to addressing the inappropriate consumption of calcium-fortified food products.

Options

There are two options for addressing this Application:

- **Option 1 – No approval**. Maintain the status quo by not amending the Code to approve the voluntary addition of calcium to the food products requested by the Applicant.

- **Option 2 – Approval**. Amend the Code by approving the voluntary addition of calcium to the requested range of food products.

Impacts

The conclusion of the impact analysis is that **Option 2**, approval of the Application, is the preferred option taking into account the dietary intake assessment and matters raised by submitters. Some of the specific considerations in reaching this conclusion were as follows:

- There are benefits to consumers of additional and/or alternative food sources of calcium.

- Dietary intake assessment indicates that there is very little risk of excess consumption of calcium.

- The potential exists to improve the calcium intake of population subgroups whose current intakes are assessed as inadequate. This potential benefit is estimated to outweigh any risks associated with inappropriate use of the calcium-fortified products as substitutes for dairy foods.

Consultation

A total of 25 submissions were received in response to the Draft Assessment released in December 2002. At Draft Assessment the Application included fruit based cordials in the list of foods to be amended in Standard 1.3.2. Of the submissions, 11 submitters unconditionally supported approval and 10 submitters opposed the Application in its entirety. Four other submitters either: supported limited permissions (variation of Option 2) or declined to support either option; in each case, the major issue of contention was the proposed permission to fortify cordial with calcium, although in general calcium fortification of fruit- based beverages was more contentious than for vegetable-based beverages, soups or savoury biscuits.

Conclusion and Statement of Reasons

FSANZ approves the draft variation to Standard 1.3.2 to permit the voluntary addition of calcium to fruit- and/or vegetable juices, fruit- and/or vegetable-drinks, soups and savoury biscuits to 25% RDI/ reference quantity – equivalent to a 'good source of calcium' content claim, for the following reasons:

- Calcium is considered to be potentially eligible for voluntary fortification (subject to risk assessment) because, in accordance with FSANZ's Regulatory Principles for the Addition of Vitamins and Minerals to Foods (Regulatory Principles), 30% of more than one population subgroup in both Australia and New Zealand has a customary intake below the (UK) Estimated Average Requirement (EAR) for calcium based on National Nutrition Surveys.

- All foods requested by the Applicant are considered to be eligible for voluntary fortification (subject to risk assessment) since the food categories meet the nutritional criteria set out in FSANZ's Regulatory Principles.

- Dietary modelling has shown that there are subgroups of the Australian and New Zealand populations who are at risk of inadequate calcium intakes. Low calcium intake is proven to be one of a number of factors contributing to osteoporosis. Increasing intakes of calcium can (over time) significantly reduce the burden of osteoporosis to the community.

- The dietary intake assessment estimates that there would be negligible risk of excess calcium intake based on the addition of calcium to all the requested foods at the maximum levels proposed. There is minimal risk of long-term substitution of milk for calcium-fortified beverages or of an inappropriate increase in fruit- or vegetable beverage consumption as a result of calcium fortification.

- The addition of calcium to all the requested foods has the potential to increase the calcium intake of the population or subgroups of the population whose current intakes are inadequate. However, this potential benefit depends on the extent to which the permission to voluntarily add calcium is taken up by industry.

- Permission for the voluntary fortification of the requested foods with calcium would provide consumers with additional and/or alternative food sources of calcium.

It is recommended that all requested food categories i.e. fruit- and vegetable juices, fruit- and vegetable- drinks, soups and savoury biscuits be permitted to be voluntarily fortified with calcium to a maximum level of 25% Recommended Dietary Intake (RDI) per reference quantity, which qualifies the food to bear a 'good source of calcium' content claim.

1. Introduction

1.1 Subject of the Application

FSANZ received an Application from Food Liaison Pty Ltd on behalf of Arnott's Biscuits Limited and Nutrinova Pty Ltd to amend Standard 1.3.2 – Vitamins and Minerals, of the Code, to permit the addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, fruit cordial, soups and savoury biscuits.

Following Draft Assessment the Applicant notified FSANZ that the request to permit fortification of fruit cordials had been withdrawn. Consequently the scope of this Application has narrowed to fruit- and vegetable- juices and drinks, soups and savoury biscuits. Further reference to the Applicant's requested list of foods in this Report now omits fruit cordials.

2. Regulatory Problem

2.1 Current regulations

2.1.1 Standard 1.3.2 – Vitamins and Minerals

A vitamin or mineral is not permitted to be added to a food unless the addition of that vitamin or mineral is specifically permitted in Standard 1.3.2 – Vitamins and Minerals or elsewhere in the Code and the vitamin or mineral is in a permitted form[1]. Standard 1.3.2 regulates the addition of vitamins and minerals to general purpose foods (not special purpose foods e.g. infant formula), and the claims that can be made about the vitamin and mineral content of the foods. Standard 1.3.2 currently permits the voluntary addition of calcium to certain general purpose foods such as breakfast cereals and most dairy products, however, there is no current permission for the voluntary addition of calcium to the non-dairy products requested by the Applicant.

2.2 Current market presence of fruit- and vegetable-based beverages with increased calcium content

Currently, some fruit- and vegetable-based beverages on the Australian and New Zealand market have an increased calcium content through either regulation in New Zealand as dietary supplements, or in Australia through the lawful use of dairy-based whey ingredients in fruit drinks.

2.3 Requested amendment to Standard 1.3.2

The Applicant requests an amendment to the Table to clause 3 of Standard 1.3.2 to permit the voluntary addition of currently permitted calcium salts specified in the Schedule to Standard 1.1.1 to a range of products so as to allow a maximum claim per reference quantity of 25% Recommended Dietary Intake (RDI)/reference quantity. The requested foods fall into two categories: those that are already permitted vitamin or mineral fortification i.e. fruit juice, vegetable juice, tomato juice, fruit drinks containing at least 25% fruit juice, and savoury biscuits containing not more than 20% fat, and not more than 5% sugar; and two new categories – soup and vegetable drinks containing at least 25% vegetable juice. For the new foods, the reference quantities proposed are 200 mL each.

[1] As specified in the Schedule to Standard 1.1.1 of the Code, unless stated otherwise in the Code.

2.4 Public health risks

Dietary modelling has shown that there are subgroups of the Australian and New Zealand populations that are at risk of inadequate calcium intakes. Low calcium intake, particularly before adult maturity, increases the risk of weaker bones and in later life, of developing osteoporosis. Increasing calcium intakes in these at risk groups may deliver public health benefits in producing healthier bones and teeth, and possibly reducing the burden of osteoporosis to the community.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet the three primary objectives 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 Council for the purposes of this paragraph and notified to the Authority.

The specific objectives of this Application are to:

1. Protect the health and safety of the community in their consumption of calcium-fortified fruit juices, fruit drinks, soups and savoury biscuits.

2. Ensure that adequate information is provided to enable consumers to make informed choices, should this Application be accepted.

4. Background

4.1 Development of Standard 1.3.2 – Vitamins and Minerals

Standard A9 – Vitamins and Minerals, of the former Australian *Food Standards Code* was gazetted in 1987. In 1995, Australia revised Standard A9 to permit voluntary addition of a total of 16 vitamins and minerals to an expanded 21 categories of general foods. In 1996, the provisions of Standard A9 were adopted with minor changes into Regulation 20A of the New Zealand *Food Regulations 1984* (NZFR). Since 1996, each country's version of the regulation expanded to include a small number of new nutrients for existing foods or new food categories.

A subsequent limited review of Standard A9 and equivalent provisions in the NZFR was the subject of Proposal P166 – Vitamins and minerals in general purpose foods, from which the joint Standard 1.3.2 – Vitamins and Minerals of the Code was developed.

4.2 Regulatory Principles for vitamin and mineral addition to general purpose foods

Regulatory Principles for the voluntary vitamin and mineral addition to general purpose foods were first developed by FSANZ's predecessor, the National Food Authority, in 1995. They were derived from the Codex *General Principles for the Addition of Essential Nutrients to Foods* (Codex General Principles) developed by the Codex Alimentarius Commission. As noted above, these Regulatory Principles were revised in 1999 through Proposal P166 as part of the development of joint Australia New Zealand food standards.

FSANZ's Regulatory Principles for the addition of vitamins and minerals to foods were clarified and elaborated in order to provide a basis for future decision-making in relation to relevant applications and proposals until such time as the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) develops policy guidance on this matter. In June 2002, the FSANZ Board granted an extension of six months to the statutory timeframe for the assessment of Application A424.

The Application has been assessed against these Regulatory Principles until the Ministerial Council release fortification policy guidance. The Regulatory Principles were presented at Attachment 2 in the Draft Assessment Report and can be found on the FSANZ website[2]. An extract from these Regulatory Principles that addresses voluntary fortification only is given at Attachment 4. However, a summary of the Regulatory Principles that relate to voluntary fortification is outlined in the Box below.

Voluntary Fortification

Specified foods may be voluntarily fortified with vitamins and minerals to potentially address situations where:

1 There is evidence of dietary inadequacy as assessed by the percentage (generally 30% or more) of the whole population or more than one age/sex subgroup whose customary vitamin or mineral intakes are below the respective (UK) Estimated Average Requirements (EAR). The nutrient of interest may also be related to a disease outcome of public health significance; and

2 The food category proposed for fortification is consistent with nationally endorsed guidance for healthy eating. To avoid the promotion (by virtue of a nutrient content claim) of foods that might increase risk factors for disease if consumed in excess amounts or that have little nutritional value, the following compositional criteria have been developed.

3 The food category generally (in ready to consume form) must:

a) have no more than 25% by ingoing weight of:

[2] Regulatory principles for the Addition of Vitamins and Minerals to Food http://www.foodstandards.gov.au/standardsdevelopment/Applications/Applicationa424calciuminjuices/a424darcalciuminjuic1838.cfm

i) added sugars[3]; and
ii) any ingredient comprising more than 75% triglyceride.

b) contain no more than 800 mg sodium per manufacturer's serve size.
c) *prior to vitamin and/or mineral addition*, must also naturally contain at least one vitamin or mineral whose content is at least 5% of the Recommended Dietary Intake (RDI) as listed in the Schedule to Standard 1.1.1 per manufacturer's serve size.

The Food Regulation Standing Committee (FRSC) has recently commenced work on new policy guidelines in relation to food fortification on behalf of the Ministerial Council to be released early in 2004. However, in accordance with the FSANZ Act, this Application has to be assessed within the statutory timeframe and cannot be delayed pending guidance from the Ministerial Council.

5. Relevant Issues

5.1 Assessment of A424 against the Regulatory Principles for voluntary fortification and issues raised by submitters

An assessment of the appropriateness of voluntary fortification in relation to both: the nutrient, calcium; and the food vehicles proposed for fortification, has been conducted. An assessment of the nutrient or food as eligible does not guarantee that a permission for the food/nutrient combination will be granted, but allows the food/nutrient combination to be considered further.

5.1.1 Eligibility of calcium for potential fortification

FSANZ's Regulatory Principles state that a vitamin or mineral may be considered to be eligible for voluntary fortification in a new food category if more than 30% of more than one age/sex population subgroup has a customary intake below the United Kingdom EAR as shown by national nutrition surveys.

Percentages of respondents to the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey with calcium intakes below the UK EAR for calcium were determined. There were a number of population subgroups with 30% or more of respondents whose calcium intake in one day was below the EAR for calcium. In Australia, more than 30% of the respondents from nine subgroups consumed less than the EAR for calcium as assessed by one-day intakes. In New Zealand, more than 30% of the respondents for eight subgroups consumed less than the UK EAR for calcium (only respondents 15 years and over were surveyed). For New Zealand, 33.9% of all respondents consumed less than the EAR. For Australia, 28.4% of all respondents consumed less than the EAR. This percentage was reduced to 18.8% when adjusted for second-day intakes.

[3] Defined as: hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or starch hydrolysate; or glucose syrups, maltodextrin and similar products; or products derived at a sugar refinery, including brown sugar and molasses; or icing sugar; or invert sugar; or fruit sugar syrup; or malt or malt extracts; or honey; or concentrated and/or deionised fruit juice.

Second-day adjustments are not currently available for subgroups or for the New Zealand population. It is likely that with adjustment for second day intakes, the number of affected subgroups would decline.

However, some subgroups have a much greater than 30% of respondents with one-day intakes below the EAR e.g. 16-18 year old females would likely still meet the Regulatory Principles criterion after adjustment for second-day intakes. Many Maori subgroups also have a high percentage of respondents with intakes below the EAR (see Attachment 2 for data on further subgroups).

Table 1: Percentage of respondents in Australia and New Zealand with dietary calcium intakes below the United Kingdom EAR for calcium (mg/day)

Age Group	Sex	Australia	New Zealand
2-3 years	Male	7.1	na
	Female	7.5	
4-6 years	Male	9.9	na
	Female	17.5	
7-10 years	Male	11.8	na
	Female	22.6	
11-12 years	Male	**37.0**	na
	Female	**34.0**	
13-15 years	Male	**33.0**	na
	Female	**44.7**	
16-18 years (Australia)	Male	29.8	na
	Female	**47.2**	
15-18 years (New Zealand)	Male	na	**44.0**
	Female		**39.4**
19-24 years	Male	19.0	28.3
	Female	**36.9**	**36.4**
25-44 years	Male	22.1	22.4
	Female	**34.8**	**37.2**
45-64 years	Male	24.1	**32.8**
	Female	**32.2**	**35.8**
65+ years	Male	27.8	**35.6**
	Female	**39.8**	**37.9**
Total Population	24 hour recall	28.4	**33.9**
	Adjusted 2nd day	18.8	na

Note. Bold text in each table indicates those groups where greater than 30% of respondents have intakes less than the EAR based on one-day intake.

In its report titled *The Burden of Brittle Bones*, Access Economics reports that in 2001, nearly two million Australians had osteoporosis-related conditions. Osteoporosis is a multi-factorial disease with calcium intake being one relevant factor. Although population-based approaches such as fortification are not considered an efficacious method for reducing population *incidence* of osteoporosis[4], increasing the calcium intake of the population is consistent with national dietary guidance and has the potential to improve currently inadequate calcium intakes. The Australian Dietary Guidelines for Children and Adolescents[5] include a guideline that recommends the consumption of milks, yoghurts, cheeses and/or alternatives, primarily based upon the calcium provided by these products..

[4] WHO. Technical report series 916- Diet, Nutrition and the Prevention of Chronic Disease. March 2003
[5] Dietary Guidelines for Children and Adolescents 2003. Sourced from http://www.health.gov.au/nhmrc/publications/pdf/n34.pdf

The New Zealand Ministry of Health Outcome Targets[6] include *increase the intake of calcium so that 75% or more of the population have a calcium intake greater than 600mg per day.*

5.1.1.1 Conclusion

Calcium is eligible for further consideration of voluntary fortification (in terms of a risk assessment framework) since:

- more than 30% of more than one age/sex population subgroup has a customary intake below the EAR as shown by national nutrition surveys; and
- calcium intake is one of several factors associated with osteoporosis, a disease of public health significance.

5.1.2 Eligibility of foods for potential fortification

The risk of nutritional inappropriateness of a food to contain, and be promoted as containing, an added vitamin or mineral should be evaluated against the potential for that addition to decrease the percentage of the identified population whose intakes are assessed as inadequate. In general terms, the food proposed for fortification should be consistent with nationally endorsed guidance for healthy eating.

Six categories of foods are proposed for calcium fortification; they comprise some non-dairy beverages, soups and most savoury biscuits. Some of the beverages under consideration contain reasonably high amounts of sugar from both natural and added sources. While juices contain mainly natural sugars, fruit drinks often contain added sugars. The dietary guidelines recommend taking care to: consume only moderate amounts of sugars and foods containing added sugars; limit saturated fat and moderate total fat intake; and choose foods low in salt[7,8]. The products under consideration mostly contain low to moderate amounts of fat, and are generally low in salt with the exception of some soups and vegetable juices.

5.1.2.1 Assessment of candidate foods against compositional criteria

The compositional criteria for assessing the suitability of a food to be voluntarily fortified is based on a similar approach to that applied to 'claimable foods' as defined in Standard 1.3.2. The compositional criteria to be applied to candidate foods for voluntary fortification are included in the Box in Section 4.2 of this Report.

The majority of candidate foods in the two new food categories to be listed in the Standard i.e. vegetable drinks and soups must meet *all* of the compositional criteria in order to be eligible for fortification. The limits on sugar and fat given in these criteria are recipe based, that is, they are stated in terms of added sugars and type of fat ingredients. This contrasts with the alternate nutrient content approach, in which the total sugars or fat content are

[6]Progress on Health Outcome Targets 1997. Sourced from www.moh.govt.nz/.../5b3ac5e440f6ccd7cc2569b8007e5e9f/ $FILE/foodandnutrients.pdf

[7] Dietary Guidelines for Australians (May 2003) Sourced from: http://www.health.gov.au/nhmrc/publications/pdf/n33.pdf

[8] Food and Nutrition Guidelines for Healthy Adults – a background paper (April 2002) Sourced from: http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/f01ce3552a33c9f3cc256b9600147891?OpenDocument

determined by nutrient analysis, but which include naturally present sugars and fats. The foods in the food categories must contain less than 800 mg sodium per serve. A moderate nutrient density of the food is assured by the requirement that the food contains, per manufacturer's serve, at least one vitamin or mineral at 5% of the RDI prior to fortification.

FSANZ recognises that not every product in a particular food category would necessarily meet the compositional criteria. However, permission for voluntary fortification of a food category would be granted (subject to a risk assessment) if the majority of products in that category met all the criteria. Thus, FSANZ recognises that *most*:

1. Savoury biscuits in the category under consideration will meet criteria c), i.e. they will naturally contain at least 5% RDI for at least one vitamin or mineral per manufacturer's serve size e.g. niacin and/or thiamin and/or phosphorus and/or iron;
2. Soups will meet criteria b), i.e. they will contain less than 800 mg sodium per manufacturer's serve size;
3. Fruit-and vegetable-based beverages will meet criteria a), i.e. they will contain no more than 25% combined added sugars and fat by ingoing weight when prepared according to directions; and
4. Fruit-and vegetable based beverages will meet criteria c), i.e. they will naturally contain at least 5% RDI for at least one vitamin or mineral per manufacturer's serve size due to their natural vitamin C or carotene content.

One submitter to the Initial Assessment Report contended that savoury biscuits are inappropriate foods to contain added calcium because they 'often have a high fat content'. However, the Application sought only to extend by one the present range of nine vitamins and minerals permitted addition to savoury biscuits. Savoury biscuits are already restricted by limits on their fat and sugar content, (not more than 200 g/kg fat and not more than 50 g/kg sugar). However, in accordance with the Regulatory Principles, the 5% limit for sugar has been expanded to include all sugars as defined in Standard 2.8.1 – Sugars and the drafting at Attachment 1 reflects this.

5.1.2.2 Conclusion

Fruit- and vegetable juices, fruit- and vegetable drinks containing at least 25% juice, soups and savoury biscuits, subject to a risk assessment, are all considered to be eligible food categories for voluntary fortification based on the criteria established in FSANZ's Regulatory Principles.

5.2 Assessment of the public health risk of permitting calcium fortification of the requested products, incorporating issues raised by submitters

An assessment of the risk of health hazards due to essential nutrient excesses, deficits or imbalances has been conducted in accordance with the following Guiding Statement that has been incorporated into the Regulatory Principles:

> *Consistent with the Codex General Principles for the Addition of Essential Nutrients to Foods, the addition of vitamins and minerals to general purpose and special purpose foods should not be permitted where no adequate nutritional rationale can be provided.*

Regulatory Principles that are elaborated in accordance with this guiding statement aim to prevent the indiscriminate addition of essential nutrients to foods thereby reducing the risk of health hazards due to essential nutrient excesses, deficits or imbalances.

The vast majority of concerns raised by submitters focused on the fortification of fruit-based beverages; very little comment addressed vegetable beverages, soups or savoury biscuits.

5.2.1 Risk of excess calcium intake

The risk to a population or subpopulation of excess consumption of calcium was discussed at length in the Draft Assessment Report.

The Upper Safe Limit (UL) of 2,500 mg calcium/day set by the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes in the United States is based on the critical endpoint of hypercalcaemia and renal insufficiency (milk alkali syndrome, or MAS). Data on MAS was considered adequate to determine an UL for calcium. The Standing Committee judged the UL for calcium to be conservative and that it should be protective for individuals who are particularly susceptible to high calcium intakes, such as those with hypercalcaemia and hyperabsorptive hypercalciuria. Additionally, a number of studies observed that daily calcium intakes of up to 2,500 mg/day would not cause MAS.

The dietary intake assessment conducted at Draft Assessment estimated one-day dietary calcium intakes, which were adjusted to incorporate second-day intakes in an attempt to gain a more accurate estimation of longer-term intakes. The second-day adjustment factor used at Draft Assessment was developed assuming all the products specified in the Application were fortified with calcium.

Cordial has since been withdrawn from the Application, and further dietary intake assessment has been undertaken (Attachment 2). A second-day adjustment factor has not yet been determined to account for the reduced range of foods. However, for the purposes of comparison, the adjustment factor developed at Draft Assessment is considered sufficiently similar to be used to adjust the estimated one-day dietary intakes derived in this Final Assessment, without cordial.

The dietary intake assessment of the original list of requested foods including cordials each at a maximum amount of 25% RDI calcium /reference quantity, had assumed 100% industry adoption of the sought after permissions. Results of the adjusted 95th percentile intake for Australian males aged 16-24 years was approximately equal to the UL for calcium (2500 mg/day). The conclusion was that this represented a minimal risk of excess calcium intake.

With the withdrawal of cordials from the Application, revised results indicate that males 16-24 years still remain most at risk of excess calcium intake. Table 2 illustrates the effect on estimated calcium intakes after the withdrawal of cordial from the Application and adjusting for longer-term intake. The estimated adjusted 95th percentile calcium intake is 2345 mg/day, which is below the UL of the group most at risk of excess calcium intake.

Modelling was again done on the assumption of a 100% uptake by industry to fortify. In reality, only a portion of manufacturers would be expected to fortify their products. Information available (e.g. NNS data) suggests that the pattern of high calcium consumption of young adult males is not continued through the life cycle. No submitters to the Draft Assessment Report commented on the risk of over-consumption.

Table 2. Estimated 95th percentile dietary intakes of calcium by Australian males aged 16 – 24 years before and after fortification and adjustment for longer-term intake

Scenario	Estimated dietary intake (mg/day)	
	Unadjusted	Adjusted
Fortification (including cordial)	2955	2550
Fortification (without cordial)	2720	2345
Baseline (no fortification)	2460	2105

5.2.1.1 Conclusion

The evidence provided by dietary modelling in the Draft Assessment Report suggested that there would minimal risk of over-consumption of calcium by permitting the fortification of the foods listed in the original Application. Subsequent modelling to reflect the withdrawal of cordial from the Application has further decreased this risk.

5.2.2 Risk of increased consumption of substitute foods

A further risk relates to the potential for inappropriate substitution of a natural source of a key vitamin or mineral by a nutritionally different food fortified with the same key vitamin or mineral based on product similarity or perceived use. An example of this would be consumers drinking fortified juice in place of their usual milk intake. The implications for inappropriate substitution include changes in nutrient intakes other than the vitamin or mineral proposed for addition.

Concerns have been raised by submitters, particularly from the nutrition/public health sector, that calcium-fortified fruit- and to a lesser extent, vegetable juices and their drink-type counterparts might be used as a substitute for milk, in particular by low income earners and children (food purchased by the parents because the children do not like the taste of milk or dairy products).

Experience in the USA during the last 15 years has shown that calcium-fortified beverages have gained an approximate 25% market share within a stable fruit-beverage market and that the fortified products are being substituted for unfortified beverages rather than for milk. FSANZ has conducted database searches over the period in which calcium-fortified juice has been available in the US and has not identified any research that supports concerns about long term substitution or increased fruit or vegetable beverage consumption.

The beverages proposed by this Application are considered to be sufficiently different in nutrient profile, taste and use from milk and similar dairy products to be considered an ongoing substitute food for these products. Moreover, it is considered that any habitual substitution of milk for juice would be by those who also preferred the other attributes of juice over milk.

Milk and dairy products are also consumed for reasons other than their calcium content such as taste, and the suitability of milk with breakfast cereal, in hot beverages and as an ingredient in baked products, sauces and custards. One submitter undertook independent research to gain an indication of the response of consumers to calcium-fortified beverages if they were available on the Australian market.

The research involved a Newspoll survey of 1200 people, that asked respondents if they would definitely, probably or not purchase calcium-fortified fruit juice, fruit drinks and or fruit based cordials. Approximately 35% of the interviewees reported they would purchase these products. Of those potential purchasers, about 50-60% said they would purchase fortified beverages as a substitute for something else. The majority of purchases made as a substitute would be used to replace non-fortified beverages including fruit juice beverages and soft drinks. Only about 8% of respondents considering purchasing any fortified beverage thought that they might use them instead of milk or water. This equates to about 1% of all 1200 respondents considering using fortified beverages as a replacement for something other than a non-fortified fruit beverage or soft drink. The Newspoll survey did not address frequency of purchase (one off or ongoing), or the likely consumed amounts. Neither did it ask respondents who indicated that they might use the fortified beverages as a replacement for milk, if they currently consumed milk. It would be reasonable to assume that the small percentage of respondents who said that they would be consuming these products in place of milk or water would not be replacing all of their milk or water intake over the long term. Figure 1 below details the executive summary of the Newspoll survey.

Figure 1: Executive summary from Newspoll Survey

Newspoll Telephone Survey – Executive Summary

Purchase intention

Calcium-fortified fruit juice beverages will not attract mass market interest, but will be of interest to a significant minority:

	Definitely would buy %	Possibly would buy %	Total would buy %
Fruit Juice	14.7	30.5	45.2
Fruit juice drink	9.1	20.6	28.9
Fruit juice cordial	10.1	22.2	32.3

Product substitution

Depending on the product, around 50-60% of purchasers would replace an existing beverage.

	Replacement purchase
Fruit juice	61.0%
Fruit juice drink	50.6%
Fruit juice cordial	63.2%

As anticipated, fortified fruit juice will mainly replace fruit juice, fortified fruit drink would replace fruit juice drink and fruit juices, fortified fruit juice cordial will replace cordials – both fruit and non-fruit juice.

Dairy Substitution

In all cases a small but significant group will buy the new calcium-fortified beverages and replace either

- Regular milk
- Modified/low fat milk
- Flavoured milk

	Milk substitution (total)
Fortified fruit juice	5.8%
Fortified fruit juice drink	12.2%
Fortified fruit juice cordial	6.1%

Both US and UK consumption trends show declining milk consumption, and an increased consumption of fruit juice. There is no evidence to suggest however, that these trends are a result of calcium-fortified beverages being available in these markets. To date there is no evidence of the effect on milk consumption by the current availability of calcium-fortified juices, regulated as dietary supplements in the New Zealand market or of a small range of fruit drinks bearing claims of a good source of calcium through the use of dairy whey ingredients.

The industry has stated that foods proposed for fortification with calcium are not intended for promotion as substitutes for dairy foods, but are intended to provide an alternative choice, in addition to calcium supplements or other calcium-fortified foods, for those already not consuming sufficient dairy products for whatever reason.

5.2.3 Risk of nutrient deficits or imbalances resulting from milk substitution

Described below is the dietary modelling that was undertaken in response to submitter concern that a reduction in milk consumption as a result of this Application could lead to compromised zinc and riboflavin intakes. The modelling was based on the worst-case scenario – a 50% reduction in milk consumption. The percentage of respondents below the EARs for riboflavin and zinc discussed below are based on one-day nutrient intakes. One-day intakes tend to exaggerate low and high intakes when compared to longer-term intakes. Therefore, in reality the percentage of respondents below the EAR, and any shifts in the percentages due to a 50% reduction in milk consumption, would not be as exaggerated as the data derived from one-day intakes described below. Some submitters expressed concern that, should substitution of calcium-fortified beverages for milk occur, there would be nutritional implications for certain subgroups of the population. Submitters to the Draft Assessment Report were concerned about the effect of milk substitution on riboflavin and zinc intakes. A complete set of results for girls and women and the effects of the proposed amendments to the Code on zinc and riboflavin intake with a worst-case scenario can be found in Attachment 2.

5.2.3.1 Riboflavin

Dietary modelling with a worst-case scenario of 50% reduction in milk consumption showed a small decrease in riboflavin intakes for each population subgroup modelled. The group whose riboflavin status would be most compromised by a 50% reduction in milk intake would be Australian females 16-18 years, also the group whose calcium intake is the most inadequate. Currently 24% of this subpopulation have riboflavin intakes less than the EAR, halving milk intake would result in 28% of the population having intakes under the EAR.

5.2.3.2 Zinc

One submitter to the Draft Assessment Report stated that currently, 75% of Australian girls and women did not reach their respective RDI for zinc, and as milk contained four times as much zinc as fruit juice, substitution of milk for calcium-fortified juice could result in even lower zinc intakes.

Dietary modelling has been undertaken to investigate the effects of a 50% reduction in milk consumption on zinc intake. Results indicated that at baseline, Australian girls and women had a lower intake of zinc than their New Zealand counterparts.

Currently, 15.1% of the Australian and 14.6% of the New Zealand populations are not meeting the UK EAR for zinc. A 50% reduction in milk intake would potentially result in 17.9% and 17.1% of the Australian and New Zealand populations respectively not achieving the EAR, an overall population increase of about 3%. The group at most risk of zinc deficiency as a result of halving their milk intake are females 12-15 years. The present 27% of this group not meeting the EAR would increase to 31% thus resulting in additional 4% of this population group not meeting the EAR. The implication of a 50% reduction in milk consumption on zinc intake is not as great in other subgroups.

5.2.3.3 Conclusion

Dietary modelling with a worst-case scenario of a 50 % reduction in milk consumption was undertaken. Results indicated that there would be a small decrease in riboflavin intakes should 50% of milk consumption be substituted. Although milk is an important dietary source of zinc, worst-case scenario modelling showed that a 50% decrease in milk consumption would result in only a modest decrease in average zinc intakes. The population group most at risk from a 50% decline in milk consumption was girls aged 12-15 years. The groups at least risk of zinc and riboflavin deficiency as a result of halving their milk intake are children 6-12 years. Considering that the scenario modelled is theoretical and very unlikely, and that the data is based on one-day intakes, it can be concluded that the proposed amendments to the Code will have minimal adverse effects on the micronutrient intake of the Australian and New Zealand populations.

The independent Newspoll survey of 1200 Australians provides evidence to support the trends seen overseas that for the most part, calcium-fortified beverages are likely to be used as substitutes for their unfortified counterparts and soft drinks. Drawing from overseas evidence, it is unlikely that calcium-fortified fruit- and vegetable-based beverages would lead to a marked decline in milk or dairy consumption.

5.2.4 Potential for increase in sugar consumption

As a consequence of any permission granted for the addition of calcium to the proposed foods, the products would be permitted to carry ‘content claims’ in accordance with Standard 1.3.2, clause 6. In general, claims to the effect that a particular food product is a ‘source’ or ‘good source’ of a vitamin or mineral may be made providing a reference quantity of the food contains at least 10% or 25% RDI respectively of the particular vitamin or mineral and that the food is a ‘claimable food’. Approval of all foods requested in the Application would mean their inclusion in the Table to Clause 3 of Standard 1.3.2 and this action would render them as ‘claimable foods’ as defined in Standard 1.3.2, clause 1.

In addition to submitters’ concerns related to the inappropriate substitution of milk for calcium-fortified beverages discussed above, submitters also raised the possibility of increased consumption of calcium-fortified foods on the basis of a their promotion as a ‘source’ or ‘good source’ of calcium.

Submitters to both the Initial and Draft Assessment Reports from the public health/nutrition sector indicated their concern that a 'good source' claim displayed on the product label of calcium-fortified products could increase the consumption of calcium-fortified beverages. An increase in consumption of products high in sugar content may have the potential to increase the risk of dental caries and over nutrition in the population.

5.2.4.1 Dental caries

One submitter to the Initial Assessment Report suggested in relation to the concern regarding dental caries, there is some evidence to suggest that the addition of calcium to juices and drinks, to some extent, counter-balances the destructive effect of sugar and acid content and thus helps protect the teeth against decay. Submitters to the Draft Assessment Report debated this with referenced evidence indicating that while calcium may help to strengthen teeth, the nature of the sugar content in fruit- and vegetable-based beverages still renders them cariogenic. Additional information was given regarding the effect of acid on teeth, in particular the negative effects of brushing immediately after consumption of acidic beverages.

The Draft Assessment Report raised the issue that fluoride in water and good dental hygiene could protect against increased caries in the event of increased consumption of fruit juices and beverages. Submitters pointed out however, that not all Australian and New Zealand water is fluoridated, and that dental health has been raised as a key health problem in New Zealand. As calcium-fortified juice is currently available on the New Zealand market, attempts were made to establish the effect that these products have had on the dental health of New Zealanders. However, no data as to the incidence of dental caries, particularly as a result of calcium-fortified juice could be found. Two dentists were personally contacted: an Associate Professor in dentistry at the University of Otago and a dentist at Auckland Children's Hospital. They indicated that no data were available to support the contention that availability of fortified juice compared with juice and other acidic beverages in general in the New Zealand market had exacerbated the oral health problems observed in New Zealand. No submissions from dentists were received in response to either the Initial or Draft Assessment Reports.

The impact of this Application on dental health would be most problematic should the consumption of fruit- and vegetable-based beverages occur in addition to other sugar-based beverages or in place of milk or water. As discussed previously, this is an unlikely long-term outcome. Two-thirds of the respondents to the aforementioned Newspoll survey stated that they would replace an unfortified beverage by a fortified counterpart (see Figure 1).

5.2.4.2 Over-nutrition

Over-nutrition resulting in an increase in overweight and obesity from consumption of fortified fruit- and vegetable-based beverages is more likely to occur when such beverages are regularly consumed in addition to the usual energy intake or as a substitute for water (or other low energy beverages). Although the energy intake of many consumers exceeds their energy expenditure as judged by the increasing prevalence of overweight and obesity in both countries, a further increase from the additional consumption of fruit- and vegetable-based beverages would require sustained change in dietary patterns to be the cause of increased weight gain. Fruit juice contains approximately 170 kilojoules/100 g and as such, by volume, is not energy dense compared to many other foods.

The Newspoll results show that very few people (less than 3% of those considering purchase of fortified beverages) would replace water with calcium-fortified beverages (see Figure 1). It is uncertain as to what proportion would consume calcium-fortified beverages in place of their entire water intake.

5.2.4.3 Conclusion

Submitter concerns about increased dental caries resulting from increased sugar intake is warranted, but should not be overstated. The Newspoll survey suggests that the majority of consumers interested in purchasing calcium-fortified fruit- and vegetable-based beverages would do so as a substitute for their unfortified sugar-containing counterparts. Trends observed in New Zealand show no effect of the availability of fortified juice on the dental health of the New Zealand population. Such practices are unlikely to, of themselves, be responsible for further increases in the rates of overweight and obesity in the Australian and New Zealand communities.

5.2.5 Inappropriateness of juice for infants

Standard 2.9.2 – Foods for Infants regulates foods for infants, and defines them as infants up to 12 months of age. This special purpose standard does not permit the addition of calcium to infant juices, nor is this Standard the focus of the Application. One submitter to the Initial Assessment Report pointed out that neither undiluted juice nor cow's milk are appropriate foods for infants. Submitters to the Draft Assessment Report reiterated this point stating that regardless of infant juice being available on the market, many infants were fed juice that was purchased for consumption by the main household. FSANZ discussed the potential usefulness of an advisory statement to the effect that 'juice should not be used as a substitute for milk in infant diets' appearing on fortified beverage labels with health professionals. Although the majority of them would agree that inappropriate feeding of juice to infants does occur, there were no data that identified the type of juice consumed by infants (fortified or not) to indicate the current extent of this practice in Australia or New Zealand.

Some consumers expressed concern that the inclusion of a 'source' or 'good source' content claim for calcium may be misleading if the consumer does not know how much calcium is absorbed and available to be used in the body. Submitters to the Draft Assessment Report were particularly concerned that some consumers may be confused by calcium content claims and therefore inappropriately substitute fortified beverages for milk in the diet of infants and children.

Discussions with New Zealand dietitians on the calcium content claim given on fortified orange juice (dietary supplement) already available on the New Zealand market were held in an attempt to establish its impact on the purchasing habits of consumers. The contacted paediatric dietitians were not aware of fortified juice in particular being incorrectly used as an infant or childhood food any more then unfortified juice as a result of calcium content claims. Some submitters argued that calcium-fortified juice would exacerbate failure to thrive and bottle teeth in infants. However, the consulted dietitians commented that milk, particularly when bottle fed, is as much of a problem as juice in its effects on failure to thrive and infant tooth decay.

5.2.5.1 Conclusion

There is anecdotal evidence that children and infants are being inappropriately fed fruit juice and juice-based beverages. However, no data exists to indicate the extent of the problem. Paediatric dietitians contacted in New Zealand were unable to provide any further information on whether the market presence of calcium-fortified juice had increased the prevalence and/or level of its consumption among infants.

5.2.6 Risk of calcium in proposed foods not being bioavailable

In response to the concerns raised regarding bioavailability, this complex issue is influenced by different factors including long term nutrient intake imbalances, nutrient interactions at a single meal and individual variations in the ability to absorb and use various nutrients in the body. FSANZ recognises that various calcium salts also have different bioavailabilities in different foods. Recent research has shown that the particular forms of calcium salts suitable for addition to fruit- and vegetable-based beverages is as bioavailable as the calcium in milk, although the effect of calcium-fortified beverages on bone health appears not to be as beneficial as that gained from milk consumption due to intrinsic factors in milk[9]. Decisions as to the suitability of particular chemical forms of vitamins and minerals are made at the time the form is approved for listing in the Code. The Applicant sought no approval for additional forms of calcium as there are many forms already permitted for use.

5.2.6.1 Conclusion

Evidence suggests that the suitable forms of calcium for addition to fruit- and vegetable-based beverages are as bioavailable as the calcium in milk, however the Applicant sought no approval for additional forms of calcium.

5.3 Risk Management

5.3.1 Options for risk management

Although the food/nutrient combinations have been assessed as eligible for voluntary fortification in Section 5.1 of this Report, risk management strategies were also considered to address the concerns raised by some submitters, mainly in relation to fruit cordial. Risk management options for cordial were discussed at length in Section 5.4.1 of the Draft Assessment Report but this section has been amended now that fruit cordial has been withdrawn from the Application.

5.3.2 Labelling statements

In both the Initial and Draft Assessment Reports submitters were invited to comment on the use of an advisory statement to the effect that 'this food is not a dairy/milk substitute'. Submissions were divided in their opinions of the value or necessity for an advisory statement; all but the dairy industry did not support the advisory statement. The dairy industry suggested a 'not suitable for children' statement similar to that for infants and children up to two years of age, which is required on low fat and reduced fat milk products.

[9] Pointtillart A, Coxam V, Seve B et al. Availability of calcium from skim milk, calcium sulfate and calcium carbonate for bone mineralisation in pigs. Reproduction Nutrition Development (2000) 40;49-61

Proposal P161 - Review of the declaration of specific labelling statements on packaged food, provides guidance as to the appropriate use of advisory statements. An advisory statement should be used when:

i) the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, or
ii) when guidance about use of a food is needed to protect public health and safety.

Advisory statements hold most value when consumers are prompted to scrutinise food labels, for example when they are at risk of consumption of particular foods due to allergy. The conclusion from the risk assessment in section 5.2 does not suggest that the risk of substitution of milk for fruit- or vegetable-based beverages, or an increased consumption of fruit- or vegetable-based beverages is of sufficient magnitude to justify an advisory statement. This information is better suited to nutritional education where the comparative merits of the two products can be fully conveyed. A "not suitable for children" statement is not appropriate because of the absence of intrinsic risk from consumption of calcium-fortified fruit juices as well as the possible inference to purchasers that the statement of unsuitability applies to the juice or drink itself.

Public health submitters to the Draft Assessment Report were also concerned that, at 25% RDI/ 200 mL, a 'good source' claim could elevate the image of fruit- and vegetable-based beverages to be the same as milk, which easily qualifies as a good source of calcium. The natural calcium content of whole milk is about 30% RDI /200 mL and Standard 1.3.2 permits addition of calcium to modified, skim and dried milks to a maximum claim of 40% RDI/ 200 mL Although the proposed variation to the Standard permits a calcium-fortified fruit or vegetable beverage to make a good source of calcium claim, the % RDI shown in the nutritional information panel would be limited to 25% compared with dairy products at higher amounts. Notwithstanding the prohibition in Standard 1.3.2 on comparative vitamin or mineral claims, the dairy industry has latitude to emphasise to consumers the high calcium content of dairy foods as well as to promote the other nutritional benefits of milk. The reason for the prohibition on comparative claims for vitamins and minerals is because of the potential for nutritional oversimplification when the nutritional merits of a food focus on only one vitamin or mineral with the consequent potential for consumers to be misled.

5.3.2.1 Conclusion

A statement advising against consumption of calcium-fortified fruit- and vegetable-based beverages is not appropriate because it does not meet the criteria for an advisory statement. A "not suitable for children" statement is also not appropriate because of the absence of intrinsic risk from consumption of calcium-fortified juices and drinks as well as the possible inference by consumers that the statement of unsuitability applies to the juice or drink itself. Nutrition education offers more potential to convey relevant messages about the relative nutritional merits of fruit- and vegetable-based beverages and milk. Although both beverage categories would be permitted to claim their calcium content as a 'good source' of calcium, the dairy industry has the opportunity to declare the actual levels of calcium in milk products, which are higher than the maximum claim for fruit- and vegetable-based beverages.

5.3.3 Education

Most submitters from the public health/nutrition sector did not believe that calcium-fortified non-dairy products, particularly cordial, could be readily incorporated into the current nutrition education message. They also considered that they do not have the resources under a limited budget to reach the culturally and linguistically diverse population that they cover. There is a belief amongst some health and nutrition professionals that fortification will eventually erode the integrity of the food supply and confuse consumers.

A counter argument was put forward by one public health/nutrition professional that these products could readily be included in the nutrition education message. Milk and dairy products would continue to be promoted as the major source of calcium.

FSANZ acknowledges that nutrition education has become more complex with the advent of functional foods, use of novel ingredients, and as a result of incremental permissions for voluntary fortification. The food supply contains several examples where foods contain nutrients and substances with specific health effects that are not intrinsic to those foods, such as high-fibre milk, bread as a source of omega-3 fatty acids, edible oil spreads with phytosterols etc. Although these products contribute to the increasingly wide variety of for example, milks, breads and edible oil spreads, they usually constitute only a small proportion of the product category. Nevertheless, the food supply is highly dynamic and manufacturers are sensitive to consumers' interest in gaining additional health benefits from their food. There is also a growing level of community interest in consuming nutritional supplements. As the food supply becomes more complex and ventures outside the traditional nutritional paradigm, public health and nutrition educators are presented with the challenge to accept the new products as being part of the food supply and to adapt their education message to address the appropriate use of these foods. While the market presence of these products does not change the fundamental message of nutrition education, a significant number of the population are not consuming adequate calcium and there are opportunities to address this nutritional problem through appropriate targeting of the nutrition message. With these caveats, education is seen as a realistic and effective risk management tool in the context of the appropriate consumption of fortified products.

5.3.3.1 Conclusion

Nutrition education has the scope to address the range of issues for consumers in relation to calcium-fortified beverages including the nutritional merits of all dietary sources of calcium as well as other risks and benefits in the context of current adequate or inadequate calcium intakes.

5.4 Potential benefits of fortification

5.4.1 Increased calcium intake in some populations

While the effectiveness of voluntary fortification to address a nutritional public health need cannot be assured because any permission is subject to the extent to which industry takes up the permission, an assessment of the potential effectiveness of a food/nutrient combination is also a consideration in deciding whether voluntary fortification will be permitted. As such, an assessment of the potential dietary impact of calcium in the proposed foods has been conducted and the version that was included in Attachment 4 of the Draft Assessment Report revised.

Currently 28.4% and 33.9% of the Australian and New Zealand populations respectively, do not meet the UK EAR for calcium. The results after the withdrawal of cordials show that fortification of all the requested foods has the potential to reduce these rates to 20.0% of the Australian and 27.5% of the New Zealand population whose calcium intakes are below the EAR should 100% of industry take up the opportunity to fortify the listed products. Specific populations whose calcium intakes stand to increase from granting the permissions for addition of calcium are: Australian females 11-18 years, which is the population group at greatest risk of not meeting the EAR for calcium. Adoption of these permissions to the fullest extent could help as many as 20% of those at greatest risk in this population group to meet the EAR ; as well as those who cannot or would not usually eat dairy products. Further details of the dietary intake assessments revised to reflect the withdrawal of cordials is given at Attachment 2.

5.4.1.1 Conclusion

Although calcium fortification cannot be considered a population strategy to solve the osteoporosis problem observed in Australia and New Zealand, the results of dietary intake assessment show that calcium fortification would help to increase calcium intakes in individuals regularly consuming fortified products. At best, a 100% uptake by industry of the proposed fortification permissions has the potential to raise to the EAR the calcium intakes of 8% Australians and 6% New Zealand population who do not currently achieve the EAR.

5.4.2 Alternative sources of dietary calcium

Nutritionists often recommend consumption of calcium supplements where calcium intake is possibly not adequate. Calcium-fortified food products could be recommended as alternative choices to calcium supplements for those with a marginally inadequate calcium intake. New Zealand dietitians commented that young children could not rely on achieving their calcium RDI through consumption of fortified juice or drinks because of the large volume that would need to be consumed. Although fortified juice and drinks might be an additional source of calcium for those with inadequate calcium intakes, they would still recommend a calcium supplement for those at risk from very low calcium intakes.

5.4.2.1 Conclusion

Although the outcome of permitting fortification of the requested foods would not result in those people who cannot drink milk or eat dairy foods meeting their entire calcium requirements, such products could provide an alternate source of calcium to contribute to the dietary intake.

6. Regulatory Options

There are two options for addressing this Application.

6.1 Option 1 – No approval

Maintain the *status quo* by not amending the Code to approve the addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, soups and savoury biscuits.

6.2 Option 2 – Approval

Amend the Code and approve the addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, soups and savoury biscuits.

7. Impacts

Calcium-fortified fruit juices and/or fruit drinks are available in certain countries such as the United States, Germany, France, the Netherlands, the United Kingdom, Finland and Spain. Calcium-fortified biscuits are available in France, Indonesia, Malaysia, Spain, Taiwan and the United States. Calcium-fortified soup is available in the United States. Calcium-fortified juices are currently available on the New Zealand market. These products are currently manufactured to the New Zealand *Dietary Supplements Regulations* 1985 (NZDSR). The New Zealand Juice Association in their submission indicated a preference for these products to be regulated as foods rather than as dietary supplements for convenience and ease of enforcement. Calcium-fortified biscuits are also available on the New Zealand market.

Some fruit drinks have also appeared on the Australian market that carry claims for 25% of the RDI for calcium per 200 mL serving. The source of calcium is stated as 'whey minerals or powder'.

7.1 Affected parties

The parties affected by the options outlined above can be broadly divided into four groups (consumers, industry, governments and health professionals including health/nutrition educators) and include:

1. Consumers in general and the following consumer sub-groups:

- Those who do not achieve adequate calcium intakes because of dietary choices, health or cultural reasons.
- Children for whom the traditional sources of calcium, such as dairy, are also a good source of protein and other nutrients.

2. Public health and nutrition educators and professionals including dietitians and dental educators from both the public and private sector.

3. The following sectors of the food industry:

- Those who will benefit from the increased permission for the voluntary addition of calcium to the proposed products.
- The dairy industry, which currently has a large market share of food sources of calcium.
- The dairy substitute (e.g. soy beverages) industry that currently provides food sources of calcium for those individuals who, for whatever reason, do not consume dairy products.
- The calcium supplement industry that provides an alternative source of calcium for those individuals who, for whatever reason, do not consume dairy products and may provide the calcium salts for fortification of food products.

4. Governments of New Zealand, the States and Territories and the Commonwealth of Australia including: food regulation enforcement agencies; and the health sector.

7.2 Impact analysis

The costs and benefits arising from any food regulatory measure varied as a result of this Application for the affected parties are considered below for each of the options identified.

7.2.1 Option 1: No approval

7.2.1.1 Consumers

- There was no feedback from consumers as to whether they are satisfied with the current range of calcium-containing foods or whether those consumers taking calcium supplements would prefer additional food choices in order to increase their calcium intake.

Benefits

- There is a range of calcium-containing foods currently on the market however; it is possible that these foods do not suit all people. Consumers may be generally aware of foods from which they can obtain dietary calcium and, if considered necessary, can adjust their calcium intake by increasing dietary sources of calcium or taking calcium supplements.

Costs

- Through the dietary intake assessment which used data from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey, FSANZ has identified some subgroups of the community for which 30% or more of respondents did not meet the EAR for calcium such as: women of most ages; adolescent and older males; and those respondents who did not consume dairy products. There may be a variety of reasons for this including; vegetarianism, milk allergy, lactose intolerance, or a dislike of milk or dairy products. Under this option, consumers not meeting the EAR for calcium would not be provided with any additional alternative dietary choices for calcium.

- Calcium inadequacy is one of several factors that contribute to osteoporosis. It is difficult to assess the extent to which the consumer incurs the health costs associated with the management of calcium deficiency status should this occur. In its report on *The Burden of Brittle Bones*, Access Economics reports that in 2001, nearly two million Australians have osteoporosis related conditions costing A$1.9 billion per annum in health costs and a further A$5.6 billion in indirect costs, representing 1.2% of GDP in 2000-2001 or A$389 for every Australian. This estimate of the total cost is an increase on the total cost of A$60 million per annum estimated by the Australian Institute of Health and Welfare (AIHW) in 1993-94 which was presented in the Initial Assessment Report.

7.2.1.2 Public health professionals

Benefits

- The current health/nutrition education messages in relation to obtaining calcium from the diet (and calcium supplements if necessary) are consistent with milk and dairy products being promoted as food sources of calcium.

  Public health educators and nutritionists have argued that it is very important to maintain the consistency of this message in order to avoid consumer confusion over the relevance of milk and dairy products in the diet and retain consistency with nationally endorsed guidelines for healthy eating.

- Additional strategies such as reorienting the health system, creating supportive environments and the development of personal skills have been listed by submitters as necessary for improving the calcium intake of the population. Some public health/nutrition submitters believe that it is more important to understand the reasons why people are not consuming adequate calcium in order to assist the community to achieve adequate calcium from their diet.

Costs

- Certain subgroups of the population still do not appear to be achieving adequate calcium intakes, despite current education programs about the roles and sources of calcium. Challenges for nutrition educators in the promotion of calcium-containing foods will remain and continue to increase with the predicted increase of osteoporosis prevalence from two million in 2001 to three million in 2021.

7.2.1.3 Industry

Benefits

- The dairy industry is currently in a strong market position in relation to provision of dietary sources of calcium in both Australia and New Zealand.

- The advantage to those sectors currently permitted to fortify with calcium, such as breakfast cereals and soy beverages, will remain.

- Submitters have not identified any other benefits to the industry sector under this option or any other industry sectors that would benefit from this option.

Costs

- There are opportunity costs for those manufacturers who may wish to fortify the proposed products with calcium. This situation is exacerbated by the potential manufacture of calcium-fortified products under the New Zealand *Dietary Supplements Regulations 1985* (NZDSR) thereby giving New Zealand manufacturers an advantage over their Australian counterparts. This advantage may be time-limited due to the future repeal of the NZDSR at a date yet to be determined, or the removal of existing foods from the scope of the NZDSR.

There are costs associated with lack of opportunity for Australian-owned and Australian-based beverage companies currently to sell to the domestic market and to export to international markets.

- It is not known to what extent Australian manufacturers are disadvantaged by the discrepancy between the Australian and New Zealand regulations.

7.2.1.4 Government

Benefits

- There may be a benefit to the government in maintaining the nutritional profile of the diet, thereby not requiring any change to nutrition education. The Central Sydney Area Health Services, South Eastern Sydney Area Health Service and the Health Department of Western Australia indicated that there are benefits in maintaining the nutrition education message in order to avoid consumer confusion. They also indicated that they do not have the resources to alter their education message. Queensland Health also identified a benefit under this option of consistency with the National Health and Medical Research Council (NHMRC) Dietary Guidelines. Not permitting fortification would help to keep the guidelines simple to follow.

Costs

- Calcium inadequacy is one of several factors that contribute to osteoporosis. As such, the health costs to governments associated with osteoporosis, as reported by Access Economics in *The Burden of Brittle Bones* are significant and expected to continue to rise.

7.2.2 Option 2: Approval

7.2.2.1 Consumers

Benefits

Industry groups in support of this Application have indicated that the following benefits would be afforded consumers by allowing the addition of calcium to the requested products:

- Fortification of the proposed products with calcium would provide consumers with additional and/or alternative food sources of calcium. Submitters have argued that consumers will make use of this additional/alternative source of calcium-containing products in the food supply and some submitters believe that these foods are appropriate to contain added calcium. This argument is based on: the consumption of some similar calcium-fortified products in the US over a number of years; the stable market for calcium-fortified juices in New Zealand; the number of similar calcium-fortified food products available internationally including soups and biscuits; the use of calcium supplements; and market research.

- For individuals who have a milk allergy or are lactose intolerant, the availability of calcium-fortified products may provide an alternative food source of calcium to the currently fortified dairy substitutes (e.g. soy beverages).

- There may be potential to reduce the direct public health costs to consumers that are associated with inadequate calcium intake. This depends on the degree to which: manufacturers take up the permission; and consumers purchase the fortified foods. It is estimated that even a conservative 1% reduction in the number of cases of osteoporosis per year may reduce the direct costs of osteoporosis by A$19 million per year. However, it should be noted that osteoporosis is a complex disease and increasing calcium intake only has a fair probability of improving the disease outcome in target groups or prevention of osteoporosis.

- The Applicant and submitters have indicated that the fortification of the proposed products with calcium will only introduce marginal costs to the manufacturer and that the manufacturer would absorb these costs. This means that the choice available to consumers would not be denied by prohibitive prices.

Costs

- As indicated by the dietary intake assessment, a large proportion of the population consumes fruit juices and fruit drinks. Therefore, fortification may have a significant impact on calcium intake and create the potential for the emergence of conditions associated with excess calcium intake for the high consumers of calcium in the population. The dietary intake assessment has indicated that there is little risk of consumers exceeding the UL for calcium of 2500 mg per day over a long period.

- Trends in the US and New Zealand (based on overall market share figures) indicate that substitution of calcium-fortified juice or drinks for milk as an alternative calcium source is unlikely to occur. However, should substitution occur in young children, the

- potential exists for symptoms resulting from malabsorption of carbohydrate and dental problems.

- Consumers may be further confused about which products they should choose as their sources of calcium.

7.2.2.2 Public health professionals

Benefits

- The additional food sources of calcium may provide health/nutrition educators with the capacity to suggest alternative options to consumers regarding how they obtain their calcium, especially for certain subgroups of the population

Costs

- Health/nutrition educators may be required to adjust the message they provide to consumers about the food sources of calcium in order to incorporate information about calcium-fortified products. Submitters from this sector believed that considerable changes would be required to the nutrition education message to prevent people from substituting calcium-fortified products for more traditional sources, such as dairy products.

As such, they believed that a substantial amount of information would be required about calcium-fortified products in order to inform the community of the nutritional implications of substituting calcium-fortified foods for milk and dairy products. They did not believe that they would have the resources to implement these changes to the nutrition education message and reach the culturally and linguistically diverse community that they serve.

- Public health submitters were concerned that a change to the Code as a result of this Application could create a precedent for more applications for permission to fortify a variety of foods, and that the result of permitting fortification would lead to a loss in the integrity of the current food supply.

7.2.2.3 Industry

Benefits

- Industry would be permitted to voluntarily add calcium to the proposed products which may potentially open up new markets or increase market share both domestically and internationally. Industry has indicated that the extent to which the voluntary permission is taken up depends on market forces but the US experience of 25% of fruit juice sales being fortified juices could be reproduced in Australia and New Zealand. Data from the Retail World Grocery Guide (2002) indicate that the biscuits market is A$939 million of which crispbread, rice crackers and crackers contribute 10%, 10% and 8% respectively. Fruit juice and drinks markets are worth A$738 million; of which 66% is juice and 34% is drink. The market for soups is worth A$361 million. It is anticipated that growth in the calcium-fortified citrus juice market would be in the range of 15% market share over the first two years (based on trends seen in the US) should a voluntary permission be granted for these products. A potential market for calcium-fortified vegetable juice and/or juice products from Australian manufacturers to Singapore in the range of 6-10 million litres for finished product has been identified based on data from the Singapore Juice and Vegetables Data Euromonitor.

- This option will allow for economies of scale in manufacturing the same products for both domestic and export markets.

- Experience from the US with fortified juices indicates that they are priced similarly to unfortified juices. With calcium fortification to 25% RDI per serve, the additional cost per serve is expected to be minimal and competitive market pressure will determine final pricing meaning that manufacturers are likely to absorb the additional cost.

- The development of new products for exporters in particular will lead to an expansion of industry production.

- This option will provide Australian manufacturers with the same opportunities as New Zealand manufacturers. The New Zealand Juice Association has expressed a preference for calcium-fortified juices to be positioned as foods rather than dietary supplements, as is currently the situation.

Costs

- The potential exists for the displacement of milk or calcium-fortified milk substitutes for the proposed products that may disadvantage the milk/dairy and/or milk/dairy substitute industry. However, this is considered unlikely to occur based on trends in other countries and the food categories proposed for fortification. The dairy industry is concerned about the potential for loss of market share if a voluntary permission for addition of calcium to the proposed products is granted. The dairy industry has stated that milk consumption is already declining and this option may encourage further decline. The Fonterra co-operative group stated that the dairy industry is also a key contributor to the New Zealand economy and this option may pose a further threat.

- Possible disadvantages exist for smaller, locally based manufacturers of fruit/vegetable juices, fruit/vegetable drinks, soups and biscuits unable to calcium-fortify, who may suffer from an actual decrease in market share. This has not been confirmed by submissions whereas on the contrary, all industry sectors with the exception of the dairy industry showed support for this option.

- There is a potential for those consumers currently taking calcium supplements to choose calcium-fortified food sources over calcium supplements and so the calcium supplement industry may be adversely affected.

7.2.2.4 Government

Benefits

- There may be the potential to reduce the public health costs associated with osteoporosis, fractures and other conditions associated with inadequate calcium intake as indicated in the Access Economics Report on *The Burden of Brittle Bones*.

- The Australian Food and Grocery Council (AFGC) has deduced that, if successfully increasing calcium intake through this fortification measure such that 10% fewer people developed osteoporosis, a future health dividend of A$190 million per annum based on year 2000 costs could be anticipated. Even a conservative 1% reduction delivers A$19 million benefit in direct costs.

Costs

- This option may require a change in education approaches to take account of the presence of calcium in foods that are not natural sources of calcium. Public health/nutrition educators have indicated that there would be additional costs involved with adjusting the education message in order to inform the culturally and linguistically diverse population about the potential nutritional implications of inappropriate consumption of the products.

- While some submissions were received from government, and most were opposed to granting a voluntary permission, no comments regarding the implications for enforcement associated with this option were received.

- The potential for increased dental health problems exist however, this is considered to be minimal based on the unlikelihood of substitution of the calcium-fortified products for traditional sources of calcium.

8. Consultation

The Draft Assessment Report for A424 was available for public consultation from 18 December 2002 until 21 February 2003. A total of 25 submissions were received, with 14 of these from Australia, seven from New Zealand and four on behalf of Australia and New Zealand or Australasia.

Of these 25 submitters, 10 unconditionally supported Option 2 (amend the Code as originally requested by the Applicant and approve the addition of calcium to the proposed products), 10 submitters opposed the Application in its entirety (support for Option 1, maintain the status quo), four submitters supported Option 2 for some of the proposed products only, and three submitters expressed the view that this Application should not be assessed in isolation and recommended a comprehensive review of Standard 1.3.2 and the regulatory principles underlying this standard. Of the five submitters who requested a review of Standard 1.3.2, one supported Option 2 and four supported Option 1 in the absence of such a review. A summary of submissions is at Attachment 3.

The Initial Assessment Report for A424 was available for public consultation from 12 December 2001 to 13 February 2002. A total of 28 submissions were received, with 21 of these from Australia, four from New Zealand and three on behalf of both Australia and New Zealand or Australasia. Of these 28 submissions, 17 were received from industry sectors, two were from consumer groups, five were from the public health sector and four were from government agencies. A summary of submissions is at Attachment 5 of the Draft Assessment Report.

8.1 Notification to the World Trade Organization

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System, FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

As a member 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.

Amending the Code to permit the use of calcium in fruit- and vegetable juice, fruit- and vegetable drinks, savoury biscuits and soups is unlikely to have a significant effect on trade. Therefore, notification will not be made to the WTO as a TBT in accordance with the WTO Technical Barrier to Trade (TBT) agreements.

9. Implementation

Approval of the Application will result in the proposed variation to Standard 1.3.2 commencing on gazettal.

10. Conclusion and Recommendation

FSANZ approves the draft variation to Standard 1.3.2 to permit the voluntary addition of calcium to fruit and/or vegetable juices, fruit and/or vegetable drinks, soups and savoury biscuits to 25% RDI/reference quantity, a level that allows a 'good source' content claim, for the following reasons:

- Calcium is considered to be potentially eligible for voluntary fortification because, in accordance with the Regulatory Principles for the addition of vitamins and minerals to foods, 30% of at least one population subgroup in both Australia and New Zealand has a customary intake below the Estimated Average Requirement (EAR) based on National Nutrition Surveys.

- All the foods requested by the Applicant are considered to be eligible for voluntary fortification since the food categories generally are consistent with FSANZ's Regulatory Principles.

- The dietary intake assessment estimates that there would be negligible risk of excess calcium intake based on the addition of calcium at the levels requested assuming 100% uptake of the permission for all the proposed foods. Overseas experience indicates that there is minimal risk of long-term substitution of calcium-fortified beverages for milk, or an increase in consumption of such calcium-fortified beverages on the basis of the approvals contained in this Report.

- The addition of calcium to all the proposed foods has the potential to increase the calcium intake for the population or subgroups of the population with a current intake assessed as inadequate. However, this potential benefit depends on the extent to which this voluntary permission is taken up by industry.

- A permission for voluntary fortification of the proposed foods with calcium would provide consumers with additional and/or alternative food sources of calcium.

The proposed drafting for of the Code is at Attachment 1 of this Final Assessment Report.

Attachments

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

2. Dietary assessment

3. Summary of Submissions

4. Regulatory Principles for the addition of vitamins and minerals to foods

ATTACHMENT 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.3.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from the* Table to clause 3, *the entry for* Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugar, *substituting* -

Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugars	35g	thiamin	0.55 mg (50%)
		riboflavin	0.43 mg (25%)
		niacin	2.5 mg (25%)
		vitamin B6	0.4 mg (25%)
		vitamin E	2.5 mg (25%)
		folate	100 µg (50%)
		calcium	200 mg (25%)
		iron	3.0 mg (25%)
		magnesium	80 mg (25%)
		zinc	1.8 mg (15%)

[1.2] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Fruit juice, reconstituted fruit juice, concentrated fruit juice –

calcium	200 mg (25%)

[1.3] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Tomato juice, concentrated tomato juice –

calcium	200 mg (25%)

[1.4] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Vegetable juice –

calcium	200 mg (25%)

[1.5] *omitting from the* Table to clause 3, *the entry for* Fruit drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit; fruit drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit, *substituting* -

Fruit and/or vegetable drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit and/or vegetable; fruit and/or vegetable drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit and/or vegetable	200 mL	folate vitamin C carotene forms of vitamin A calcium	refer to clause 8 refer to clause 8 refer to clause 8 200 mg (25%)

[1.6] *inserting in the* Table to clause 3 -

Composite products

Soups, prepared for consumption in accordance with directions	200 mL	calcium	200 mg (25%)

ATTACHMENT 2

DIETARY INTAKE ASSESSMENT

A 424 – Addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, soups and savoury biscuits

Summary

A dietary intake assessment was considered necessary to determine the potential impact of the fortification of the proposed products with calcium on the calcium intake of the population as a whole and of various sub-groups of the population. The dietary intake assessment investigated the risk to consumers with high calcium intakes exceeding the Upper Safe Limit (UL) and the potential effectiveness of fortification of the proposed foods with calcium.

Data from national nutrition surveys show a sizable portion of the population in Australia and New Zealand do not obtain adequate calcium intakes from their food consumption habits and the naturally occurring calcium content of foods and the small amount of existing calcium fortification. Particular population groups with low calcium intakes include adolescent and adult females in Australia and New Zealand, New Zealand Maori, Australians of Asian ethnicity and non-dairy consumers in Australia and New Zealand.

It is considered unlikely that high consumers of calcium will exceed the UL for calcium from the diet alone on a long-term basis. Fortification of the products proposed in this Application with calcium has the potential to increase the calcium intake of the population groups identified as being potentially at risk of inadequate calcium intake. However, there may still be some groups not meeting their calcium requirements, even after fortification.

Dietary modelling indicates that fortification of the products proposed in this Application would have minimal adverse impact on the intake of various micronutrients found in milk, should milk be substituted by calcium-fortified beverages.

Background

The Applicant is seeking a voluntary permission for calcium to be added to fruit - and vegetable juices, fruit – and vegetable drinks, soups and savoury biscuits to provide alternative sources of calcium in the diet, particularly to population groups that may be at risk of inadequate dietary calcium intake. The requested level of addition of calcium to these products would provide not more than 25% of the Recommended Dietary Intake (RDI) of calcium per reference quantity.

Since the Draft Assessment, cordial has been withdrawn from the Application. The dietary modelling conducted at Draft Assessment has been repeated with adjustments to reflect the withdrawal of cordial. In addition, submitters to the Draft Assessment Report commented on the potential substitution of milk by calcium-fortified beverages. A submission raised specific concern about the effect of substitution on zinc and riboflavin intakes for particular age and sex groups of the population. Dietary modelling was conducted to estimate the effect of substituting milk consumption with calcium-fortified beverages.

Dietary Intake Assessment by FSANZ

Dietary modelling was conducted by FSANZ to estimate potential dietary intakes of calcium for Australia and New Zealand when a number of foods are fortified with calcium. The intake assessments include calcium intake from other sources in the diet, but not from supplements. Information on calcium intake from supplements was not available to be included in the dietary intake assessment.

The dietary intake assessment was conducted using dietary modelling techniques that combine food consumption data with nutrient content data, developed for the respective 1995 and 1997 National Nutrition Surveys (NNSs), to estimate the intake of the nutrient from the diet. The dietary intake assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary intake = food nutrient concentration x food consumption

The potential dietary intake of calcium from fortification of the proposed products with calcium was estimated by combining:

- usual patterns of food consumption, as derived from the NNS data; and
- the existing levels of calcium in foods and the levels of calcium proposed by the Applicant for the particular products.

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both surveys used a 24-hour food recall methodology to collect food consumption data.

Assumptions made in the dietary intake assessment

Assumptions made in the dietary intake assessment include:

- all the foods within the group contain calcium at the specified/proposed levels, unless stated otherwise;
- all consumers of foods from the food groups to be fortified consume the fortified version;
- consumption of foods are actual amounts as recorded in the NNSs; and
- calcium contained in foods is 100% available (no distinction is made between the bioavailability of calcium that occurs naturally in foods and calcium salts used for fortification).

Limitations of the dietary intake assessment

A limitation of estimating dietary intake over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile intakes are likely to be higher than actual high percentile intakes over a lifetime.

A second 24-hour recall was conducted on a subset of the respondents to each NNS. Together with the Australian Bureau of Statistics (ABS), FSANZ has recently developed a procedure to account for second day nutrient intakes by the use of factors that adjust the first day intake to gain a more accurate estimation of longer-term nutrient intakes. At present this approach is adopted only for Australia and adjustment factors have been determined for only a limited number of scenarios. The dietary modelling conducted at Draft Assessment incorporated second day adjustment factors for the total population group (before and after calcium fortification) and males aged 16 to 24 years age group (after fortification only) for Australia.

Cordial was withdrawn from the Application after Draft Assessment, however a second-day adjustment factor to reflect this withdrawal has not yet been developed. For the purpose of comparison however, the adjustment factor developed for the male 16-24 years age group at Draft Assessment was considered suitable to adjust the revised one-day dietary intakes derived in this Final Assessment for the same age group. Second day adjustments will have no impact on estimated mean calcium intakes, but would likely reduce estimated high calcium intakes and increase low one-day intakes.

FSANZ's dietary intake assessment does not take into account calcium intake from mineral supplements.

Estimating the Risk of Excess Calcium Intake

In order to determine if the level of intake of calcium will be of public health and/or safety concern, the estimated dietary intakes were compared to an UL of intake. Australia and New Zealand have not set an UL for calcium, but the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes in the United States has set an UL of 2.5 g calcium/person/day. In this report an UL of 2.5 g calcium/person/day was used.

Dietary Intake Assessment provided by the Applicant

The Applicant highlighted the importance of adequate calcium intakes for the whole population. Data from the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS were provided, detailing calcium intakes and food consumption for the Australian and New Zealand populations. Data on median calcium intakes indicated that all male age groups met their RDI, except males over the age of 45 years that had a calcium intake just under the relevant RDI, whereas females generally did not have adequate calcium intakes in relation to their respective RDIs. Data on the percentage of foods consumed by various age groups in the population indicates that a very high proportion of Australians consume milk and milk products, the major source of calcium in the diet, yet there are still some groups with inadequate calcium intakes.

The Application did not provide estimated calcium intakes of the at risk groups outlined, assuming fortification of the proposed products.

Assessing the Eligibility and Potential Effectiveness of Calcium Fortification

FSANZ's Regulatory Principles state that a vitamin or mineral may be considered to be eligible for voluntary fortification if more than 30% of more than one age/sex population subgroup has a customary intake below the United Kingdom Estimated Average Requirements (EARs) as shown by national nutrition surveys.

Survey data were analysed to determine if more than 30% of any population subgroups had customary calcium intakes below the EAR. Modelling was also conducted to assess whether fortification of the products specified in the Application might increase calcium intakes in subgroups with low calcium intakes. Estimated dietary calcium intakes before and after fortification were compared to EARs for calcium. The EARs vary depending on age and sex. The age and sex groups and their respective EARs included in the dietary modelling are shown in Table 1.

Table 1. Population groups included in dietary modelling and their respective EARs

Age group (years)	Sex	UK EAR for calcium (mg/day)
2-3	Male	275
	Female	275
4-6	Male	350
	Female	350
7-10	Male	425
	Female	425
11-12	Male	750
	Female	625
13-15	Male	750
	Female	625
16-18 (15-18 for NZ)	Male	750
	Female	625
19-24	Male	525
	Female	525
25-44	Male	525
	Female	525
45-64	Male	525
	Female	525
65+	Male	525
	Female	525

Scenarios for dietary modelling

The dietary intake assessment for calcium was conducted for both Australian and New Zealand populations and compared to EARs for the age groups shown in Table 1.

Dietary modelling was also conducted for the following population groups considered to be at risk of low calcium intakes:

- New Zealand Maori (New Zealand only);
- People of Asian ethnicity[10] (Australia only); and
- Non-dairy consumers[11] (Australia and New Zealand).

These population groups were modelled using the same age groups listed in Table 1.

Potential changes in consumption patterns were explored previously at Initial Assessment. The model assumed that parents allow children (6-12 years) to substitute calcium-fortified beverages for milk as a drink and source of calcium.

[10] People of Asian ethnicity are those who were born in an Asian country and are now living in Australia
[11] Non-dairy consumers were those who did not consume products such as milk, cheese, yoghurt, cream and frozen milk products.

The potential impact on the intake of calcium and other nutrients found in significant quantities in milk (protein, vitamin A and riboflavin) as a result of this substitution was investigated. It was assumed that there would be a 50% decrease in milk consumption as a result of substitution.

This scenario was adjusted for the Final Assessment Report to estimate the effect of a 50% reduction in milk consumption on the zinc and riboflavin intakes of population groups highlighted by submitters to the Draft Assessment Report as already being at risk of low zinc and riboflavin intakes. The age groups identified were teenage girls and women. Children aged 6-12 years were also included in this scenario. The UK EARs for zinc and riboflavin are shown below in Table 2.

Table 2. United Kingdom EARs for zinc and riboflavin

Age group (years)	Sex	EAR (mg/day)	
		Zinc	Riboflavin
1-3	Male and female	3.8	0.5
4-6	Male and female	5.0	0.6
7-10	Male and female	5.4	0.8
11-14	Male and female	7.0	-
11+	Male	-	1.0
11+	Female	-	0.9
15+	Male	7.3	-
15+	Female	5.5	-

Calcium Concentration levels

The levels of calcium fortification in foods used in the models were derived from information provided by the Applicant on serve sizes and the RDI. The Applicant proposes to fortify products to a level so that one reference quantity will provide no more than 25% of the RDI for calcium. The RDI assumed in calculating the modelling concentration levels was 800 mg. Although there are varying RDIs for different age and sex groups in the population, an RDI of 800 mg was used for this purpose, as this is the general RDI referred to in *Standard 1.3.2 - Vitamins and Minerals* of the Australia New Zealand Food Standards Code. The reference quantities were provided by the Applicant and are 200 mL for fruit - and vegetable juices and drinks, 200 mL for soups and 35 g for savoury biscuits. These are based on the reference quantities specified in Standard 1.3.2. The foods and proposed levels of fortification are shown below in Table 3.

Table 3: Proposed fortification levels of calcium in foods

Food Name	Fortification Level (mg/100g)*
Fruit - and vegetable juices and drinks	100
Soup	100
Savoury biscuits	571

* For dietary modelling purposes, 100 g is assumed to be equivalent to 100 mL for beverages.

How were the dietary intakes calculated?

The DIAMOND program contains existing levels of calcium in foods as determined in the 1995 Australian NNS or 1997 New Zealand NNS and also allows scenario calcium concentrations to be assigned to food groups. Scenario calcium concentrations were applied to fruit - and vegetable juices, fruit – and vegetable drinks, soups and savoury biscuits (less than 200 g/kg of fat).

The DIAMOND program multiplies the specified concentration of calcium by the amount of food that an individual consumed in order to estimate the intake of calcium from each food. Once this has been completed for all of the foods containing calcium, the total amount of calcium consumed from all foods is summed for each individual. Population statistics (mean and high percentile intakes) are then derived from the individuals' ranked intakes.

Results

The percentages of respondents, from various population subgroups, with estimated pre- and post-fortification calcium intakes below the EAR are described below. This data is presented in more detail in Table 7 to Table 12 in the Appendix to this attachment. Population groups with greater than 30% of respondents having a calcium intake less than the EAR are highlighted in these tables (appearing in bold font in each table).

Pre-fortification calcium intake

Adequacy of calcium intake

General population

The number of respondents with an estimated calcium intake below the EAR was generally higher for females than males. Females aged 16-18 years had the greatest percentage of respondents below the EAR for Australia (47%). Females aged 13-15 years also had over 40% of respondents below the EAR. All other Australian female age groups over the age of 10 years had greater than 30% of respondents below the EAR (Table 7).

The greatest percentage of Australian male respondents with an estimated calcium intake below the EAR came from the 11-12 years age group (37%). Males aged 13-15 years also had greater than 30% of respondents below the EAR, while males aged 16-18 years had 30% of respondents below the EAR. Young children (less than 11 years) had the lowest percentage of respondents with calcium intakes below the EAR for Australia.

The total Australian population had 28% of respondents with estimated calcium intakes below the EAR. However, when adjustments were made to account for second day intakes, this level was reduced to 19% of respondents below the EAR for calcium.

For New Zealand, males aged 15-18 years had the highest percentage of respondents (44%) with estimated calcium intakes below the EAR. All other New Zealand age and gender groups had over 30% of respondents with estimated calcium intakes below the EAR, with the exception of males aged 19-24 years (28%) and 25-44 years (22%). The total New Zealand population had 34% of respondents with estimated calcium intakes below the EAR. Second day adjustment factors are not currently developed for New Zealand data.

New Zealand Maori

Just over 40% of all New Zealand Maori respondents had an estimated calcium intakes below the EAR. Males aged 25-44 years was the only group to have less than 30% of respondents with an estimated calcium intake below the EAR. The other population groups ranged from 39% (females 25-44 years) to 63% (females aged 65 years and over) of respondents with estimated calcium intakes below the EAR (Table 9).

Australians of Asian ethnicity

Almost 42% of the total number of respondents of Asian ethnicity had estimated calcium intakes below the EAR. A number of age groups had over 60% of respondents with an estimated calcium intake below the EAR, including females aged 13-15 years, 16-18 years and 65 years and over. Only children (10 years or younger) had less than 30% of respondents below the EAR for calcium (Table 10).

Non-dairy consumers

The percentage of non-dairy consumers below the EAR was much higher for each population sub group and for the total population in both Australia and New Zealand. Over 80% of total respondents who reported not consuming dairy products had estimated calcium intakes below the EAR for both countries (Table 11).

These results show that a large number of population groups do not get adequate calcium intakes from their food consumption habits and the naturally occurring calcium content of foods.

Risk of Excess Calcium Intake

The greatest estimated 95th percentile calcium intake was for the male 16-24 years age group in Australia (2460 mg). This level of intake is just below the UL of 2500 mg/day and is unadjusted for second-day nutrient intake. If the adjustment factor developed for this age group at Draft Assessment is applied, this estimated intake is reduced to 2105 mg/day. Although this adjustment factor was developed for a slightly different scenario (calcium fortification of the originally requested foods), it is likely to be very similar to a factor developed for the pre-fortification calcium intake reported here.

Post-fortification calcium intake

Increase in proportion of calcium adequacy

General population

Fortification of the proposed products (now excluding cordial) reduced the percentage of respondents with estimated calcium intakes below the EAR for calcium. New Zealand males aged 15-18 years had the greatest percentage of respondents with a post-fortification calcium intake less than the EAR (37%). Other population groups with more than 30% of respondents below the EAR after fortification were New Zealand females aged 15-18, 19-24, 25-44 and 65+ years, and Australian females aged 16-18 years.

However, the percentage of respondents with estimated calcium intakes below the EAR for Australian females aged 16-18 years, fell from 47% before fortification to 30% assuming the proposed foods are fortified and all respondents consumed the fortified version of the food. Similar reductions were experienced for most age/gender groups for Australia and New Zealand after fortification (Table 8).

The percentage of total respondents with an estimated post-fortification calcium intake below the EAR was 20% and 28% for Australia and New Zealand respectively. These levels are approximately 8% and 6% lower than pre-fortification estimates for Australia and New Zealand respectively.

New Zealand Maori

If the proposed products were fortified, almost 36% of all New Zealand Maori respondents had an estimated calcium intake below the EAR, compared to 40% before fortification. Although all age and gender groups had a reduced percentage of respondents below the EAR after fortification, only two groups had less than 30% of respondents below the EAR for calcium (males aged 19-24 years and 25-44 years). Males and females aged 65 years and over still had 50% and 58% of respondents respectively, with estimated post-fortification intakes below the EAR for calcium (Table 9).

Australians of Asian ethnicity

The percentage of Asian respondents with estimated post-fortification calcium intakes less than the EAR was 30%, compared to almost 42% before fortification. Most age and sex groups had similar reductions, however, females aged 65 years and over still had 57% of respondents with estimated calcium intakes below the EAR (Table 10).

Non-dairy consumers

Fortification of the proposed products reduced the number of respondents with an estimated calcium intake below the EAR for non-dairy consumers in Australia and New Zealand. The percentage of respondents with estimated post-fortification calcium intakes below the EAR for the total population of Australia was 60%, compared to 81% before fortification. The reduction was not as large for the total New Zealand population, falling from 86% to 73% after fortification. Only three population groups for Australia and New Zealand (Australian males and females 2-3 years and males 7-10 years) had fewer than 30% of respondents below the EAR after fortification (Tables 11 and 12).

Although the number of respondents in some of the age and sex groups of the Asian and non-dairy consumers scenarios was quite small, particularly for children, the results for these age and gender groups generally followed the trend of the total population with younger children having a lower proportion of respondents below the EAR than adolescents and adults.

In general, these results show that when the proposed foods are fortified with calcium, intakes of calcium may increase and there would be fewer people not meeting their calcium requirement. However, there may still be some groups of the population with large numbers of respondents not meeting their requirements, even with maximal uptake of the permission to fortify.

Risk of excess calcium intake

The dietary intake assessment for the Initial Assessment Report highlighted the potential for the 95th percentile calcium intake of males aged 15-24 years to exceed the UL for calcium if all the proposed products were fortified with calcium. The estimated 95th percentile calcium intake for this population group, based on one day unadjusted intakes, was 3080 mg/day.

At Draft Assessment the estimated one-day intake was adjusted to take into account the effect of second day intakes. The second day adjustment factor determined by the ABS applies to the 16-24 years age group, so this was the age group included in the dietary modelling at Draft Assessment.

The withdrawal of cordial from the Application after Draft Assessment had the effect of lowering the estimated high intakes of calcium by young adult males. The adjusted estimated 95th percentile calcium intake is reduced below the UL for calcium (to 2345 mg/day) with calcium-fortified cordial removed from the modelling. Although the second-day adjustment factor used was developed while cordial was still included in the Application, the withdrawal of cordial is likely to have only a very small effect on this factor, and hence on the adjusted values presented above.

These results are summarised in the following Table 4.

Table 4. Estimated 95th percentile dietary intakes of calcium by Australian males aged 16 – 24 years before and after fortification and adjustment for longer-term intake

Scenario	Estimated dietary intake (mg/day)	
	Unadjusted	Adjusted
Fortification (including cordial)	2955	2550
Fortification (without cordial)	2720	2345
Baseline (no fortification)	2460	2105

These results indicate that fortification of the proposed foods will not result in high intakes that may be of a public safety concern for any population or population sub-group.

Half-substitution of milk with calcium-fortified beverages

Before milk consumption was reduced by 50% the population group with the greatest percentage of respondents with riboflavin intakes below the EAR was females aged 16-18 years (24.3%). If milk consumption was reduced by 50% the same age group still had the greatest percentage of respondents below the EAR for riboflavin, at 27.5%. Children aged 6-12 years had the lowest percentage of respondents with riboflavin intakes below the EAR before and after milk substitution.

Females aged 12-15 years had the greatest percentage of respondents with estimated zinc intakes below the EAR before a reduction in milk consumption (27.3%). This percentage increased to 30.6% when it was assumed there was a 50% reduction in milk consumption as a result of the substitution of milk with calcium-fortified beverages. Females aged 65 years and over had similar, although slightly lower percentages of respondents below the EAR. New Zealand females aged 16-18 years had the lowest percentage of respondents below the EAR at baseline (12.6%) and after substitution of milk (14.7%).

Table 5. Percentage of respondents in Australia with intakes below the United Kingdom EARs for zinc and riboflavin before and after milk substitution

Nutrient	Model	Age group (years)				
		Male and female 6-12	Female 12-15	Female 16-18	Female 19-64	Female 65+
Riboflavin	baseline	9.5	17.1	24.3	17.9	17.0
	substitution	11.9	20.1	27.5	21.7	22.2
Zinc	baseline	15.9	27.3	16.1	15.5	23.4
	substitution	19.3	30.6	20.2	18.2	27.0

Table 6. Percentage of respondents in New Zealand with intakes below the United Kingdom EARs for zinc and riboflavin before and after milk substitution

Nutrient	Model	Age group (years)		
		Female 16-18	Female 19-64	Female 65+
Riboflavin	baseline	13.7	17.1	15.3
	substitution	17.9	23.0	23.8
Zinc	baseline	12.6	14.8	16.3
	substitution	14.7	17.2	20.8

Modelling presented previously at Initial and Draft Assessment

Potential changes in consumption patterns were explored previously at Initial Assessment. The model assumed that parents allow children (6-12 years) to substitute calcium-fortified fruit cordial for milk as a drink and source of calcium. The potential impact on the intake of calcium and other nutrients found in significant quantities in milk (protein, vitamin A and riboflavin) as a result of this substitution was investigated. It was assumed that there would be a 50% decrease in milk consumption, substituted by a 50% increase in calcium-fortified fruit cordial consumption. It was assumed that other products specified in the Application were not fortified with calcium. Modelling could only be undertaken with Australian data.

Before this substitution scenario, children aged 6-12 years had estimated mean protein, vitamin A and riboflavin intakes greater than their respective RDIs[12] (288%, 195% and 165% respectively). Based on the substitution modelling above, the estimated mean intakes of protein, vitamin A and riboflavin were all slightly lower, but still greater than their respective RDIs (268%, 180%, and 142% respectively). Not further dietary modelling was undertaken based on this model at Draft Assessment.

At Draft Assessment a fortification scenario was conducted in an attempt to make a more realistic estimate based on experience in the US market, where 25% of the fruit and vegetable juice market contains calcium-fortified juices. Therefore, for this scenario it was assumed that 25% of fruit and vegetable juices would be fortified, rather than all fruit and vegetable juices as is assumed in the other fortification scenarios.

[12] Protein RDI: 4-7 years = 18g, 8-11 years = 27g, males 12-15 years = 42g, females 12-15 years = 44g.
Vitamin A RDI: 4-7 years = 350ug, 8-11 years = 500ug, 12-15 years = 725ug.
Riboflavin RDI: 4-11 years = 1mg, 12-15 years = 2 mg.

The percentages of all respondents to each NNS in Australia and New Zealand below the EAR for calcium were only slightly higher (2%) than the original scenario assuming all fruit and vegetable juices were fortified, and were 8% and 7% less than the percentage of respondents with pre-fortification calcium intakes below the EAR. The effect of this scenario on the estimated post-fortification intake of high consumers was small. It is likely that very similar results would be obtained if cordial were deleted from the modelling.

Conclusion

Data from the 1995 Australian and 1997 New Zealand National Nutrition Surveys indicates that a number of population groups are potentially at risk of having dietary calcium intakes below the EAR for calcium in Australia and New Zealand from the general diet. The proportion of adolescent and adult females with estimated calcium intakes below the EAR for calcium is generally higher than for young children and males. Other population groups, such as New Zealand Maori, Australians of Asian ethnicity and particularly non-dairy consumers have a large proportion of people with estimated calcium intakes below the EAR.

Fortification with calcium of the products proposed in this Application has the potential to increase the calcium intake of the population groups identified as being potentially at risk of inadequate calcium intake and thereby reduce the number of people with calcium intakes below the EAR for calcium.

The adjusted post-fortification intakes of Australian males aged 16-24 years presented in the Draft Assessment Report resulted in an estimate of high calcium intake that was lower than that based solely on one-day intake. The adjusted 95th percentile calcium intake was very close to the UL. The withdrawal of cordial from the Application reduced the adjusted estimate of 95th percentile intake of calcium after fortification to 2345 mg/day. It is considered unlikely that the UL would be exceeded from the diet alone on a long-term basis given the conservative nature of modelling assumptions.

Dietary modelling indicates that fortification of the products proposed in this Application would have minimal adverse effects on the intake of various micronutrients found in milk should 50% of milk consumption be substituted by calcium-fortified beverages.

The estimated calcium intakes presented above do not include calcium intakes from supplements. As no data are available on calcium intakes from supplements, it is difficult to determine what impact supplement intake may have.

Appendix

Table 7: Percentage of respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium before fortification

Age Group	Sex	Australia	New Zealand
2-3 years	Male	7.1	na
	Female	7.5	
4-6 years	Male	9.9	na
	Female	17.5	
7-10 years	Male	11.8	na
	Female	22.6	
11-12 years	Male	**37.0**	na
	Female	**34.0**	
13-15 years	Male	**33.0**	na
	Female	**44.7**	
16-18 years (Australia)	Male	29.8	na
	Female	**47.2**	
15-18 years (New Zealand)	Male	na	**44.0**
	Female		**39.4**
19-24 years	Male	19.0	28.3
	Female	**36.9**	**36.4**
25-44 years	Male	22.1	22.4
	Female	**34.8**	**37.2**
45-64 years	Male	24.1	**32.8**
	Female	**32.2**	**35.8**
65+ years	Male	27.8	**35.6**
	Female	**39.8**	**37.9**
Total Population	24 hour recall	28.4	**33.9**
	Adjusted 2nd day	18.8	na

Note. Bold text in all tables indicates those groups where greater than 30% of respondents have intakes less than the EAR.

Table 8. Percentage of respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium after fortification*

Age Group	Sex	Australia	New Zealand
2-3 years	Male	2.9	na
	Female	3.3	
4-6 years	Male	7.9	na
	Female	9.3	
7-10 years	Male	7.4	na
	Female	13.0	
11-12 years	Male	23.5	na
	Female	19.1	
13-15 years	Male	23.6	na
	Female	28.3	
16-18 years (Australia)	Male	20.5	na
	Female	**30.3**	
15-18 years (New Zealand)	Male	na	**36.7**
	Female		**32.8**
19-24 years	Male	13.6	19.3
	Female	25.6	**31.1**
25-44 years	Male	16.0	18.3
	Female	25.8	**30.4**
45-64 years	Male	18.1	27.4
	Female	22.5	27.7

Age Group	Sex	Australia	New Zealand
65+ years	Male	19.7	28.2
	Female	27.9	**31.2**
Total Population	24 hour recall	20.0	27.5
	Adjusted 2nd day	na	na

*Assuming all proposed products (now excluding cordial) in the Application are fortified with calcium.

Table 9. Percentage of Maori respondents in New Zealand with intakes below the United Kingdom EAR for calcium before and after fortification*

Age Group	Sex	Pre-fortification	Post-fortification
15-18 years (New Zealand)	Male	**51.7**	**44.8**
	Female	**50.0**	**50.0**
19-24 years	Male	**59.6**	22.2
	Female	**43.5**	**39.1**
25-44 years	Male	26.9	22.7
	Female	**39.1**	**33.5**
45-64 years	Male	**43.7**	**40.8**
	Female	**48.5**	**42.6**
65+ years	Male	**54.5**	**50.0**
	Female	**63.2**	**57.9**
Total Population	15 years and above	**40.6**	**35.8**

*Assuming all proposed products in the Application (now excluding cordial) are fortified with calcium.

Table 10. Percentage of respondents of Asian ethnicity+ in Australia with intakes below the United Kingdom EAR for calcium before and after fortification*

Age Group	Sex	Pre-fortification	Post-fortification
2-3 years	Male	0	0
	Female	0	0
4-6 years	Male	22.2	22.2
	Female	20.0	20.0
7-10 years	Male	10.0	0
	Female	12.5	0
11-12 years	Male	**33.3**	**33.3**
	Female	**50.0**	**50.0**
13-15 years	Male	**66.7**	**33.3**
	Female	**83.3**	**50.0**
16-18 years	Male	**75.0**	**50.0**
	Female	**66.7**	**50.0**
19-24 years	Male	**42.1**	**36.8**
	Female	**37.9**	13.8
25-44 years	Male	**42.1**	27.6
	Female	**48.7**	**35.0**
45-64 years	Male	**31.6**	28.9
	Female	**36.0**	28.0
65+ years	Male	**31.8**	18.2
	Female	**61.9**	**57.1**
Total Population	2 years and above	**41.9**	30.0

+ Born in an Asian country and living in Australia at the time of the 1995 National Nutrition Survey.
*Assuming all proposed products in the Application (now excluding cordial) are fortified with calcium.

Table 11: Percentage of non-dairy consuming respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium before fortification

Age Group	Sex	Australia	New Zealand
2-3 years	Male	**50.0**	na
	Female	25.0	
4-6 years	Male	**66.7**	na
	Female	**84.2**	
7-10 years	Male	**63.0**	na
	Female	**79.2**	
11-12 years	Male	**90.0**	na
	Female	**87.5**	
13-15 years	Male	**92.3**	na
	Female	**100.0**	
16-18 years (Australia)	Male	**84.6**	na
	Female	**90.9**	
15-18 years (New Zealand)	Male	na	**100.0**
	Female		**100.0**
19-24 years	Male	**66.7**	**87.0**
	Female	**90.9**	**93.8**
25-44 years	Male	**72.8**	**76.0**
	Female	**84.5**	**87.2**
45-64 years	Male	**77.2**	**82.4**
	Female	**85.7**	**80.8**
65+ years	Male	**76.7**	**83.3**
	Female	**96.4**	**96.3**
Total Population	24 hour recall	**81.0**	**85.8**

Table 12: Percentage of non-dairy consuming respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium after fortification*

Age Group	Sex	Australia	New Zealand
2-3 years	Male	12.5	na
	Female	16.7	
4-6 years	Male	**50.0**	na
	Female	**57.9**	
7-10 years	Male	37.0	na
	Female	**58.3**	
11-12 years	Male	**90.0**	na
	Female	**62.5**	
13-15 years	Male	**76.9**	na
	Female	**75.0**	
16-18 years (Australia)	Male	**53.8**	na
	Female	**66.7**	
15-18 years (New Zealand)	Male	na	**70.0**
	Female		**92.9**
19-24 years	Male	**50.0**	**56.5**
	Female	**61.8**	**87.5**
25-44 years	Male	**53.6**	**78.0**
	Female	**62.0**	**74.4**
45-64 years	Male	**59.8**	**76.5**
	Female	**63.8**	**69.2**
65+ years	Male	**63.3**	**83.3**
	Female	**67.9**	**85.2**
Total Population	24 hour recall	**59.7**	**72.5**

*Assuming all proposed products in the Application (now excluding cordial) are fortified with calcium.

ATTACHMENT 3

SUMMARY OF SUBMISSIONS

Submitter	Option	Appropriate foods	Labelling	Health/Nutrition Education	Costs and Benefits	Standard 1.3.2	Other Comments
Australia							
Public health							
Public Health Association of Australia Julie Woods	Option 1	Fortification will increase level of sucrose intake and provide a false impression that fruit drinks are superior to whole fruit.		Application will erode nutrition and food integrity. Creates confusion about what needs to be consumed in a healthy diet. Considers Application to fall outside the codex philosophies of preserving integrity of national food supply and support of food based nutritional education activities.	Potentially puts broader nutritional status of community at risk by displacing dairy products.	Seeks to have Standard 1.3.2 reviewed and strengthened in accordance with codex principles before it can be applied to a range of different nutrients and food groups.	Refers to and repeats submission for IAR.
Industry							
Australian Self-Medication Industry Jonathon Breach	No defined comment -weighted towards Option 1	Questions whether foods in A424 will actually reach those subgroups of consumers at risk of a low calcium intake.	Concerned that industry and manufactures will make prohibited health claims that will not be acted against.				Concerned that if A470 proceeds, consumers will be confused between those foods manufactured under A470 and A424.

							Concerned manufactures will use ingredients with instable shelf life. Concerned about fortified foods exacerbating drug – nutrient interactions.
Unilever Australia Julie Newlands	Option 2	Earlier submission not in favour of cordial as vehicle for calcium because of potential for increased consumption of inappropriate foods, how ever as proposal accepts cordial as eligible food, do not consider an advisory statement or education effective risk management options for the issue.				Oppose the scope of this Application being limited to only a few foods – would like to see other vehicles for consideration for fortification. Would like to see a review of S1.3.2 prior to other Applications being considered.	Support development of new policy guidelines as being recommended by FRSC prior to considerations of any other Applications I this area. Considers both cordial and soups should/should not refer to directions for preparation, not only soup as in the case of this proposal.
Australian Fruit Juice Association David Goldberg	Option 2						Fully supports Application.

Australian Food and Grocery Council	Option 2		Agrees with no requirement for statement to effect that food not be substituted for milk.		Considers risk of distortion of food supply to be adequately addressed by USA data. Risk analysis appropriate within constraints of 'regulatory' principles.	Considers total revision of Standard 1.3.2 required – due to anomalies created by this Application should it be passed-crisp-bread products permitted to contain calcium, bread for which it can be a substitute will not. Similarly fruit juice can have calcium added but dairy type products not allowed vitamin c added.	Do not agree with regulatory principles but consider FSANZ operated with in them.
Cadbury Schweppes Neil Smith	Option 2	All foods recommended.	Believe that consumers will be able to clearly identify fortified products due to current labelling regulations.		Consumers will be able to differentiate between milk and milk products and fortified products, unlikely to believe that they are substitutes. Important source of calcium to people unable to eat dairy products.	Supports draft Standard 1.3.2 variation.	
Australian Dairy Corporation Anita Wells	Option 1 fruit juices drinks and cordials. Option 1 for biscuits. Option 2 for soups, so long as there is a clear definition of soup.	Do not consider A424 to be consistent with current Australian dietary guidelines: 'encourage water as a drink' or 'eat only moderate amount of sugars and foods containing added sugars'.	Standard 1.2.3 clause 2 requires advisory statement-considering news poll research showed some consumers are likely to consume fortified beverages as substitute to milk, that these fortified beverages	NNS 75% of Australian teenage girls and women had zinc intakes <RDI. Milk contains four times as much zinc as fruit juice, fruit drinks virtually zinc free. Recommend a risk assessment for	Negative impact on dental health: 1998 58% 9 year olds 59% of 15 year olds experiences dental caries. Year 1998-1999 dental services cost state excess of $300 million. Case Control study reported children with dental erosion drank		Recommend that A424 be deferred until standard 1.3.2 is reviewed. In reference to IAR – expert advice from independent health professionals were ignored in

		Key health professionals in US are concerned about the drink choices made by American children, particularly the high intake of fruit juice and the low intake of milk. As result have issued warning statements in to suitability of fruit juices as a drink choice. ADC concerned that approval of A424 may lead to similar problems in Australia. Do not consider fortification of cracker type biscuits appropriate. Substitution of bread (56g) for cracker biscuits (35g) would increase energy, salt and fat intake and lower protein and magnesium intakes.	also carry an advisory statement. In addition to the advisory statement, ADC recommends that calcium-fortified products should also carry a substitution warning statement for example ”this product does not supply the same vitamins and minerals as milk”.	zinc. Dietary modelling of assessed effects on riboflavin intake was carried out in children 6-12 years. ADC concerned of potential effects on riboflavin intakes in other groups at risk of low intake – girls and women 12-64 years. Recently recommended that calcium-fortified foods marketed specifically for the elderly contain phosphate salt to ensure full benefits of calcium realised and to guard against inducing phosphorus insufficiency. ADC believe this should be considered in relation to A424. Evidence suggests that milk more beneficial to bone health than consumption of calcium-fortified	carbonated drinks, fruit cordial and fruit juice more frequently than erosion free contemporaries. 20% of children’s and teenager’s intake of sugar from fruit and vegetable juices and drinks. Glass of pineapple juice or apple juice contains as much sugar as glass of coke or lemonade. Even with the addition of calcium cannot assume that drinks will be non-cariogenic unless they are carbohydrate free. Fruit juice is acidic there for erosive to teeth. ADC believes that concerns about dental health are valid and will be a cost of an increase in added consumption of fruit juices, drinks and cordials. Since introduction of calcium-fortified juices in to US market, sales of fruit juice and fruit drinks have increased and milk consumption		favour of unreferenced statements from a party who clearly have a vested interest. ADC would like to point out that lactose intolerance and milk allergy are very different conditions. Where as it is essential that individuals with milk allergy exclude all sources of milk from the diet, this is not necessary for everyone with lactose intolerance.

				foods devoid of other bone-building nutrients. Fear that addition of juice in to diet will contribute to increase in obesity.	has fallen to much greater extent than in Australia. UK trends similar. Evidence from US suggests that significant amounts of public money has been spent on consumer nutrition education campaigns as result of high fruit juice intake. ADC contracted and independent news poll survey of 1200 respondents. Executive summary: <u>Purchase intention</u>: Calcium-fortified fruit juice beverages will not attract mass market interest, but will be of interest to a significant minority: *Fruit Juice* Def would buy- 14.7% Poss would buy- 30.5% Total would buy- 45.2% *Fruit juice drink* Def would buy- 9.1% Poss would buy- 20.6% Total would buy- 28.9% *Fruit juice cordial* Def would buy- 10.1% Poss would buy- 22.2%		

					Total would buy- 32.3% **<u>Product substitution</u>** Depending on the product, around 50-60% of purchasers would replace an existing beverage. Replacement purchase: *Fruit juice* 61% *Fruit juice drink* 50.6% *Fruit juice cordial* 63.2% As anticipated, fortified fruit juice will mainly replace fruit juice, fortified fruit drink would replace fruit juice drink and fruit juices, fortified fruit juice cordial will replace cordials – both fruit and non-fruit juice. **<u>Dairy Substitution</u>** In all cases a small but significant group will buy the new calcium-fortified beverages and replace either - Regular milk - Modified/low fat milk - Flavoured milk Specifically Milk substitution (total) *Fortified fruit juice* 5.8% *Fortified fruit juice drink* 12.2% *Fortified fruit juice cordial* 6.1%		

Nestle Australia Ltd Robyn Banks	Option 2						
Murray Goulburn Co-operative Co Ltd Wendy Morgan	Option 1		Only foods with a similar nutritional composition should be promoted as suitable substitute for dairy foods. Reduced fat milk packaging has advisory statement, considers that fruit and vegetables juices require advisory statement.		A number of components of dairy products contribute to their beneficial effects on bone health – not just calcium. There is a need to review the evidence for calcium from different food sources on bone health, including- Bioavailability of calcium and other dietary factors implicated in bone health, and bone formation and bone resorption.	Recommend two changes to be included in Standard 1.3.2 clause 4. 1. Comparing, whether expressed or implied, the nutritional contribution to the diet of the food on the basis of its vitamin and/or mineral fortification with that of any other food, except where expressly permitted in this Code: or 2. Whether expressed or implied, that, on the basis of its vitamin and/or mineral fortification, the food is substitute for any other food, except where expressly permitted in this code; or…	Recommends more research in countries with fortification in respect to uptake of fortified juices, substitution in the diet, decreases of milk, significant changes in health. Concerned promotion of calcium-fortified foods will exacerbate consumer misconceptions about lactose intolerance and dairy allergy. Recommend additional consumer research with emphasis on vulnerable groups.

National Foods Ltd H Ferguson	Option 1 In particular does not support permission for calcium to be added to biscuits containing up to 20% fat, or fruit cordials.	Draft std for biscuits less than 200 g/kg of fat. This equates to 20% fat, which does not equate to low fat in any definition in the code of practice for nutrient claims. Should give consideration to consensus of nutrition professionals recommending reduction of fat and sugar intake. 20% fat is not a low fat food. Bioavailability of calcium from fruit juices has not been assessed.	Low and reduced fat milk products required to carry advisory statement. No evidence that mothers will not substitute juices for milk for children under the age of two years. To insure that nutritional inadequacy is avoided, fruit juice, being low fat food, should require a warning statement as for low fat milk.	Education not previously seen by FSANZ as realistic or effective tool for management of risk in relation to milk consumption for infants. However, FSANZ does see education as realistic and effective risk management tool to allay public health fears of skewed dietary patterns. These views are inconsistent.	Substitution of milk and juice has been based on US and NZ data, not taking in to consideration different pricing and availability of juices in these markets. Agree that there is a standard for infant foods , however infants 6-12 months will drink and eat foods purchased for regular consumption with in the household.	Complete review of Vitamin and minerals standard. Existing standard not based on restoration or equivalence but rather on fortification for some selected sections of the food industry. Current vitamin and mineral standard inadequate and inflexible, not based on good science.	Resulting standard has created huge opportunities for innovation in some sectors of the food and beverage industries and stymied innovation in others.
Berri Ltd David Goldberg	Option 2				Will enable Australia to be equitable to other fruit juice producing countries, and provide consumers with a greater choice as to which foodstuffs they can use to acquire calcium requirements.		

Dairy Farmers Research and Development Norm Reynolds	Not clear – definitely against permission for cordials	Concern about appropriateness of fortification of *fruit cordials* due to amounts of sugar.	Support the maximum claim reference quantity 200 mg in 200 mL.		Concerned that fortification of fruit juice products may lead to a substitution for milk products resulting in a decrease in protein and riboflavin intake.		
Cocoa Cola Oceania	Option 2			Significant numbers of consumers where low uptake of dietary calcium is a potential health risk and alternative options provide additional health and well being.	Provides consumers with greater choice in selecting a 'good source' of calcium.		Offers Australian/New Zealand manufacturers greater ability to meet need for standards in other international markets.
Sanitarium Health Food Company T. Guy R. Truswell	Option 1 – Biscuits and soups only. Does not support modification of Standard 1.3.2 to allow voluntary addition of calcium to fruit and vegetable juice and drinks or fruit cordials.	Fruit juice and cordials are not consistent with principles for fortification due to amount of sugar in cordials.			Substitution of cordial/juices for milk should have modelled for magnesium and vitamin B12 as milk is an important dietary source. Study in US found consumption of sugar-sweetened fruit drinks associated with obesity in children. Promotion of high sugar drinks such as juice and cordial will increase energy intakes in a population currently experiencing a rise in obesity.	Do not support modification of standard 1.3.2, but recommend that should the revision be passed that the standard prevent the use of fortified juices and products be used as ingredients in other foods to enable claims regarding calcium to be made.	

Government							
CSIRO Dr Mavis Abbey	Option 2	Support the view that these food categories will provide consumers with additional or alternative sources of calcium.					
Queensland Health Gary Beilby	Option 1 Strongly oppose fortification of all foods	Food categories not all consistent with general dietary guidelines. Savoury crackers <10% fat not considered by nutritionists to be low fat. 25% of ingoing weight of added sugar inconstant with NHMRC accepted healthy eating advice. Serving sizes for sodium are arbitrary. Cordial not acceptable food for NHFA FIP program. Consider nearly all foods to contain at least one vitamin or	Question who will regulate promotion of fortified products. Indicate that consumers are influenced by nutrient content claims. Concerned that food will be able to be promoted as 'sources' or 'good sources' of calcium.	Not all water in Australia has fluoride added.	Risk of dental decay not adequately assessed in report. Calcium does not prevent dental decay- sugar promotes dental decay. Current advertisements implying fortified juice will aid dental health are questionable. Calcium strengthens teeth but does not effect decay. People with special clinical needs who do not/cannot consume dairy products would have needs better meet by supplementation than relying on drinks high in sugar, and biscuits high in saturated fat. No estimation on effect to oral health costs. Risk of inappropriate substitution of dairy foods for calcium-fortified juices and cordial not adequately addressed.	Comprehensive review of Standard 1.3.2 required before hundreds of fortification Applications need to be processed. Regulatory principle No 3 requires urgent review.	FSANZ processing this Application may compromise FRSC decision.

		mineral, make more sense to have at least 5% of RDI of mineral in question before fortification allowed.			In the mid 90's fruit juice consumption in US preschoolers increased from 3.2 to 5.5 f oz/day consistent with a decline in milk intake. Question evidence that fortification of relevant proposed products in NZ reduced the degree of inadequate calcium intake. Question why no data from other countries with fortified juices not considered and only USA data.		
Other							
Jo Rankine Consumer	Option 2 as long as the calcium used to fortify is biologically available.						
Food Technology Association of Victoria David Gill	Option 2						

New Zealand							
Public Health							
Crown Public Health Janelle Mackie	Option 1	Suggested foods generally high in sugar and/or fat.			Consumption of foods high in sugar and fat have potential to be detrimental to children with the link with oral health and obesity issues in New Zealand. Confusion amongst consumers may result in substitution of fortified products for milk – compromising intakes of riboflavin, protein and vitamin D.		Price is barrier to milk for some people, added cost of calcium-fortified foods may also be a barrier to subgroups of population who are in need of additional calcium.
Agencies for Nutrition Action Christina McKerchar	Option 1	Fruit juice/fruit juice drinks high in sugar and already contribute considerable amount of energy to diet. Promotion of fruit juice consumption inconsistent with national nutrition guidelines for healthy eating.		Likely that fruit juice will be marketed as a good source of calcium and good for dental health – consumers will not realise the negative impact on health from the high amounts of sugar.	Maori and Pacific Islanders already have high prevalence of obesity. Excessive sugar consumption contributes to obesity risk, thus fortification of high sugar products not consistent with public health measures to decrease obesity.		Concerned about the impact of this Application on Maori and Pacific people who have a high incidence of obesity and diabetes.

Regional Public health Service, Auckland District health – Nutrition Team Christine Cook	Option 1	Current goal to limit energy provided by sugar to 15% total energy intake. Fruit juice/ fruit drinks high sugar carrier for calcium.	Potential confusion for consumers if products such as juice, soup and crackers are promoted as good sources of calcium.	People will be confused by labelling of calcium content and may give to infants resulting in diarrhoea and dehydration.	Fortification of juice will result in decreased milk intake. Juice being high in sugar and contributor to obesity. Experience shows that milk intolerant individuals are satisfied with variety sources of calcium available to them. Negative impact on dental carries – cannot assume that all people have good oral hygiene practices. Lack of information on the bioavailability of calcium in different foods. Juice not recommended in young children due to potential to cause diarrhoea and dehydration.		Provide alternate strategies for increasing calcium intake and reducing osteoporosis risk. Investigate reasons was to why people are consuming inadequate amounts of calcium and develop strategies to address these. Strengthen promotion of other factors known to assist in prevention of osteoporosis – such a weight bearing exercise, and reducing salt intake.
New Zealand Dietetic Association Helen Wallwork	Option 1	Fruit juice/ fruit drinks high sugar carrier for calcium. Current goal to limit energy provided by sugar to 15% total energy intake.	Potential confusion for consumers if products such as juice, soup and crackers are promoted as good sources of calcium.	People will be confused by Labelling of calcium content and may give to infants resulting in diarrhoea and dehydration.	Lack of information on the bioavailability of calcium in different foods. Excessive sugar consumption from fruit juice, drinks and cordials contributes to increased obesity risk		Nutrients should be only added to food that naturally carry a source of that nutrient unless widespread deficiency. Provide alternate strategies for

		Juice not recommended in young children due to potential to cause diarrhoea and dehydration.			Experience shows that milk intolerant individuals are satisfied with variety sources of calcium available to them Negative impact on dental carries – not reasonable to assume good dental hygiene practises.		increasing calcium intake and reducing osteoporosis risk. Investigate reasons was to why people are consuming inadequate amounts of calcium and develop strategies to address these. Strengthen promotion of other factors known to assist in prevention of osteoporosis – such a weight bearing exercise, and reducing salt intake.
Industry							
Fonterra Joan Wright	Option 1 Refers to ADC submission – accepts permission for soup as acceptable						Vitamins and Minerals Standard should be reviewed as matter of urgency rather than take piecemeal approach to fortification as exemplified in this Application

New Zealand Juice Association John Robertson	Option 2 for juice.	Fortified juice products available in NZ for 3 years, these products have tended to be substituted for non-fortified products. Difference between milk and juice is significant enough that it is unlikely for the complete substitution of one for the other.			Positive aspects of juice in relation promotion of vegetable and fruit intake in 5+ per day promotion.	Supports proposed variation to S1.3.2 in respect of fruit and vegetable juices	Commented on MoH statement that one glass of fruit juice can constitute one serve of fruit.
Government							
NZFSA Carole Inkster	Option 1	Recognises that there is a public health benefit for additional calcium for some sectors of population but believes better foods than proposed in A424.			Obesity is epidemic that is being addressed by national strategies. Fruit juices and drinks high is sugar and hence dietary energy. By recognising these as potential sources of calcium, we will encourage consumption and thus potentially increasing the risk of overweight and obesity. Poor dental health recognised as a concern in public health of New Zealand – and is a key area of concern in the New Zealand Health Strategy. Fruit juice and fruit drinks as an alternative source of calcium may add to dental caries.		FRSC has set up working group to develop overarching policy guidance for fortification of food supply. Work begins in February aim to deliver recommendations to Ministers before end of 2003. Fortification of certain foods with a single nutrient may be a different policy direction than may be recommended by the FRSC

					New Zealand food and nutrition guidelines recommend to reduce the consumption of foods high in sugar, with specific recommendation for children that consumption of sugary drinks be reduced. A424 is inconsistent with national public health strategies.		working group.

ATTACHMENT 4

REGULATORY PRINCIPLES FOR ADDITION OF VITAMINS AND MINERALS TO FOODS

Introduction

During the 1990s and into this decade, the predecessors of Food Standards Australia New Zealand (FSANZ) have developed regulatory principles as required to guide decisions in relation to the addition of vitamins and minerals to categories of foods such as: general purpose foods; and special purpose foods. Permissions for addition of vitamins and minerals to foods are given in Standard 1.3.2 (general purpose foods), in each of the standards contained in Part 2.9 (special purpose foods) of the *Food Standards Code*.

The regulatory principles for addition of vitamins and minerals to general purpose and special purpose foods are based to some extent on the Codex *General Principles for the Addition of Essential Nutrients to Foods* (Codex General Principles) developed by the Codex Alimentarius Commission. The Codex General Principles embody the concepts of risk and effectiveness and are based on sound nutritional principles established within a conventional nutritional paradigm as well as providing standardised definitions of relevant terms.

Regulatory Principles

Risk and Effectiveness

Consideration of the addition of vitamins or minerals to any food/nutrient combination will be made in the context of a risk assessment and, where appropriate, effectiveness assessment framework. Risk assessment of vitamin or mineral addition applies to all categories of foods and purposes of addition, whereas, assessment of effectiveness applies only to mandatory fortification and addition to special purpose foods. An assessment of the potential effectiveness of a food/nutrient combination is also a consideration in deciding whether voluntary fortification will be permitted however, the achievement of effectiveness cannot be assured. Achievement of effectiveness would be assessed by measurement of an expected increase in the food or supply, or evidence of a decline in public health indicators of disease, and would depend on the selected food's level of vitamin or mineral addition and the directions for intake or pattern of consumption by the target population group.

Risk Assessment Framework

Because the risk of excess vitamin or mineral consumption derives from the entire food and supplemental intake, and in many cases can be quantified through nutrient specific upper tolerable limits, standard methods can be applied to consideration of risk of total consumption from current and proposed sources. Within the context of all regulatory principles, specific decisions about the addition of vitamins and/or minerals to foods, including setting an upper limit in any single food, are based on the risk to the population as a whole or to identified subgroups or excess vitamin or mineral intake. Assessment of such intakes takes account of food and where information is available, supplement consumption, under existing and proposed conditions.

The risk to the population or identifiable subgroups of excess consumption of a vitamin or mineral is quantified by estimating the total consumption (worst case) of that vitamin or mineral from both natural and proposed added sources by undertaking a dietary intake assessment. This estimate is compared with the Tolerable Upper Intake Level (UL) for that vitamin or mineral, as determined by the Food and Nutrition Board, Institute of Medicine, National Academy of Sciences in the US[13].

The UL is the highest level of daily nutrient intake that is likely to pose no risks over time of adverse health effects to almost all individuals in the general population. As intakes increase above the UL, the risk of adverse effects also increases. ULs are derived from a risk-based approach that accounts for total intake of a nutrient from food, water and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only, not total intake.

Where a potential risk to the population or subgroups of exceeding the UL for a particular nutrient is identified, the fortification scenario models used in the dietary intake assessment are further refined to take into account uncertainties and limitations of the data. For example, where voluntary permission is being considered, information on the market share of the proposed fortified product in Australia New Zealand or other countries are used as a guide for scenario models rather than assuming that there will be 100% uptake of the permissions by industry. In other words, the models are refined and assessed in order to ascertain whether or not the potential risk is realistic. If the potential for excess consumption still exists, the following risk management strategies could be applied:

- no permission for the nutrient addition granted;
- limited range of food or amount of the nutrient (e.g. limited to less than 25% RDI per reference quantity or 'source' claim only i.e. 10-<25% RDI per reference quantity); or
- permission granted for nutrient addition in conjunction with labelling advice about the risks.

Guiding Statement

To underscore the regulatory principles and to provide a clear rationale for the addition of vitamins and minerals to foods, a new high-level Guiding Statement has been developed which applies to the regulatory principles for general purpose foods and special purpose foods.

The Statement embodies the concepts of assessment of risk and, where appropriate, of effectiveness that together form the framework within which the regulatory principles are applied. Because the risk of excess vitamin or mineral consumption derives from the entire food and supplemental intake, and in many cases can be quantified through nutrient specific upper tolerable limits, standard methods can be applied to consideration of risk of total consumption from current and proposed sources.

[13] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences (1998) '*A risk assessment model for establishing upper intake levels for nutrients*', National Academy Press, Washington DC.

On the other hand, effectiveness is context specific and needs to be considered on a case-by-case basis in accordance with the purpose of the fortified food. Achievement of effectiveness would be assessed by measurement of an expected increase in the food or food supply, or evidence of a decline in public health indicators of disease, and would depend on the selected food's level of vitamin or mineral addition and the directions for intake or pattern of consumption by the target population group.

Guiding Statement

Consistent with the Codex *General Principles for the Addition of Essential Nutrients to Foods,* the addition of vitamins and minerals to general purpose and special purpose foods should not be permitted where no adequate nutritional rationale can be provided. Regulatory principles that are elaborated in accordance with this Guiding Statement aim to prevent the indiscriminate addition of essential nutrients to foods thereby reducing the risk of health hazards due to essential nutrient excesses, deficits or imbalances.

This Statement is based on that proposed by Health Canada[14] who contends that without such a Policy Recommendation:

- there is a risk that the addition of vitamins and minerals to foods would become disconnected from nutritional need, health benefit or purpose;

- food fortification could potentially seriously undermine the concept of total diet by encouraging consumers to rely on only a few, highly fortified foods rather than a well-balanced diet consisting of a variety of foods consumed in moderation; and

- the addition of vitamins and minerals to foods at levels that cannot be nutritionally justified would carry an implicit message to consumers that some benefit may accrue from consumption of micronutrients at those levels.

The development of a Guiding Statement clarifies for FSANZ, potential applicants, and all stakeholders that permission for the addition of vitamins and minerals to general purpose and special purpose foods cannot be sought on grounds other than according to the established regulatory principles.

The relevant regulatory principles in relation to general purpose foods are presented below.

Background

General purpose foods are those that are generally available for consumption by all members of the community. Regulatory principles for the voluntary vitamin and mineral addition to general purpose foods were developed in 1995 and derived from the Codex General Principles. These regulatory principles were last reviewed in 1999 as part of the development of joint Australia New Zealand food regulation, and are the following:

[2] Health Canada (1999) *Addition of Vitamins and Minerals to Foods: Proposed Policy Recommendations*: Bureau of Nutritional Sciences, Food Directorate, Health Protection Branch. Ottawa.

1. 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 basic 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 present at a level which would contribute at least 5% of the RDI in a reference quantity of the food[15].

2. Specified foods may be fortified with vitamins and minerals to [potentially] address situations where there is reasonable evidence for a nutritional need in the population.

3. Vitamins and minerals may be added, for the purpose of nutritional equivalence, to specified foods that substitute for certain basic foods.

4. Food categories which, historically to 1995, have been fortified with a vitamin or mineral by a significant proportion of manufacturers (on the basis of market share) may, subject to no identified risks to public health and safety, continue to be fortified with those vitamins and minerals at moderate levels.

5. In general, claims to the effect that the particular food product is a 'source' or a 'good source' of a vitamin or mineral may be made providing a reference quantity of the food contains at least 10 percent or 25 percent of the RDI respectively for the particular vitamin or mineral and the food is a 'claimable'[16] food.

In addition, Australia and New Zealand have mandated particular fortification measures in order to address one or more aspects of demonstrated serious public health need, although Australia has historically mandated and continued for the time being, more measures than New Zealand.

Clarification and Elaboration

Several of the previously developed principles for voluntary addition are sufficiently elaborated to serve current regulatory requirements and need no further discussion. These principles relate to modified restoration; nutritional equivalence; and the content claim criteria. The historical precedent previously employed is now retained only as a footnote to the clarified regulatory principles for completeness. Further clarification has been provided as to the conditions pertaining to voluntary and mandatory fortification however, this is not relevant for discussion here. Neither is the clarification of the principles for mandatory fortification presented here

Voluntary fortification

Voluntary fortification is where food regulation permits industry to choose to add specified vitamins and/or minerals to particular foods to address certain public health concerns.

[15] This Regulatory Principle was modified from the Codex General Principle of restoration

[16] 'Claimable food' is defined in Standard 1.3.2 – Vitamins and Minerals as at least 90% by weight of primary foods, or foods permitted voluntary addition, or a mixture of these (excluding butter, cream, edible oils, edible oil spreads and margarine) and water.

Permission for such addition would be granted after an assessment of risk, not only of excess vitamin or mineral consumption but also of increased consumption of potentially inappropriate foods that would be promoted on the basis of their enhanced nutrient profile. Depending on the extent of such risks, a maximum regulatory limit or maximum claim could be imposed, or the food not approved for fortification.

Where regulation permits voluntary addition, it is the food manufacturer who decides whether vitamins or minerals are to be added to his product; commercial considerations are a significant factor in such decisions. From a public health perspective, permission for voluntary addition cannot be routinely relied upon to target improvements in public health even if the industry indicates its intention to fortify particular products. This means that the community should be prepared to bear the opportunity cost to public health if industry chooses not to take up the regulatory permissions for voluntary fortification.

Eligibility of vitamin or mineral for voluntary fortification

Because of the uncertain impact of future permissions to voluntary fortify, it is appropriate that voluntary fortification be directed to lower intensity food-related public health concerns such as the proportion of the population or population subgroup whose customary nutrient intakes are inadequate. This is similar to the Canadian approach but requires the following three elements to be determined:

- appropriate nutrient reference values;
- percentage of identified population subgroups whose intakes of vitamins or minerals are inadequate; and
- appropriate population subgroups for comparison of intakes and reference values.

Nutrient reference values

Several nutrient reference values can be used to assess nutrient intakes: most common for assessment of adequacy of intake are the Estimated Average Requirement (EAR), or Recommended Dietary Intake (RDI) or equivalent term.

An RDI is a nutrient intake estimate that allows for a safety margin, by accommodating variations in absorption and metabolism and applies to group rather than individual needs. RDIs are designed to meet the needs of practically all healthy people. An EAR is a value that represents the median requirement for the dietary intake of a particular nutrient in a given population group. Values for EARs are often determined as part of the methodology for establishing recommended intakes for macronutrients, vitamins and minerals; both the United Kingdom and the United States/Canada establish EARs for this purpose[17,18]

[17] Food and Nutrition Board, United States Institute of Medicine (2000) *'Dietary Reference Intakes: Applications in Dietary Assessment'* National Academy Press, Washington DC; p73-105.

[18] *Dietary Reference Values for Food, Energy and Nutrients for the United Kingdom'* Crown Publications, London; p3-10.

At the time of this report, no EARs had been established for Australian or New Zealand populations, although several Australian RDIs[19] were previously developed by the addition of a safety margin to a predetermined average requirement.

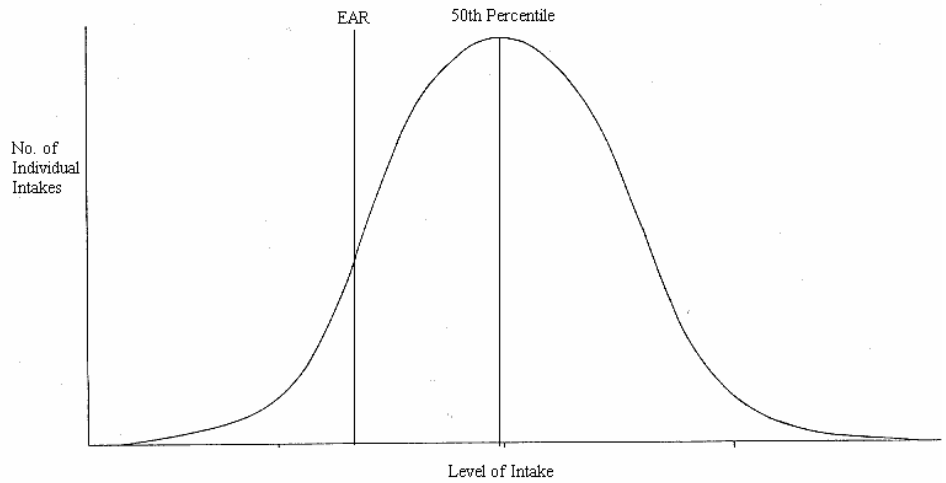
An EAR can be used as a public health benchmark for comparing and evaluating nutrient intakes and is useful for this purpose because it is established directly from evidence of nutrient requirements and applies specifically to large populations.

EARs established by other countries will be used to assess the adequacy of intakes, as Australia and New Zealand are yet to establish EAR values. Only the United States and the United Kingdom have established EARs for their populations. The United States Dietary Reference Intakes for vitamins and minerals are the most recent (1998-2001) and comprehensive, however the Dietary Reference Values produced by the United Kingdom are generally more compatible with Australian RDIs. In a few cases the United States EAR is equivalent to, or greater than the Australian RDI! Use of such values to assess population intakes at this time however could lead to greater emphasis being placed on these nutrients without confirmation that such an approach is appropriate for Australia and New Zealand. Therefore United Kingdom EARs are preferred in the assessment of adequacy of nutrient intakes. If such values do not exist, then United States values should be used as an alternative.

Percentage of the population with inadequate vitamin or mineral intakes

Figure 2 shows a diagrammatic representation of the way in which the distribution of intakes and requirements relate. The area under the intake curve to the left of the EAR represents the proportion of the population whose intake is considered inadequate.

Figure 2: Distribution of nutrient intake showing location of EAR when about 30% of the population's intake is below the EAR



[19] National Health and Medical Research Council (1991) *'Recommended Dietary Intakes for Use in Australia'*. Australian Government Publishing Service, Canberra; p3, 27.

The adequacy of a nutrient intake can be assessed according to the percentage of the population whose intake is below the EAR. Where the percentage is greater than 50%, the distribution of intakes has shifted to the left of the distribution of requirements because the EAR represents the median requirement for the population[5]. Such a shift reflects the situation where there is an increased probability of individuals within the population group having an intake below their respective requirements for a nutrient, with greater percentages below the EAR reflecting a greater probability of inadequacy. The converse of this trend is also true: smaller proportions of the population whose intake is below the EAR reflect situations where there is a reduced probability of inadequate intakes.

The selection of a percentage of the relevant population group whose customary intakes are considered to be inadequate and therefore who may benefit from voluntary fortification, is arbitrary. Clearly, the greater the proportion of the population whose intakes are below the EAR, the more conservative the decisions to permit voluntary fortification, but the greater potential impact of any permitted fortification. On balance, FSANZ accepts that a case for voluntary fortification could be made if the percentage of the population or population subgroup whose customary vitamin or mineral intakes are below the EAR is at least 30%.

Population subgroups

An assessment of the adequacy of intakes of population subgroups as well as for the total population is important given the differences in food intake between the sexes and throughout the lifecycle. The population subgroups used in the two sets of selected overseas nutrient reference values are themselves inconsistent and also inconsistent with those given for the Australian RDIs, which were used to describe the population groups in the Australian and New Zealand National Nutrition Surveys. This inconsistency can be overcome in an assessment of dietary adequacy however, because FSANZ's dietary exposure software program DIAMOND will shortly be able to aggregate the data for specified age/sex groups according to the EAR population subdivisions, and it is anticipated that second day adjustment factors will be able to be applied according to those subdivisions in the future. It is not envisaged that adequacy of intake of smaller population groups would need to be assessed.

Summary

The eligibility of particular vitamins or minerals to be permitted voluntary fortification in new foods would be considered in cases where the population group intake of that vitamin or mineral is assessed as inadequate. The following points summarise the basis for that assessment.

1. Adequacy of the vitamin and mineral intakes of the total population or population subgroups should be assessed by reference to the Estimated Average Requirement (EAR) established for that vitamin or mineral.

2. The EARs established by the United Kingdom should be preferentially used. If no such EAR value exists, then United States EAR values should be used as an alternative.

3. A vitamin or mineral may be considered to be eligible for voluntary fortification in a new food if more than 30% of the whole population or more than one subgroup has a customary intake as shown by national nutrition surveys to be below the EAR

4. Population subgroups are defined as those given for the UK Dietary Reference Values.

Eligibility of food for voluntary fortification

The risk of nutritional inappropriateness of the food product to contain, and be promoted as containing, an added vitamin or mineral should be evaluated against the potential for that addition to decrease the percentage of the identified population whose intakes are assessed as inadequate.

Currently, the range of general purpose foods that are permitted to carry claims of natural vitamin or mineral content is restricted to those having a favourable nutritional profile and often less than 10% added sugars and fats. The food industry has shown increasing interest in adding vitamins and minerals to a greater range of foods than currently permitted. Many of these new foods would not be considered as core or basic foods and are often of relatively low nutrient density prior to fortification; they often contain significant proportions of added sugars, salt and/or fats. Promotion of voluntarily fortified foods usually includes reference to the food's increased vitamin or mineral content such as by a highlighted nutrient content claim on the front display panel accompanied by a Nutrition Information Panel (NIP) that quantifies the relevant vitamin or mineral content elsewhere on the package. The promotion of such foods may confuse consumers as to the overall nutritional integrity or undesirability of the product if they are unable to interpret or unaware of the nutrition information also on the label.

But are there any risks of expanding the range of foods eligible to contain added vitamins and minerals to include those of inherently lower nutritional value? The findings of two such studies shed light on this issue. In the results of a copy test of nutrient content claims and food health claims in advertising[20], the "Halo Effect Component" was described. This research used word and pictorial advertisements to investigate the use by consumers of claims for foods that contain high levels of a beneficial nutrient such as fibre or calcium, but also contain high levels of a nutrient (such as sodium, saturated fat, or cholesterol) that, in sufficient quantity, can increase the risk of a diet-related disease. Respondents on average underestimated the level of risk-increasing nutrients in these products when only quantitative written information (in the advertisement) about the risk-increasing nutrients were provided and required direct verbal information about these risk-increasing nutrients in order to correctly evaluate the healthfulness of the food product.

The results of another study[21] suggest that the presence of added value information (i.e. 'new' information such as a content claim or a low fat claim) is an important condition on whether or not a claim will have an impact. Results of this study also show that the presence of a nutrient content claim is significantly associated with a greater probability of a search limited to the front panel, relative to a search that involves looking at the Nutrient Facts panel. This would imply that consumers are less likely to look at the NIP (and therefore assess the quantities of other nutrients) of a product if it bears a nutrient content claim on the front.

[20] Murphy, D., Hoppock, T.H. and Rusk, M.K. (1998) '*Generic Copy Test of Food Health Claims in Advertising'*. Federal Trade Commission. Sourced from http://www.ftc.gov/opa/1998/9811/food.htm

[21] Roe, B., Levy, A.S. and Derby, B.M. (1999) '*The impact of health claims on consumer search and product evaluation outcomes: results from FDA experimental data*'. Journal of Public Policy and Marketing 18 (1), pp 89-105.

The relative importance that consumers place on the presence of 'new' and positive information and a nutrient content claim on the front of a product suggest that it is important to establish criteria for selection of appropriate food vehicles for the addition of vitamins and minerals. Research suggests that consumers in general have difficulty weighing up positive information against the negative information.

Therefore specified foods may be voluntarily fortified with vitamins and minerals to potentially address situations where the food proposed for fortification is consistent with nationally endorsed guidance for healthy eating. To avoid the promotion (by virtue of a nutrient content claim) of foods that might increase risk factors for certain diseases if consumed in excessive amounts or that have little nutritional value, compositional criteria should be applied to the selection of appropriate food vehicles for nutrient addition.

The risk of potentially increased consumption of inappropriate foods

Foods that have been voluntarily fortified should be consistent with officially endorsed guidance for healthy eating such as the Dietary Guidelines. There is potential for consumers to receive conflicting messages if foods such as confectionery and high fat and sugar desserts claim to be sources or good sources of added nutrients while the Dietary Guidelines recommend the consumption of these types of foods in small quantities or in moderation.

A further risk relates to the potential for inappropriate substitution of the fortified food for a natural source of the vitamin or mineral based on product similarity or perceived use. This risk relates to a natural source of the vitamin or mineral being substituted for a fortified product which does not meet the Codex definition of a substitute food. A substitute food is defined in the Codex General Principles as:

> *a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.*

The implications for inappropriate substitution include changes in nutrient intakes other than the vitamin or mineral proposed for addition. If such a risk is identified, risk management strategies could be employed. For example, if calcium-fortified orange juice displaces milk as a source of calcium, this may impact on the intake of other nutrients contained in milk that are not present in orange juice and orange juice does not meet the definition of a substitute food under the Codex General Principles. At present, data for confirming such a risk is limited and market data is the best available for obtaining a longer term picture of consumer patterns.

There may be a need for new consumer education about how to use fortified foods as part of healthy eating. In instances when voluntary permissions are granted, consumers may find it difficult to know whether they should select fortified foods or not. Education programs would be important so that consumers did not lose sight of the value of the total diet.

Monitoring programs which would record the levels of uptake of the voluntary permissions granted would be useful to assess the potential effectiveness in assisting the population or identified sub-groups of the population to increase their intake of a particular nutrient.

Criteria for food selection

The proposed criteria for assessing the suitability of the food to be voluntarily fortified is based on a similar approach to that applied to 'claimable foods' as defined in Standard 1.3.2 – Vitamins and Minerals, and also that proposed for appropriate use of health claims. Although these criteria are not strictly consistent with the composition of previously permitted foods, for the first time they provide sufficient detail to guide manufacturers and regulators on the voluntary addition of vitamins and minerals to foods.

The food category generally (in ready to consume form) must:

1) have no more than 25% by ingoing weight of:

   a) added sugars[22]; and
   b) any ingredient comprising more than 75% triglyceride.

2) contain no more than 800 mg sodium per manufacturer's serve size.
3) *prior to vitamin and/or mineral addition,* must also naturally contain at least one vitamin or mineral whose content is at least 5% of the Recommended Dietary Intake (RDI) as listed in the Schedule to Standard 1.1.1 per manufacturer's serve size.

The limits on sugar and fat however are stated in terms of ingredients or added sugar- and fat-ingredients (recipe based) rather than on the total sugar or fat content (nutrient analysis) which might otherwise include naturally present sugars and fats. A moderate nutrient density of the food is assured by the requirement that the food contain, per manufacturer's serve, at least one vitamin or mineral at 5% of the RDI. The sodium limit is generous in keeping with the currently permitted voluntarily fortified foods but it was still considered important to exclude some high salt foods.

VOLUNTARY FORTIFICATION

Specified foods may be voluntarily fortified with vitamins and minerals to potentially address situations where:

1 There is evidence of dietary inadequacy as assessed by the percentage (generally 30% or more) of the whole population or more than one age/sex subgroup whose customary vitamin or mineral intakes are below the respective (UK) Estimated Average Requirements. The nutrient of interest may also be related to a disease outcome of public health significance; and

2 The food proposed for fortification is consistent with nationally endorsed guidance for healthy eating. To avoid the promotion (by virtue of a nutrient content claim) of foods that might increase risk factors for disease if consumed in excess amounts or that have little nutritional value, the following compositional criteria have been developed.

[22] Defined as: hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or starch hydrolysate; or glucose syrups, maltodextrin and similar products; or products derived at a sugar refinery, including brown sugar and molasses; or icing sugar; or invert sugar; or fruit sugar syrup; or malt or malt extracts; or honey; or concentrated and/or deionised fruit juice.

3 The food category generally (in ready to consume form) must:

a) have no more than 25% by ingoing weight of:
   i) added sugars[10]; and
   ii) any ingredient comprising more than 75% triglyceride.
b) contain no more than 800 mg sodium per manufacturer's serve size.
c) *prior to vitamin and/or mineral addition*, must also naturally contain at least one vitamin or mineral whose content is at least 5% of the Recommended Dietary Intake (RDI) as listed in the Schedule to Standard 1.1.1 per manufacturer's serve size.

The application of this Regulatory Principle should provide clear guidance on the appropriate foods for voluntary vitamin and mineral addition to assist industry in making application to amend the Code and to inform FSANZ's internal decision-making processes.

ATTACHMENT 5

FIRST REVIEW REPORT

APPLICATION A424

FORTIFICATION OF FOODS WITH CALCIUM

1. Objectives of Review

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) has requested a First Review of a draft variation to Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code). Food Standards Australia New Zealand (FSANZ) is required to notify the Ministerial Council on the outcome of this Review by May 2005.

Application A424 – Fortification of Foods with Calcium seeks to amend Standard 1.3.2 – Vitamins and Minerals of the Code to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits.

In May 2004, the Ministerial Council adopted a Policy Guideline on *Fortification of Food with Vitamins and Minerals* (Policy Guideline), which provides guidance on the addition of vitamins and minerals to food. In accordance with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ in developing or reviewing food standards must have regard to Ministerial policy guidance.

Therefore, the objective of this Review is to reconsider the draft variations to Standard 1.3.2 taking into account the Ministerial Council's concerns as outlined in Section 2, and the recently adopted Policy Guideline.

2. Review on Grounds Requested by the Ministerial Council

The Ministerial Council has requested a First Review of Application A424 on the grounds that the draft Standard:

- is not consistent with the objectives of the legislation which establishes FSANZ;
- does not protect public health and safety;
- does not promote consistency between domestic and international food standards where these are at variance;
- does not provide adequate information to enable informed choice; and
- places an unreasonable cost burden on industry or consumers.

3. Background

In December 2001, FSANZ received an Application from Food Liaison Pty Ltd on behalf of Arnott's Biscuits Limited and Nutrinova Pty Ltd to amend Standard 1.3.2 – Vitamins and Minerals of the Code, to permit the voluntary addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, fruit cordial, soups and savoury biscuits. During the assessment process the Applicant notified FSANZ that fruit cordials were withdrawn from the requested list of foods. Consequently the scope of Application A424 was narrowed to fruit- and vegetable- juices and drinks, soups and savoury biscuits.

In September 2003, the FSANZ Board approved the Final Assessment of Application A424, including the draft variations to Standard 1.3.2 and notified the Ministerial Council. This decision permitted the voluntary addition of calcium to the foods as requested by the Applicant. As policy guidance on fortification was still pending, Application A424 was assessed against FSANZ's *Regulatory Principles for Vitamin and Mineral Addition to Foods* (Regulatory Principles).

In December 2003, the Ministerial Council sought a First Review of the draft variations to Standard 1.3.2 and agreed to allow FSANZ until May 2005 to complete the review in anticipation of the completed Policy Guideline.

In May 2004, the Ministerial Council adopted the new Policy Guideline that provides guidance on the addition of vitamins and minerals to food. The Policy Guideline is divided into 'High Order' Policy Principles, which are based on FSANZ's statutory objectives, and separate 'Specific Order' Policy Principles for both mandatory and voluntary fortification. A copy of the Policy Guideline is at Attachment 1. With the release of the Policy Guideline, the Regulatory Principles are now superseded.

4. Options

There are three options proposed for consideration under this review:

1. re-affirm approval of the draft variations to Standard 1.3.2 of the Code as notified to the Ministerial Council; or

2. re-affirm approval of the draft variations to Standard 1.3.2 of the Code subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft variations to Standard 1.3.2 of the Code as notified to the Ministerial Council.

5. Ministerial Council Review Grounds

The First Review of the draft variations to Standard 1.3.2 has been undertaken addressing the matters stated in the Ministerial Council's request (as listed above) and also having regard to the new Policy Guideline. Any issues relevant to the Policy Guideline that are not dealt with directly in the Ministerial Council's grounds for review have been included in Section 5.6 of this report.

5.1 Inconsistency with the objectives of the legislation which establishes FSANZ

FSANZ commenced work and completed its assessment of Application A424 prior to the adoption of the Policy Guideline. Consequently this Review of the draft variations to Standard 1.3.2 will be undertaken in accordance with section 10 objectives of the FSANZ Act, which includes having regard to the new Policy Guideline.

Accordingly this review will address the Policy Guideline's 'Specific Order' Policy Principles for voluntary fortification as they relate to Application A424 and by so doing, will seek to address the 'High Order' Policy Principles, which reflect the FSANZ statutory objectives as set out in section 10 of the FSANZ Act.

5.2 Protection of public health and safety

5.2.1 Risk of calcium inadequacy/deficiency

The first 'Specific Order' Policy Principle for voluntary fortification requires that the permission to voluntarily add vitamins and minerals to food should only be permitted if one or more of five prerequisites is met (see Attachment 1). The first 'prerequisite' states that the voluntary addition of vitamins and minerals to food can be permitted *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 sub-clinical evidence of deficiency or by data indicating low levels of intake.*

FSANZ has assessed the adequacy of calcium intakes of the total population and population subgroups by reference to the United Kingdom estimated average requirement (EAR) for calcium[23] in the absence of Australian or New Zealand official EAR reference values.

Nutritional inadequacy can be defined as more than 3% of the population having nutrient intakes below the EAR[24]. National data[25] indicates that 28.4% and 33.9% of the Australian and New Zealand populations respectively, do not meet the EAR for calcium. Particular population groups with low calcium intakes include adolescent and adult females in Australia and New Zealand, New Zealand Maori, Australians of Asian ethnicity and non-dairy consumers in Australia and New Zealand.

5.2.1.1 Conclusion

There is considerable evidence to indicate that there is an inadequate intake of calcium in the Australian and New Zealand populations, which meets one of the five prerequisites for permitting voluntary fortification in accordance with the first 'Specific Order' Policy Principle of the Policy Guideline.

5.2.2 Potential to address deficit

The second 'Specific Order' Policy Principle for voluntary fortification is 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.*

The Final Assessment Report for Application A424 demonstrated that the addition of calcium to all proposed food categories has the potential to increase the calcium intake for the population or subgroups of the population whose intakes were assessed as inadequate. Increasing the calcium intake of the population is consistent with national dietary guidance and has the potential to improve current inadequate calcium intakes. The extent of the potential benefit, however, will depend on the uptake of this voluntary permission by industry.

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[23] EARs have not yet been established for the Australian and New Zealand populations and so the United Kingdom EAR has been selected, as it is more compatible with the current range of Australian and New Zealand RDIs.

[24] United States Institute of Medicine (2003) *Dietary Reference Intakes: Guiding Principles For Nutrition Labeling And Fortification, Committee on Use of Dietary Reference Intakes in Nutrition Labeling, Food and Nutrition Board*, National Academy Press, Washington DC.

[25] Australian National Nutrition Survey (1995) & New Zealand National Nutrition Survey (1997)

The issue of bioavailability was also examined at Final Assessment and it was concluded that the addition of calcium to the proposed food categories has the *potential to address the deficit*. It was noted that bioavailability is a complex issue and is affected by different factors, including long term nutrient intake imbalances, nutrient interactions at a single meal and individual variations in the ability to absorb and use various nutrients in the body. It was also recognised that various calcium salts have different bioavailabilities in different foods.

In relation to this matter, the Final Assessment Report concluded that recent research had shown that the particular forms of calcium salts suitable for addition to fruit- and vegetable-based beverages were as bioavailable as the calcium in milk, although the effect of calcium-fortified beverages on bone health appeared not to be as beneficial as that gained from milk consumption due to intrinsic factors in milk[26].

5.2.2.1 Conclusion

The potential exists to improve the calcium intake of population subgroups whose current intakes are assessed as inadequate and so meets the requirement of the second 'Specific Order' Policy Principle for voluntary fortification.

5.2.3 Risk of excess calcium intake

The sixth 'Specific Order' Policy Principle states that *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 first part of this policy principle that relates to detrimental excesses will be discussed in this section (5.2.3) whereas the second part relating to dietary imbalances is discussed in Section 5.2.4.

At Final Assessment, FSANZ assessed the risk to the population of consuming excess calcium by estimating the total consumption of calcium from both natural and the proposed added sources and then comparing this to the Tolerable Upper Intake Level (UL) for calcium (2500 mg/day) [27]. The dietary intake assessment indicated that there is little risk of consumers exceeding the UL for calcium over a long period.

5.2.3.1 Conclusion

There is minimal risk to the population of consuming excessive amounts of calcium from a diet containing the calcium-fortified food requested in Application A424 and so this assessment meets, in part, the requirements of the sixth 'Specific Order' Policy Principle for voluntary fortification.

[26] Pointtillart A, Coxam V, Seve B et al. Availability of calcium from skim milk, calcium sulfate and calcium carbonate for bone mineralisation in pigs. Reproduction Nutrition Development (2000) 40;49-61

[27] Food and Nutrition Board, Institute of Medicine, National Academy of Sciences (1998) '*A risk assessment model for establishing upper intake levels for nutrients*', National Academy Press, Washington DC.

5.2.4 Risk of dietary displacement

The remaining part of the sixth 'Specific Order' Policy Principle is that *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 imbalances of vitamins and minerals in the context of total intake across the general population.*

At Final Assessment, FSANZ concluded that the risk of dietary displacement from consuming calcium fortified soup and/or biscuits would be minimal. The main risk identified by permitting calcium-fortified foods, as requested by Application A424, is that fruit- and vegetable- juices and drinks could displace milk in the diet. This does not apply to those individuals who, for whatever reason, do not consume milk.

However, an independent survey of 1200 Australians[28] (see Attachment 2) and overseas data indicated that there is minimal risk of long-term substitution of calcium-fortified beverages for milk. These beverages are considered to be sufficiently different in nutrient profile, taste and use from milk and so are not considered to be an ongoing substitute food.

Although both the United States and the United Kingdom consumption trends show a decline in milk consumption and an increase in fruit juice intake, there is no evidence to suggest that these trends are the result of calcium-fortified beverages being available in the market place.

Using a worst-case modelling scenario, FSANZ undertook dietary modelling assuming a 50 % reduction in milk consumption due to substitution with calcium-fortified beverages. The results showed a small decrease in riboflavin and zinc intakes. It was noted, however, that the scenario modelled was theoretical, highly unlikely based on consumer research and included data based on one-day intakes only. It is therefore expected that the proposed amendments to the Code would have minimal adverse effects on the micronutrient intake, supplied by milk, of the Australian and New Zealand populations.

5.2.4.1 Conclusion

There is minimal risk to the population of dietary displacement as a result of substitution with calcium-fortified products proposed by Application A424. This fulfils the remaining part of the sixth 'Specific Order' Policy Principle for voluntary fortification.

5.2.5 Overall conclusion in relation to public health and safety

In terms of public health and safety, the overall conclusion is that:

- there is potential to improve the calcium intake of population subgroups whose current intakes are inadequate;
- the risk to the population of consuming excessive amounts of calcium is minimal; and
- the risk of dietary displacement as a result of substitution with calcium-fortified products of current milk drinkers proposed by Application A424 is also minimal.

[28] Beanham S *et al* (2003) Australian Dairy Corporation Issues Research: Calcium-fortified Drinks Executive Summary

5.3 Inconsistency between domestic and international food standards

Although Codex has not established a standard for voluntary fortification, it has established guidelines that define a set of General Principles[29]. (Codex does not distinguish between voluntary and mandatory fortification). There is alignment between the Codex General Principles and the Policy Guideline with respect to fortification on the basis of inadequacy. The FSANZ Board's decision on Application A424 is consistent with international guidance which asserts that the addition of essential nutrients to foods should be on the basis of 'demonstrated need' which includes 'estimates indicating low levels of intake of nutrients'.

As the permissions for the addition of calcium to the products in Application A424 are voluntary, they do not create an inconsistency between domestic and international food standards.

5.3.1 Conclusion

While there are no international standards for voluntary fortification, only guidelines per se, the Policy Guideline is consistent with these guidelines with respect to fortification on the basis of inadequacy. Permitting the voluntary addition of calcium to foods as proposed by Application A424 would therefore not create inconsistency between domestic and international food standards.

5.4 Provision of adequate information to enable informed choice

The seventh 'Specific Order' Policy Principle for voluntary fortification states that *the fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food*.

Under current labelling requirements, an added vitamin or mineral must be listed in the ingredient list and if a nutrition content claim is made in relation to a food, the nutrient is required to be listed in the Nutrition Information Panel on the label.

'Source' or 'good source' calcium claims for fortified foods can be made provided that a reference quantity of the proposed food for fortification contain at least 10% or 25% of the recommended dietary intake (RDI) respectively for calcium. The above requirements would provide consumers with factual information as to the amounts of fortificant in the food. These labelling requirements are also in accordance with the additional policy guidance for voluntary fortification which states:

> *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.*

There is a risk that the inclusion of a 'source' or 'good source' content claim for calcium may mislead consumers as to the nutritional quality of fortified foods.

[29] Codex Alimentarius Commission (1991) *General Principles for the Addition of Essential Nutrients to Foods.*

The 'Halo Effect Component'[30] has been described where respondents underestimate the level of risk-increasing nutrients in products (e.g. sugar) that also carry claims about beneficial nutrients (e.g. calcium).

To help mitigate this risk, FSANZ supports and acknowledges the role nutrition education can play in providing information in relation to the role of calcium-fortified products in the overall diet.

5.4.1 Conclusion

FSANZ considers that current labelling requirements provide consumers with adequate information as to the presence and amount of calcium in the food and in doing so, meets the requirement of the seventh 'Specific Order' Policy Principle for voluntary fortification.

Given the extent of calcium deficiency in the overall population, FSANZ considers that the potential benefit derived from the additional calcium sources significantly outweigh any possible risks of consumer deception and any associated consequences.

5.5 Cost burden on industry or consumers

The proposed variations to Standard 1.3.2 – Vitamins and Minerals leave the decision whether to fortify certain foods to industry. Such decisions would necessarily take account of any increased costs and whether a more highly priced product would be sustainable in the market place. Consumers would be financially disadvantaged *only* if the price of calcium-fortified food rose significantly compared to non-fortified counterparts, *and* all manufacturers chose to fortify their respective products thus denying consumer choice. Experience from overseas indicates that this is unlikely.

Industry would be permitted to voluntarily add calcium to the proposed products which may potentially open up new markets or increase market share both domestically and internationally.

5.5.1 Conclusion

Amending the Code to permit the voluntary addition of calcium in fruit- and vegetable juice, fruit- and vegetable drinks, savoury biscuits and soups is unlikely to increase the cost burden on industry or consumers.

5.6 Other issues relevant to the Policy Guideline

5.6.1 Consistency with National Nutrition Policies and Guidelines

The third and fourth 'Specific Order' Policy Principles for voluntary fortification respectively state that *permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand*; and *permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.*

[30] Murphy, D., Hoppock, T.H. and Rusk, M.K. (1998) '*Generic Copy Test of Food Health Claims in Advertising*'. Federal Trade Commission. Sourced from http://ftc.gov/opa/1998/9811/food.htm

The dietary guidelines recommend consuming only moderate amounts of sugars and foods containing added sugars; limiting saturated fat and moderate total fat intake; and choosing foods low in salt[31,32].

At Final Assessment, FSANZ utilised compositional criteria in relation to the fat, sugar and salt content of the proposed food categories to determine consistency with nutrition policies and guidelines. It was concluded that the majority of products met the compositional criteria and so fortification of these products would be consistent with general dietary guidance.

FSANZ is unaware of any evidence to indicate that the fortification of these products with calcium would result in an increased consumption that is inconsistent with national nutrition policies and guidelines. On the contrary, survey data[33] (see Attachment 2) indicates that it is more likely that fortified products would be substituted for non-fortified counterparts.

5.6.1.1 Conclusion

The above findings are in accordance with the third and fourth 'Specific Order' Policy Principles for voluntary fortification.

5.6.2 Alcoholic beverages

The fifth 'Specific Order' Policy Principle states *fortification will not be permitted in alcoholic beverages*. As the categories of food being considered for fortification by Application A424 do not include alcoholic beverages, this policy principle is not relevant to this Review.

6. Impact Analysis

This First Review has not identified issues that are likely to change the impact analysis as presented at Final Assessment. Specific considerations in reaching this conclusion are:

- there are benefits to consumers of additional and/or alternative food sources of calcium;
- dietary intake assessment indicates that there is very little risk of excess consumption of calcium; and
- the potential exists to improve the calcium intake of population subgroups whose current intakes are assessed as inadequate. This potential benefit is estimated to outweigh any risks associated with inappropriate use of the calcium-fortified products as substitutes for dairy foods.

[31] Dietary Guidelines for Australians (May 2003) Sourced from: http://www.health.gov.au/nhmrc/publications/pdf/n33.pdf

[32] Food and Nutrition Guidelines for Healthy Adults – a background paper (April 2002) Sourced from: http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/f01ce3552a33c9f3cc256b9600147891?OpenDocument

[33] Beanham S *et al* (2003) Australian Dairy Corporation Issues Research: Calcium-fortified Drinks Executive Summary

7. Conclusion and recommendation

The First Review concludes that the preferred option is Option 1 as supported by the Statement of Reasons below. This reaffirms the approval of the draft variations to Standard 1.3.2 of the Code (at Attachment 3) as notified to the Ministerial Council.

7.1 Statement of Reasons

- Permitting the voluntary addition of calcium to foods as proposed by Application A424 has been assessed as being consistent with the objectives of the FSANZ Act, which are mirrored in the 'High Order' Policy Principles of the Policy Guideline, as well as satisfying all seven 'Specific Order' Policy Principles for voluntary fortification.

- In terms of public health and safety, calcium can be considered eligible for voluntary fortification of fruit- and vegetable juices and drinks, soups and savoury biscuits because:
  - there is considerable evidence to indicate inadequate intakes of calcium in the Australian and New Zealand populations;
  - the addition of calcium to all the proposed foods has the potential to increase the calcium intake for the population or subgroups of the population with a current intake assessed as inadequate;
  - the dietary intake assessment estimates that there would be negligible risk of excess calcium intake based on the addition of calcium at the levels requested assuming conservative 100% uptake of the permission for all the proposed food;
  - overseas experience and Australian surveys indicate that there would be minimal risk to the population of dietary displacement as a result of substitution with calcium-fortified food; and
  - it is unlikely that the food categories selected for voluntary fortification with calcium would promote consumption patterns inconsistent with nutrition polices and guidelines.

- As the permissions for the addition of calcium to the products proposed by Application A424 are voluntary, they do not create an inconsistency between domestic and international food standards.

- Current labelling requirements would provide consumers with adequate information as to the presence and amount of calcium added to the proposed food categories to enable them to make an informed choice.

- The permissions for the addition of calcium to the products proposed by Application A424 are voluntary and so any uptake by industry will be based on a business decision and consumers will be able to choose whether to select calcium fortified foods, as it is highly unlikely that all the food categories proposed by Application A424 will be fortified.

Attachments

1. Ministerial Council's Policy Guideline on Fortification of Food with Vitamins and Minerals
2. Excerpt from FSANZ Final Assessment Report for Application A424 - Fortification Of Foods With Calcium detailing Newspoll survey data.
3. Draft variations to the *Australia New Zealand Food Standards Code.*

ATTACHMENT 1

Policy Guideline
Fortification[1] 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
   (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:

[1]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.

(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:

- 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.
- Be required only if it is assessed as the most effective public health strategy to address the health problem.
- Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
- 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.
- 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

Assessment of alternative strategies – consideration must be comprehensive and include for example assessment of voluntary fortification and education programs.

Requirement to label – no mandatory requirement to label as fortified however, consideration should be given, on a case by case basis, to a requirement to include information in Nutrition Information Panel.

Monitor/Review – any agreement to require fortification should require 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 sub-clinical 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[2]).

  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.
- 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.

[2] 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.

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 2

Excerpt from FSANZ Final Assessment Report for Application A424 – Fortification of Foods with Calcium detailing Newspoll survey data.

Newspoll Telephone Survey – Executive Summary

Purchase intention

Calcium-fortified fruit juice beverages will not attract mass market interest, but will be of interest to a significant minority:

	Definitely would buy %	Possibly would buy %	Total would buy %
Fruit Juice	14.7	30.5	45.2
Fruit juice drink	9.1	20.6	28.9
Fruit juice cordial	10.1	22.2	32.3

Product substitution

Depending on the product, around 50-60% of purchasers would replace an existing beverage.

	Replacement purchase
Fruit juice	61.0%
Fruit juice drink	50.6%
Fruit juice cordial	63.2%

As anticipated, fortified fruit juice will mainly replace fruit juice, fortified fruit drink would replace fruit juice drink and fruit juices, fortified fruit juice cordial will replace cordials – both fruit and non-fruit juice.

Dairy Substitution

In all cases a small but significant group will buy the new calcium-fortified beverages and replace either

- Regular milk
- Modified/low fat milk
- Flavoured milk

	Milk substitution (total)
Fortified fruit juice	5.8%
Fortified fruit juice drink	12.2%
Fortified fruit juice cordial	6.1%

ATTACHMENT 3

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.3.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from the* Table to clause 3, *the entry for* Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugar, *substituting* -

Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugars	35g	thiamin	0.55 mg (50%)
		riboflavin	0.43 mg (25%)
		niacin	2.5 mg (25%)
		vitamin B6	0.4 mg (25%)
		vitamin E	2.5 mg (25%)
		folate	100 µg (50%)
		calcium	200 mg (25%)
		iron	3.0 mg (25%)
		magnesium	80 mg (25%)
		zinc	1.8 mg (15%)

[1.2] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Fruit juice, reconstituted fruit juice, concentrated fruit juice –

calcium	200 mg (25%)

[1.3] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Tomato juice, concentrated tomato juice –

calcium	200 mg (25%)

[1.4] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Vegetable juice –

calcium	200 mg (25%)

[1.5] *omitting from the* Table to clause 3, *the entry for* Fruit drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit; fruit drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit, *substituting –*

Fruit and/or vegetable drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit and/or vegetable; fruit and/or vegetable drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit and/or vegetable	200 mL	folate vitamin C carotene forms of vitamin A calcium	refer to clause 8 refer to clause 8 refer to clause 8 200 mg (25%)

[1.6] *inserting in the* Table to clause 3 -

Composite products

Soups, prepared for consumption in accordance with directions	200 mL	calcium	200 mg (25%)

ATTACHMENT 6

SECOND REVIEW REPORT

APPLICATION A424

FORTIFICATION OF FOODS WITH CALCIUM

Decision

FSANZ <u>re-affirms</u> its approval of the draft variations to Standard 1.3.2 of the *Australia New Zealand Food Standards Code* **(at Attachment 1) as notified to the Ministerial Council. This decision permits the voluntary addition of calcium to fruit- and vegetable juices/drinks, soups and savoury biscuits because:**

1. there is considerable evidence to indicate inadequate intakes of calcium in the Australian and New Zealand populations;
2. the addition of calcium to the requested foods has the potential to increase calcium intakes in those population groups currently assessed as inadequate;
3. there is negligible risk of excess calcium intake;
4. there is negligible risk of displacement of other nutrients;
5. bi-national and overseas experience indicate that there is minimal risk to the population of dietary displacement as a result of substitution with calcium-fortified food;
6. in the context of the likely substitution of fortified beverages for their unfortified counterparts, the risk of increasing rates of obesity and dental caries/erosion is minimal;
7. it is unlikely that the requested food categories will promote consumption patterns inconsistent with nutrition polices and guidelines and increase consumption of foods high in sugar, salt and fat; and
8. current labelling requirements provide consumers with adequate information as to the presence and amount of calcium added to the requested food categories.

Summary Table

MATTERS ADDRESSED IN THE SECOND REVIEW

MINISTERIAL COUNCIL ISSUE	FSANZ'S RESPONSE
1. Protection of public health and safety.	• Ministerial Council members contacted to seek clarification on concerns and request evidence in support of the grounds for review. • FSANZ's position on the role of food regulation in promoting health gain has been further elaborated. • The extent of calcium inadequacy/deficiency reassessed using draft NHMRC/MoH Nutrient Reference Values. • The risk of excess calcium intakes reassessed using draft NHMRC/MoH Upper Levels. • Further assessment of the potential for other nutrients being displaced as a result of milk substitution. • Further assessment of the risk of sweetened beverages contributing to increased rates of obesity and dental caries/erosion. • Further assessment of bioavailability issues and the impact on bone health.
2. Consistency with existing policy guidelines set by the Ministerial Council. • Promote consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand (i.e. reduce milk consumption and increase fruit juice consumption) • Promote increased consumption of foods high in sugar, salt and fat.	• TNS social research commissioned to critically review the findings of the Dairy Australia Newspoll research examining the likely substitution of calcium-fortified beverages for milk. TNS social research also undertook a limited literature review to evaluate the validity of their findings. • Additional market research obtained from the Applicant providing further information on consumer views/perceptions of different drinks and the key factors driving usage. • Australian and New Zealand market trends obtained on the sale of juices with added calcium. • Additional information on market trends for fortified juices and milk consumption obtained from the following countries; United States, United Kingdom and Germany. • Provided further details on FSANZ's implementation of Ministerial Council's Policy Guideline requirements in relation to voluntary fortification not promoting increased consumption of foods high in sugar, salt and fat. • Further explanation and clarification provided with respect to the compositional criteria for selecting appropriate food vehicles.
3. Provision of adequate information to enable informed choice.	• Further explanation provided regarding the impact of the proposed health claims framework in moderating the potential influence of health claims on consumers' food choices. • Further assessment of the bioavailability of the various forms of added calcium.

1. Introduction

In May 2005, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a Second Review of Application A424 – Fortification of Foods with Calcium. This Application seeks to amend Standard 1.3.2 – Vitamins and Minerals of the *Australia New Zealand Food Standards Code* (the Code) to permit the voluntary addition of calcium to fruit- and vegetable juices and drinks, soups and savoury biscuits.

The purpose of the Second Review is to respond to the concerns raised by the Ministerial Council, as outlined in Section 3. The main focus of the Review is the likelihood of the requested calcium-fortified foods:

- being inappropriately substituted for milk;
- promoting the increased consumption of foods high in sugar, salt and fat; and
- being less effective in contributing to bone health than traditional sources of calcium.

FSANZ has addressed these issues by seeking additional information from key stakeholders, undertaking further assessments and engaging external expertise.

2. Objectives of review

The objective of the Second Review is to reconsider the draft variations notified to the Ministerial Council by FSANZ in March 2005 in light of the Council's concerns as outlined in Section 3.

3. Grounds for the Review

A Second Review was requested on the grounds that approval of the draft variations:

- does not protect public health and safety;
- is not consistent with existing policy guidelines set by the Ministerial Council; and
- does not provide adequate information to enable informed choice.

Additional comments provided by Ministers included the following statements:

- The calcium fortification of the types of food encompassed by this Application does not protect public health and safety.

- The Application is inconsistent with interpretation of the '*Specific Order' Principles – Voluntary Fortification* of the Ministerial Policy Guideline *Fortification of Food with Vitamins and Minerals* in two key areas. Fortification of fruit juice with calcium will promote:

    - consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand (i.e. reduce milk consumption and increase fruit juice consumption); and
    - increased consumption of foods high in sugar, salt and fat.

Further advice was also been requested on the following matters:

- Whether consideration was given to the proposed, revised National Health and Medical Council (NHMRC) Nutrient Reference Values (currently subject to consultation) in assessing the adequacy of calcium by the Australian and New Zealand populations.

- Whether the proposed, revised NHMRC Nutrient Reference Values document was considered when assessing the tolerable upper intake levels of calcium.

- What consideration was given to water consumption being displaced by fortified fruit and vegetable juices/drinks (noting that dietary guidelines encourage choosing water as a drink)?

4. Background

In December 2001, FSANZ received an Application from Food Liaison Pty Ltd on behalf of Arnott's Biscuits Limited and Nutrinova Pty Ltd to amend Standard 1.3.2 – Vitamins and Minerals of the Code, to permit the voluntary addition of calcium to fruit- and vegetable juices, fruit- and vegetable drinks, fruit cordial, soups and savoury biscuits. During the assessment process the Applicant notified FSANZ that fruit cordials were withdrawn from the requested list of foods. Consequently the scope of Application A424 was narrowed to fruit- and vegetable- juices and drinks, soups and savoury biscuits.

In September 2003, the FSANZ Board approved the Final Assessment of Application A424, including the draft variations to Standard 1.3.2 and notified the Ministerial Council. This decision permitted the voluntary addition of calcium to the foods as requested by the Applicant.

In December 2003, the Ministerial Council sought a First Review of the draft variations to Standard 1.3.2. They allowed FSANZ until May 2005 to complete the review in anticipation of policy guidance on the addition of vitamins and minerals to food.

In May 2004, the Ministerial Council adopted the *Fortification of Food with Vitamins and Minerals* (Policy Guideline) (at Attachment 2). In undertaking the First Review, FSANZ addressed the issues raised by the Ministerial Council in light of the Policy Guideline. In March 2005 the FSANZ Board reaffirmed its approval of the draft variations to Standard 1.3.2.

In May 2005 the Ministerial Council sought a Second Review of the draft variations to Standard 1.3.2. FSANZ sought an extension until 30 September 2005 to complete the Review, so that Ministerial Council members could be contacted to obtain additional information underpinning the request for a Second Review.

From comments received by FSANZ, it appears that the main concern underpinning the request for a Second Review is the potential for this Application to increase the consumption of juices/drinks and reduce consumption of milk and water. The Second Review thus focuses primarily on this issue.

5. Ministerial Council Review Grounds

5.1 Protection of public health and safety

5.1.1 Role of food regulation in promoting health gain

Government as a whole has a responsibility to protect and promote the health and safety of the population. This occurs through the coordinated and inter-sectoral actions of key agencies within the public health system.

Protecting public health and safety refers to the actions taken by society to prevent disease, prolong life and promote health. The Ottawa Charter for Health Promotion (WHO, 1986) identifies a range of personal, social, economic and environmental factors, which can influence the health status of individuals or populations. Access to a safe and nutritious food supply is central to promoting health and wellbeing.

One of the major objectives of developing food regulatory measures is to protect public heath and safety by ensuring that the Australian and New Zealand populations have access to a safe and nutritious food supply. Food regulation can establish wide-ranging parameters applicable at the population level and can support public health interventions. However, food regulation, in itself, is generally not an effective intervention to address public health issues, particularly issues multi-factorial in nature.

FSANZ's primary function is the development, variation and review of food standards. These standards relate to individual foods and food components. While a varied diet contributes to good nutrition, there are many factors which influence food choice. Therefore food standards alone cannot determine an individual's diet and hence dictate an individual's health status.

The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) contains three primary objectives that focus the activities of FSANZ on protecting public health and safety, enabling informed consumer choice and preventing misleading and deceptive conduct. The FSANZ Act also establishes goals for FSANZ to achieve which include:

- a high degree of consumer confidence in the food supply;
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently; and
- the provision of adequate information relating to food to enable consumers to make informed choices.

These and other elements of the FSANZ Act guide the approach taken to the development of food standards and also the role that food standards play in the protection of public health and safety.

Within 'protection of public health and safety' a continuum exists whereby 'safety' frequently refers to single-issue, strongly causally related risks to health whereas 'public health' implies a longer-term, often multi-factorial health outcome. The effectiveness of regulation differs across the continuum, with regulation commonly being more effective when applied to safety risks and much less clear-cut when applied to mitigation of public health risks.

Thus, FSANZ's regulatory approach differs depending on the nature of the risk identified, the strength of the relationship between dietary intake and health outcome, and the level of scientific uncertainty associated with the issue.

Furthermore, FSANZ has a narrow range of tools to use in food regulation. These include unconditional permissions, compositional and/or labelling requirements, and where necessary, prohibition or restriction. In considering the application of these tools, FSANZ adopts a comprehensive risk analysis process which systematically identifies, and determines the most appropriate options for managing any risks using the best available evidence.

While FSANZ's primary objective is the protection of public health and safety, FSANZ must also have regard to its other statutory objectives, for example the promotion of fair trading, the desirability of an efficient and competitive food industry and policy guidelines formulated by the Ministerial Council. Underpinning these considerations is the government requirement for minimum effective regulation.

In addressing broader public health issues, FSANZ seeks to support, strengthen and complement public health initiatives thereby maximising opportunities where possible to protect public health. However, FSANZ's ability to impact on broader health issues is limited. Primarily this occurs by helping to create supportive environments e.g. food labelling to enable consumers to make an informed choice in the context of their individual diet.

5.1.1.1 FSANZ's Regulatory Approach for Permitting the Voluntary Addition of Calcium to Foods

In having regard to the Policy Guideline, FSANZ has needed to predict the likely impact of this Application on food selection preferences; either substitution of the calcium-fortified product for its unfortified counterpart, increased consumption of these products or displacement of other foods.

Due to the inherent difficulties in attempting to predict future food consumption patterns, FSANZ's regulatory response for this Application is more focused on providing consumers with adequate information to make informed food choices rather than placing restrictions and prohibitions on these calcium-fortified products.

5.1.2 Risk of calcium inadequacy/deficiency

At Final Assessment, FSANZ used the Estimated Average Requirement (EAR)[34] as the most appropriate reference value to determine the extent of calcium inadequacy/deficiency in the Australian and New Zealand population. The United Kingdom (UK) EAR for calcium was selected as it more closely aligns with the current Australian/ New Zealand Recommended Dietary Intake values.

[34] The EAR is a value that represents the median requirement for a particular nutrient in a population group.

At Final Assessment, FSANZ defined inadequacy as at least 30% of people in two or more population subgroups having calcium intakes below the EAR[35]. A comparison of calcium intakes against the EAR revealed that seven Australian population subgroups (across ages 11+ years) and five New Zealand population subgroups (across ages 15+ years) had more than 30% of individual intakes below the EAR for calcium. FSANZ concluded that the risk of calcium inadequacy was sufficient to consider voluntary fortification.

FSANZ acknowledges that the New Zealand and Australian National Nutritional Survey (NNS) data are 8 and 10 years old respectively. Conducting dietary modelling based on 1995/1997 NNS food consumption data provides the best estimate currently available of actual consumption of foods and nutrient intakes. It should be noted that while the NNS may not include information regarding some food products that are now available on the market, for staple foods such as breads, cereals, meats, fruits and vegetables and milk etc, which make up the majority of the diet for most Australians and New Zealanders, the data derived from the 1995 NNS is likely to still be representative today (Cook *et al*, 2001).

It is also acknowledged that, since the data were collected for the NNS, there has been an increase in the range of products that are fortified with nutrients. Consequently, the nutrient databases from the NNS may not be entirely representative of the nutrient levels in some foods that are now on the market. Likewise, the limitation of there being no data in DIAMOND on the use of complementary medicines (Australia) or dietary supplements (New Zealand) is also acknowledged.

The dietary modelling is used as a tool to guide risk management decisions. It provides an estimate of intake and a guide to the extent of any potential safety concerns. Two-day adjustments have been used where possible to take 'usual intake' into account. In addition, where necessary, FSANZ will make highly conservative assumptions in order to help address the potential uncertainties in the intake assessments. Further, FSANZ believes that whilst there are some limitations due to the age of the NNS data used for intake assessments, the overall conclusions and basis for risk management decisions are robust.

During the First Review of Application A424, FSANZ was aware of the draft NHMRC/MoH[36] Nutrient Reference Values (NRVs). However, the draft values for calcium were not used, as there was no certainty that these values would reflect the final NHMRC/MoH recommendations.

[35] Since the release of the Final Assessment, FSANZ has revised the definition of nutritional inadequacy and as outlined in the *Fortification Implementation Framework* inadequacy is now defined as more than 3% of the population having intakes below the EAR. The change from 30% to 3% therefore means that the Application A424 Final Assessment results on calcium inadequacy are underestimates by the standards of the *Fortification Implementation Framework.*

[36] NHMRC/MoH = National Health and Medical Research Council/Ministry of Health

Table 1: Comparison of The NHMRC/MOH and UK EARs for Calcium

NHMRC/MoH Age Groups (years)		NHMRC/MoH Draft EAR (mg)	UK Age Groups (years)		UK EAR (mg)
1-3		360	1-3		275
4-8		520	4-6		350
9-11		800	7-10		425
12-18	males	1050	11-18	males	750
	females	1050		females	625
19-50	males	840	19-50	males	525
	females	840		females	525
51-70	males	840	51+	males	525
	females	1100		females	525
71+	males	1100			
	females	1100			

FSANZ notes that the NHMRC/MoH draft calcium EAR is higher than the UK EAR (Table 1). Therefore, the assessment of calcium inadequacy undertaken at Final Assessment may now be viewed as an underestimate. Consequently, the application of the draft NRVs reinforces the conclusions reached on the extent of calcium inadequacy at Final Assessment.

5.1.2.1 Conclusion

The Final Assessment and First Review concluded that there is considerable evidence to indicate inadequate intakes of calcium in the Australian and New Zealand populations. The application of the draft NHMRC/MoH NRVs reinforces, the conclusions reached on the extent of calcium inadequacy in Australian and New Zealand populations.

5.1.3 Potential to address the calcium deficit

The potential for this voluntary fortification to 'address the deficit' (as identified in the Policy Guideline 'Specific Order' Policy Principles for voluntary fortification) requires an assessment of the expected increase of added calcium in the food or food supply. In the case of voluntary fortification, the potential for this increase is dependent on:

- the level of industry uptake;
- the pattern of consumption by the target population group;
- the selected food's level of calcium addition; and
- consumer acceptance of the newly fortified food.

For Application A424, FSANZ modelled the maximal calcium fortification in the proposed food vehicles on population calcium intakes at Draft Assessment. This modelling was conducted against the UK EAR, and the results are presented in Table 2.

The results show a clear decrease in the percentage of Australian and New Zealand populations that consume inadequate amounts of calcium following maximal fortification.

However, given the proposed calcium additions are voluntary and reliant on industry uptake, FSANZ cannot determine the actual impact of the proposed calcium fortification. These figures instead reflect the potential of the proposed fortification to address inadequate Australian and New Zealand calcium intakes.

5.1.3.1 Conclusion

The proposed fortification permission has the **potential** to increase the calcium intake in those population groups currently obtaining an inadequate calcium intake. However, it is not possible for FSANZ to accurately predict the impact of this voluntary fortification permission on actual calcium intakes.

Table 2: Percentage of Respondents with Calcium Intakes below the UK EAR before and after Fortification

Age Group	Sex	Australia		New Zealand	
		Before fortification	After fortification	Before fortification	After fortification
2-3 years	Male	7.1	1.2	ND	ND
	Female	7.5	3.3		
4-6 years	Male	9.9	4.3	ND	ND
	Female	17.5	4.0		
7-10 years	Male	11.8	4.4	ND	ND
	Female	22.6	7.8		
11-12 years	Male	37.0	19.1	ND	ND
	Female	34.0	14.9		
13-15 years	Male	33.0	19.2	ND	ND
	Female	44.7	24.7		
16-18 years (Australia)	Male	29.8	16.3	ND	ND
	Female	47.2	25.2		
15-18 years (New Zealand)	Male	NA	NA	44.0	30.3
	Female			39.4	28.5
19-24 years	Male	19.0	12.2	28.3	16.6
	Female	36.9	22.6	36.4	27.3
25-44 years	Male	22.1	14.8	22.4	16.7
	Female	34.8	24.4	37.2	28.3
45-64 years	Male	24.1	17.3	32.8	24.7
	Female	32.2	21.6	35.8	26.7
65+ years	Male	27.8	18.3	35.6	27.3
	Female	39.8	26.7	37.9	29.5
Total Population	24 hour recall	28.4	18.2	33.9	25.4
	Adjusted 2nd day	18.8	6.7	NA	NA

ND = Data for 2-15 year-old children is not available from the New Zealand NNS.

NA = Not Applicable

5.1.4 Risk of excess calcium intake

At Final Assessment, FSANZ assessed the risk to the population of consuming excess calcium by estimating the total consumption of calcium from both natural and the proposed added sources and then comparing this to the United States (US) tolerable upper intake level for calcium of 2500 mg/day (Food and Nutrition Board, 1998). The dietary intake assessment indicated that there is little risk of consumers exceeding the tolerable upper intake level for calcium over a long period.

The US tolerable upper intake level for calcium was selected as the most appropriate benchmark because the US had recently revised all their nutrient reference values.

FSANZ considered the US tolerable upper intake level to be the most relevant and up-to-date reference value on which to base its decision-making. The NHMRC/MoH is currently proposing an upper limit equivalent to the US tolerable upper intake level and so the conclusions of the Final Assessment remain the same in respect to the risk of excess calcium intake.

5.1.4.1 Conclusion

There is minimal risk to the population of consuming excessive amounts of calcium from a diet containing the calcium-fortified food as requested in Application A424.

5.1.5 Risk of displacement of other nutrients

Using a worst-case modelling scenario, FSANZ undertook dietary modelling assuming a 50 % reduction in milk consumption due to substitution with calcium-fortified beverages at Final Assessment. The results showed a small decrease in riboflavin and zinc intakes. It was noted, however, that the scenario modelled was theoretical, highly unlikely based on consumer research and included data based on one-day intakes only. It is therefore expected that permitting the addition of calcium to the requested foods would have minimal adverse effects on the micronutrient intake, as supplied by milk, of the Australian and New Zealand populations.

The results of this modelling are provided in Table 3, and show that the impact of the proposed fortification on these nutrients is minimal.

Table 3: Percentage of Respondents in Australia with Intakes below the UK EARs for Zinc and Riboflavin before and after Milk Substitution

Nutrient	Model	Age group (years)				
		Male and female 6-12	Female 12-15	Female 16-18	Female 19-64	Female 65+
Riboflavin	baseline	9.5	17.1	24.3	17.9	17.0
	substitution	11.9	20.1	27.5	21.7	22.2
Zinc	baseline	15.9	27.3	16.1	15.5	23.4
	substitution	19.3	30.6	20.2	18.2	27.0

However, the impacts on vitamin B_{12} and protein intakes were not assessed as part of the Final Assessment. Therefore, FSANZ has included these two nutrients in the Second Review using a more direct assessment process.

Tables 4 and 5 have been constructed from Australian and New Zealand NNS data. Tables 4 and 5 respectively show that milk makes a significant contribution to both protein and vitamin B_{12} intakes, especially in younger groups.

Table 4: Per Cent Contribution of Dairy Milk to Vitamin B_{12} Intakes in Australian and New Zealand Population Groups

Age Group (yrs)	Percentage Contribution (%) including flavoured milk
Australia	
2-5	40.3
6-12	25.7
13-18	20.2
19 +	14.8
New Zealand	
15 +	15.1

Table 5: Per Cent Contribution of Dairy Milk to Protein Intakes in Australian and New Zealand Population Groups

Age Group (yrs)	Percentage Contribution (%) including flavoured milk	
	Male	Female
Australia		
2-11	16.1	15.4
12-18	11.9	9.4
19+	7.3	9.2
New Zealand		
15 +	9.0	11.0

Tables 6 and 7 show a comparison between mean vitamin B_{12} and protein intakes and the respective Recommended Dietary Intakes (RDI). It is apparent that mean vitamin B_{12} and protein intakes are well above the current and draft NHMRC/MoH RDIs.

Table 6: Mean Vitamin B_{12} Intakes in Australian and New Zealand Population Groups

Age Group (yrs)	Mean Vitamin B_{12} intake (µg/day)	Current RDI (µg/day)	Draft NHMRC/MoH RDI (µg/day)
Australia			
2-5	2.8	1.0-1.5	0.7-1.0
6-12	3.6	1.5-2.0	1.0-1.5
13-18	4.5	2.0	1.5-2.0
19+	4.5	2.0	2.0
New Zealand			
15 +	4.8	2.0	2.0

Table 7: Mean Protein Intakes in Australian and New Zealand Population Groups

Age Group (yrs)		Mean protein intake (g/day)	Current RDI (g/day)	Draft NHMRC/MoH RDI (g/day)
Australia				
2-3		53	18	14
4-7		61	24	20
8-11	Male	82	38	40
	Female	69	39	35
12-15	Male	101	60	65
	Female	74	55	45
16-18	Male	120	70	65
	Female	80	57	45
19+	Male	109	55	64
	Female	74	45	46
New Zealand				
15 +	Male	109	55	64
	Female	73	45	46

The data from Tables 4-7 indicate that if the entire milk content of the diet (a highly conservative scenario) was substituted for a product without a significant vitamin B_{12} content (e.g. fruit juice), then mean vitamin B_{12} intakes would decrease, yet still remain above the RDI for all population subgroups. For example, milk contributes 27% of 6-12 year-old Australian vitamin B_{12} intakes, however a reduction in the 3.6 µg/day mean intake by 27% results in a new mean intake of 2.6 µg/day, which is well above the 2.0 µg/day RDI. A similar situation occurs for protein, where population subgroup mean intakes are even higher than their respective RDIs.

As the RDI represents an intake that is capable of meeting the needs of nearly all the population, a potential reduction in mean vitamin B_{12} or protein intakes to a level above their RDI does not represent a risk to Australian and New Zealand populations.

5.1.5.1 Conclusion

If calcium-fortified foods displaced milk in the diet, the impact on protein, riboflavin, zinc and vitamin B_{12} intakes would be minimal, with respect to meeting requirements because current intakes are significantly higher than the RDI.

5.1.6 Risk of increasing rates of overweight and obesity

FSANZ's approach in assessing the potential risk of overweight and obesity from this Application has been to first determine the likely impact on food selection preferences. The possible ensuing scenarios include:

- the substitution of calcium-fortified products for its unfortified counterpart;
- increased consumption of the requested food categories;
- displacement of other foods; or

- a combination of all the above.

The likely substitution scenarios are discussed in detail in Section 5.2. The main conclusion is that fortified products will be substituted for their unfortified counterparts, making the overall dietary impact neutral. While FSANZ acknowledges the evidence linking the increased consumption of sugar-containing beverages[37] to increased rates of overweight and obesity, on this basis of the likely substitution scenario, the risk of potentially increasing rates of overweight and obesity from this Application appears to be minimal.

5.1.7 Risk of increasing dental caries/erosion

FSANZ recognises that diet can play a significant role in the development of dental problems, by increasing the exposure of teeth to an acidic environment. However, as indicated in Section 5.1.6, the context for assessing the potential risk of increased rates dental caries/erosion is framed by the need to identify the likely impact of this Application on food selection preferences.

5.1.7.1 Dental Caries

Dental caries is the progressive destruction of the teeth by acids that are generated by bacteria in the mouth. There is a well-established link between dental caries and sugar consumption. Dental caries is a multifactorial disease, influenced by tooth composition, exposure to fluoride and the type of bacteria in the mouth (Woodward and Walker, 1994). However, a regular and high intake of sugars from dietary sources remains one of several primary risk factors in the development of dental caries (Moynihan, 2002; World Health Organization, 2003). In particular, sugar-containing beverages are major contributors to this dietary risk factor (Levy *et al*., 2003; Moynihan and Petersen, 2004), and there is evidence that increased intakes of sugar-containing beverages (including juices) are associated with an increased risk of dental caries ($p<0.001$) (Marshall *et al*., 2003).

5.1.7.2 Dental Erosion

Dental erosion involves the chemical etching and irreversible loss of dental hard tissue by exposure to non-bacterial acids (Moynihan and Petersen, 2004a; British Nutrition Foundation 2005). Dental erosion has become a recent dental health issue, as its prevalence has increased over the last decade in developed nations. Emerging evidence based on observational studies has shown a strong association between acidic beverages and the development of dental erosion (Moynihan and Petersen, 2004b). The World Health Organization has reviewed the evidence for soft drinks and fruit juice, and concluded that strength of evidence linking these beverages to dental erosion can be categorised as showing a 'probable' association (World Health Organization, 2003).

[37] 'Sugar-containing beverages' in the context of this review refers to those products containing sucrose and fruit derived sugars (e.g. fructose). These beverages include standard carbonated beverages, fruit juices and drinks, and cordials, but not milk-based beverages.

The association with acidic beverages is tempered by other evidence, which shows that dental erosion requires an individual to be predisposed to the development of the condition, either through non-dietary behaviours or physiological characteristics (Moss, 1998). The Australian Dental Association (2002) therefore recommends the avoidance of acidic foods/ drinks by:

- individuals with diseases, or using medication that reduces the flow of saliva;
- athletes with a dry mouth;
- those sipping drinks during interrupted sleep; and
- those who use chewable vitamin tablets.

FSANZ has been unable to identify any prevalence rates for dental erosion in Australia. One New Zealand study on children has been identified, which indicates that 82% of children may have some form of tooth wear (Ayers *et al*., 2002). However, this figure may not represent the prevalence of dental erosion in the study population, as the authors did not distinguish between dental erosion and other forms of tooth wear (Mahoney and Kilpatrick, 2003).

European 1990-1995 data (predominantly the UK) show that 5-50% of their populations experience some degree of dental erosion, with a 25-30% prevalence rate being the most widely cited figure (Gandara and Truelove, 1999; Moynihan 2002). Although these data do not indicate the degree of the erosion experienced by those with the condition or the extent of predisposing factors, they do show that the dental condition exists at substantial levels within European populations, and therefore at potentially significant levels in developed nations such as Australia and New Zealand (assuming comparable conditions).

5.1.7.3 Conclusion

FSANZ recognises the association between the intake of sugar-containing/acidic beverages and dental caries/erosion. However, on the basis of the likely substitution scenario, as described in Section 5.2, FSANZ believes that the risk of increasing dental caries/erosion as a result of this Application is minimal.

5.1.8 Bioavailability of calcium-fortified foods

Bioavailability can be influenced by many factors making it a highly variable attribute of vitamins and minerals. Because of this variability, a wide variety of research techniques have been applied to the measurement of bioavailability. These techniques include physiological investigations in animals and humans, and *in vitro* assessments (Heaney, 2001).

5.1.8.1 The Variable Nature of Bioavailability

Despite the current research methods that have been developed, a large degree of uncertainty still remains with any findings on vitamin and minerals bioavailability, as there are a wide variety of modifying factors that can confound results from scientific studies. Even with advances in research methodology, current studies on bioavailability continue to be limited by their design, as they are all highly controlled experiments that do not reflect outcomes in actual human conditions.

Confounding modifiers of bioavailability include the nutrient's release from the food matrix during digestion, physical interaction between other food components during digestion, and the form of the nutrient.

There are also a number of host-related modifiers, including the host's nutritional status, developmental state, gastrointestinal secretions, mucosal cell regulation, and gut microflora (Fairweather-Tait and Southon, 2004). A major influence on bioavailability is also the interaction between foods within a meal.

Any assessment of vitamin and mineral bioavailability therefore must recognise that *in vitro* studies, and studies examining the fasting consumption of a single food, are unlikely to provide an accurate assessment of vitamin or mineral uptake and regulation within the body (Heaney 2001).

5.1.8.2 Studies on Calcium Bioavailability

For calcium, studies have shown that age plays the most significant role in determining how much of the nutrient is absorbed, rather than its source or chemical form (United States Institute of Medicine, 1997).

The impact of confounding factors is significant for calcium, and can lead to inappropriate conclusions on its bioavailability. For example, when the various forms of calcium are compared to each other, short-term biochemical assessments (e.g. changes in serum calcium following calcium intakes) indicate that different forms of calcium (including dairy sources) have different bioavailabilities (Talbot *et al*., 1999; Heller *et al*., 2000; Kenny *et al*., 2004).

However, assessments of the different forms on physiological parameters, such as bone mineral density, show that a wide range of different calcium sources, both supplemental and food types, have approximately the same impact (Reid, 2005). Although high doses of different supplemental calcium forms (such as calcium carbonate, calcium citrate-malate, and calcium lactate-gluconate) have been shown on occasions to differ in their impact on bone mineral density, the overall difference in the impact between these forms is not significant (Dawson-Hughes *et al*., 1990; Chevalley *et al*., 1994; Prince *et al*., 1995; Ruegsegger *et al*., 1995). More importantly, comparisons between similar doses of supplemental and dairy-based sources of calcium indicate that their impact on bone mineral density is approximately the same (Lau *et al*., 2002; Reid, 1993).

The above studies demonstrate that while assessments under isolated, experimental conditions on the different forms of calcium show variations in bioavailability, these variations are not reproduced over the longer-term when the different forms are used in actual human life situations. As a specific example, calcium carbonate is widely cited as having a poor bioavailability *in vitro*, yet the bone mineral density comparisons with dairy-based calcium listed above include this form of supplemental calcium (Reid, 1993). The reasons for these differing results from experimental and actual life studies becomes apparent when consideration is given to the wide variety of confounding factors that can affect bioavailability.

5.1.8.3 Conclusion

There are a large number of factors influencing bioavailability, including the host's nutritional status, developmental state, gastrointestinal secretions, mucosal cell regulation, gut microflora and other nutritional factors in a meal. These confounding factors mean that assessments of vitamin and mineral bioavailabilities in isolated experimental conditions are not always reproduced when assessments are made of the impact from bioavailability on health endpoints.

This is the case with the different forms of calcium, which do not show any appreciable difference in their impact on bone mineral density, even though experimental measurements of calcium bioavailability show variations across high doses of the different forms.

This comparable impact on health endpoints means that in the context of the variety of foods on the market, foods with added calcium are likely to have a similar impact on bone and dental health as traditional sources of calcium.

5.1.9 Impact of milk protein constituents on bone density

Dairy foods contain a number of substances that have been shown to have a role in bone metabolism. These substances include:

- Lactoferrin, an iron binding protein. Lactoferrin has been shown *in vitro* and in animal studies (mice) to promote bone cell growth (Cornish *et al*., 2004; Naot *et al*., 2005);

- Osteoprotegerin, an immune system regulator. *In vitro* results indicate that milk-derived osteoprotegerin is able to promote bone cell growth (Vidal *et al*., 2004); and

- Milk basic protein, which is a protein fraction found within milk. Consumption of milk basic protein at supplemental doses (40-300 mg/day) in randomised controlled trials of humans has been shown to increase bone mineral density and serum level markers of bone growth (Aoe *et al*., 2001; Toba *et al*., 2001; Yamamura *et al*., 2002).

FSANZ has not been able to identify any information relating to other milk constituents and bone health. The information provided above, while indicating a relationship between certain milk constituents and bone health, is not sufficient to confirm such an association. A larger body of evidence would be required to allow for a direct association between the identified substances and bone health outcomes.

5.1.9.1 Conclusion

Dairy products are recognised as important food products capable of contributing more to an individual's diet than just calcium. However, there is insufficient evidence to conclusively associate specific milk components with changes in bone health. On this basis, FSANZ believes there is insufficient scientific evidence to allow for a comparison between the impacts of milk and calcium-fortified juice on bone health on the basis of milk protein constituents.

5.1.10 Conclusion

FSANZ has undertaken a robust and extensive assessment of the public health and safety implications of this assessment and concluded:

- there is considerable evidence to indicate inadequate intakes of calcium in the Australian and New Zealand populations;
- the addition of calcium to all the proposed foods has the potential to increase the calcium intake for the population or subgroups of the population with a current intake assessed as inadequate;
- there is negligible risk of excess calcium intake;

- there is negligible risk of dietary displacement of other nutrients;
- in the context of the likely substitution of fortified beverages for their unfortified counterparts, the risk of increasing rates of obesity and dental caries/erosion is minimal;
- the issue of bioavailability is highly complex but data exists showing that added forms of calcium can contribute to bone health as effectively as naturally occurring food sources of calcium.

5.2 Inconsistency with existing policy guidelines set by the Ministerial Council

The Ministerial Council considered that this Application is inconsistent with the interpretation of the '*Specific Order' Policy Principles – Voluntary Fortification* of the Policy Guideline in two key areas. Council members stated that fortification of fruit juice with calcium will reduce milk consumption and increase fruit juice consumption and promote increased consumption of foods high in sugar, salt and fat.

5.2.1 Risk of promoting consumption patterns inconsistent with nutrition policies and guidelines of Australia and New Zealand.

The Australian and New Zealand nutrition policies and guidelines relevant to this review are outlined below:

AUSTRALIAN NUTRITION POLICIES AND GUIDELINES

Australian Dietary Guidelines relevant to this review (NHMRC, Adults and Children & Adolescents, 2003)

- Eat plenty of vegetables, legumes and fruit.
- Include milks, yoghurts, cheeses and/or alternatives.
- Drink plenty of water.
- Limit saturated fat and moderate total fat intake.
- Choose foods low in salt.
- Consume only moderate amounts of sugars and foods containing added sugars.

Specific recommendations for fruit intakes

- The Australian *Guide to Healthy Eating's* recommendations for fruit include raw, stewed or canned varieties, with rather less emphasis on fruit juices and dried fruit, although a modest intake of both (say, one serving a day is acceptable).

Specific recommendations for fluid intakes

- Adequate fluid consumption is an integral component of a healthy diet. Water is a good source of fluids as it can hydrate without adding additional energy to the diet. Nevertheless other drinks such as milks, fruit juices, low energy soft drinks beverages can add variety and in some cases (e.g. milks and juices) can add valuable nutrients to the diet. Intakes of fluids containing substantial amounts of added sugars should be moderated.

For children, specific recommendations apply to the use of fruit juice

- For children aged 6 months to 2 years, avoid too much fruit juice – a maximum of 120 ml/day before 12 months and 240 ml/day after 12 months.
- For children aged 1 to 6 years, the intake of fruit juice should be limited to 150 ml/day. For children aged 7 to 18 years, juice intake should be limited to 240-360 ml a day (two servings a day)
- Children should be encouraged to eat whole fruits to meet their recommended daily fruit intake.
- Fruit juice should not be consumed as a substitute for fresh fruit. Fresh fruit is a good source of dietary fibre and is of higher nutritional value than fruit juice.

NEW ZEALAND NUTRITION POLICIES AND GUIDELINES

New Zealand Dietary Guidelines relevant to this review (MoH, 2003)

- Eat plenty of vegetables and fruits.
- Have milk and milk products in your diet, preferably reduced or low-fat options.
- Prepare foods or choose pre-prepared foods, drinks and snacks:

    - with minimal added fat, especially saturated fat
    - that are low in salt; if using salt, choose iodised salt
    - with little added sugar; limit your intake of high-sugar foods;

-
- Drink plenty of liquids each day, especially water.

Food and Nutrition Guidelines for Healthy Adults: A background paper.

- Limit the consumption of fruit juice, cordial, energy and soft drinks because of their high sugar content.
- To reduce dental decay, restrict the frequency of eating foods and drinking beverages with a high sugar content. If eating sugary foods, take them at mealtimes instead of as snacks between meals.
- Choose food and drinks that are low in sugar to avoid excess energy intake. Remember that non-alcoholic beverages such as soft drinks and fruit juices are a dietary source of sugar.
- Food and Nutrition Guidelines for Healthy Children Aged 2-12 Years: A background paper (MoH, 1997).
- Children should be encouraged to drink water as a beverage from an early age.
- Children should be offered drinks of cool water rather than fruit juices and cordials.
- Because of the risk to dental health, fruit juices should always be diluted and offered with meals rather than between meals.
- Milk contributes valuable calcium, protein and energy, but excessive quantities between and at mealtimes may spoil a child's appetite for other foods.

Food and Nutrition Guidelines for Healthy Adolescents: A background paper (MoH, 1998)

- Water intake should be encouraged during adolescence. Milk, especially reduced fat milks, are also recommended.
- Carbonated drinks should be restricted. Plain water instead of soft drinks with a meal is recommended. It is also recommended to dilute fruit drinks before consumption.

Therefore, in the context of the above nutrition polices and guidelines, FSANZ explored the likelihood that the voluntary fortification of juices/drinks, soups and savoury biscuits with calcium would promote:

- increased consumption of juices/drinks;
- decreased consumption of milk;
- decreased consumption of water;
- increased consumption of sugar;
- increased consumption of salt; and
- increased consumption of fat.

5.2.1.1 Market trends

A key concern underpinning this review request is the potential for calcium-fortified juices/drinks to reduce milk intakes. To help ascertain the impact of fortified juices/drinks on milk consumption, FSANZ examined worldwide market trends of these beverages. Attachment 3 provides a detailed description of the market trends in New Zealand, Australia, United States (US), United Kingdom (UK) and Germany for fortified juices and milk. A synopsis of the main trends is outlined below.

In Australia[38] and New Zealand[39], juices with added calcium have been on the market for several years, yet have developed only a relatively small stable niche market. There is no evidence that their market presence has contributed to a decline in milk consumption.

In the US, UK and Germany, fortified juices have been available since the mid-1980s. These products have been aggressively marketed by major drink multinationals who have invested considerably in the development, marketing and distribution of these products. As a result, calcium-fortified juices are now well established and are regarded as mainstream. In the US and the UK these products can also be actively promoted as milk substitutes. This situation is unlikely to occur in Australia and New Zealand however due to the current restriction on comparative claims for vitamin and mineral content[40].

Despite their market success in the US, UK and Germany, there is no evidence that the introduction of fortified juices has increased the worldwide trend of declining milk consumption.

[38] In Australia calcium is added to orange juice as a component of an ingredient (i.e. seaweed extract).
[39] In New Zealand calcium can be added to juices by virtue of the New Zealand *Dietary Supplements Regulations 1985.*
[40] Subclause 4(b) of Standard 1.3.2 – Vitamins and Minerals of the Code

On the contrary, various population surveys in these countries indicate that milk consumption, especially in children and adolescents, has remained relatively stable since the introduction of fortified beverages (Alexy *et al*., 2002; Park *et al*., 2003; MAFF and Office for National Statistics, 2004). Recent market sales have also shown slight increases in milk production and consumption in these countries (American Beverage Association, 2004; Milch & Markt, 2004; Milch & Markt, 2005).

5.2.1.2 Consumer Research

5.2.1.2.1 Dairy Australia Consumer Research

There is a general lack of quantitative, market based evidence to help predict the likely impact of calcium-fortified juices/drinks, soups and savoury biscuits on food selection preferences. To help address this issue, Dairy Australia commissioned consumer research[41] to examine the likely substitution of calcium-fortified beverages for milk.

This research was included as part of a Newspoll telephone omnibus survey in February 2003 and involved a national sample of 1200 respondents aged 18 years and over. The sample was representative of the Australian population and post-weighted to reflect the population distribution by the Australian Bureau of Statistics.

The main finding of this Dairy Australia research is that calcium-fortified beverages will not attract mass-market interest, but will be of interest to a 'significant minority'. It is anticipated that fortified juices will mainly replace unfortified juices, fortified fruit drinks will replace unfortified fruit drinks and fortified cordials will replace unfortified cordials. However, it is projected that a small but significant group will buy the new calcium-fortified beverages and substitute them for either regular, low fat or flavoured milk.

There have been varying interpretations as to the significance of the Dairy Australia research. While FSANZ notes that the Dairy Australia research reported that a small number of respondents substituted fortified beverages for milk, the research did not address the frequency of purchase or the likely amounts consumed. On this basis, at Final Assessment FSANZ concluded that it was reasonable to assume that these respondents would not be replacing their entire milk intake over the long term. Thus, FSANZ concluded that it would be unlikely that calcium-fortified foods would replace staple foods, such as milk, in the diet to any significant extent.

In contrast, some key stakeholders believe that the Dairy Australia research clearly demonstrates that the availability of calcium-fortified beverages will lead to an undesirable increase in the consumption of fruit juices and/or inappropriate substitution of milk. To help address this discrepancy, FSANZ commissioned TNS Social Research to undertake a critical review of the Dairy Australia research.

[41] Sandra Beanham and Associates (2003) Australian Dairy Corporation Issues Research: Calcium-Fortified Drinks

5.2.1.2.2 TNS Social Research

TNS Social Research evaluated the findings of the Dairy Australia research by re-analysing the initial data of the Newspoll survey and then reviewing the conclusions reached by both Dairy Australia and FSANZ. TNS Social Research also undertook a limited literature review to evaluate the validity of these conclusions. A copy of the TNS Social Research report is given at Attachment 4.

The main findings of the TNS report are:

- there is likely to be relatively little impact of calcium-fortified drinks on the purchase of milk products for the population as a whole;
- less than 2% of the population would shift from a milk product to a calcium-fortified juice product;
- due to the high margin of error associated with the small sample size, it is not possible to draw meaningful conclusions about the profile of those who may shift from milk to calcium-fortified juice products;
- if substitution did occur, it is not possible to identify the number of milk serves that would be replaced or for how long this would occur;
- re-analysis of the data showed that a greater proportion of respondents would shift from a 'soft drink' to a calcium-fortified juice, when compared to the shift from milk to these products; and
- the limited impact of calcium-fortified drinks is generally supported within the literature, with little or no evidence that directly links the increase in consumption of calcium-fortified juice to a decrease on the consumption of milk products.

5.2.1.2.3 Market Research on Beverage Consumption Patterns

As part of a market research project undertaken in 2002, Julie Dang and Associates[42] investigated consumer views/perceptions of different drinks and the key factors driving usage. The research consisted of a sample of 170 males and females, aged 25-60 years. The main conclusions of this research were that consumers view juices, tap water and milk differently and as such, are unlikely to substitute between these three categories.

The research indicated that consumers viewed juice as being a nutrition 'booster' that supports healthy living whereas milk is perceived as being 'preventive' and 'protective' with specific functional benefits for bones. In contrast, tap water is perceived as being a 'thirst quencher'. The different usage drivers mean that it is unlikely that these drinks will be substituted for each other as they satisfy specific consumer needs.

[42] Dang & Associates (2002) *Fruit & Vegetable Juice: Need State Study. A Quantitative Study Prepared for Campbell's Soups Australia.*

It was also noted that milk is consumed in a variety of ways, for example on cereal or in cooking, which cannot be substituted by juices or water. In addition, the consumption times for these beverages varies, with milk mainly drunk in the evening, water in the middle of the day and juice in the morning. These differences reduce the likelihood of substitution across drink types.

5.2.2 Risk of promoting increased consumption of foods high in sugar, salt and fat

Another key concern underpinning this review request is that the nominated food vehicles will promote the increased consumption of foods high in sugar, salt and fat.

5.2.2.1 Policy Guideline Requirements

Some stakeholders contend that the nominated food vehicles (i.e. fruit juices/drinks, soups and savoury biscuits) are not low in sugar, salt and fat but this is not a requirement of the Policy Guideline. Rather, the Policy Guideline focuses on voluntary fortification not promoting increased consumption of foods high in sugar, salt and fat. For example, if fortified foods were simply substituted for their unfortified counterparts, then regardless of their fat, sugar and salt content, the net result would be neutral in terms of the dietary intake of these nutrients.

There is concern, however, that fortified products will be actively marketed and promoted and as a consequence, increased amounts of the fortified foods will be consumed. In this situation, rather than substituting the same amount of fortified food for the unfortified counterpart, more will be consumed.

Thus in assessing the potential for voluntary fortification to promote the increased consumption of foods high in sugar, salt and fat, FSANZ needs to try to predict the most likely scenario, either substitution or increased consumption, or a combination of both.

5.2.2.2 Compositional Criteria for Food Vehicles

At Final Assessment, FSANZ utilised compositional criteria, as outlined in *FSANZ's Regulatory Principles for Vitamin and Mineral Addition to Foods* (Regulatory Principles), to help assess the suitability of these potential food vehicles. It was concluded that the majority of products satisfied the compositional criteria and so would be eligible for voluntary fortification. However, with the release of the Policy Guideline, FSANZ's Regulatory Principles were superseded and currently FSANZ does not have specific compositional criteria for classifying foods high in fat, sugar & salt.

Although the Policy Guideline provides general guidance on the selection of appropriate food vehicles for voluntary fortification, it does **not** provide specific criteria as to the suitability of the food vehicle.

5.2.2.2.1 Juices/Drinks

Listed below are the total sugars contents for various different beverages currently on the market.

Beverage Category	Total Sugars (g/100 ml) *
Carbonated, sugar based soft drinks	9.1 – 14.8
Fruit juices	5.3 – 14.1
Fruit juice drinks	9.4 – 14.6
Vegetable juices	1.4 – 3.3
Cordials (ready to drink)	9.7 - 14.8
Milk (plain, full fat)	4.7
Skim milk	5.0

* = Data derived from *AUSNUT Special Edition (2) – Australian Food and Nutrient Database for Nutrient Labelling: Release 2* Australia New Zealand Food Authority (2002)

Generally, vegetable juices contain the least amount of sugars and soft drinks and cordials contain the most. On average, juice drinks contain slightly less sugars than soft drinks and slightly more than juices. In contrast, milks contain approximately half the sugar content of juices/drinks.

The impact of this proposed voluntary fortification on total sugar intake is dependent on the amount of calcium-fortified beverages consumed and the products displaced in the diet. The TNS research (at Attachment 4) reported that the majority of consumers would substitute a fortified product for its unfortified counterpart and thus the dietary impact would be neutral. For those respondents who did report substituting a fortified juice for a different product, more reported shifting from a soft drink to a fortified juice than from milk to a fortified juice. These findings, together with the market research outlined in Section 5.2.1, lend support for calcium-fortified beverages not increasing consumption of foods high in sugar.

5.2.2.2.2 Savoury Biscuits

In ensuring consistency with existing permissions for the addition of vitamins and minerals to biscuits, the draft variations to Standard 1.3.2 at Attachment 1 stipulate that calcium can only be added to biscuits containing no more than 20g/100g fat and no more than 5g/100g sugar. In effect, only plain crackers and crisp-breads meet these criteria, as all sweetened biscuits currently on the market exceed the sugar limit and many small high fat crackers exceed the fat limit. While these fat and sugar restrictions are considered moderately lenient, they will prevent high sugar and high fat biscuits from being fortified with calcium.

The Applicant submitted that in keeping with the consumers' concern for health and well-being as a prime motivator for purchasing calcium-fortified products, it would be inadvisable and poor marketing to fortify high fat biscuits. They report that this target audience is highly responsive to the fat content of foods.

FSANZ is unaware of any consumer research that has examined the impact of calcium-fortified savoury biscuits on food selection preferences. However, based on the substitution patterns observed in the Dairy Australia research and TNS research for juices/drinks, it would be reasonable to assume that calcium-fortified savoury biscuits would be substituted for their unfortified counterparts and in so doing, would not increase the consumption of foods high in fat.

5.2.2.2.3 Soups

The draft variations to Standard 1.3.2 at Attachment 1 do not stipulate a sodium restriction for soups. The sodium content of soups currently on the market generally ranges from 300-400 mg/100 g. As indicated above, market research has shown that calcium-fortified products appeal to consumers who are concerned with their health and well-being. It is therefore in the manufacture's interest to ensure these products are not perceived as being contrary to healthy eating guidelines.

FSANZ is also unaware of any specific consumer research that has examined the impact of calcium-fortified savoury soups on food selection preferences. However, if calcium-fortified soups are only substituted for their unfortified counterparts, it is reasonable to assume that this would not increase the consumption of foods high in salt.

5.2.2.3 Influences on consumer purchasing and consumption patterns

Consumers' purchasing and consumption patterns are influenced by an array of factors including product branding (to guarantee quality and provide taste reassurances), in store visibility, labelling, dietary preferences, health considerations and pricing.

The TNS Report notes that the consumption of functional foods is increasing, largely driven by consumers' concern for their health and well-being. They report that *consumer perceptions of food products, particularly in relation to their heath and well-being, will ultimately rest on the product's branding and labelling.*

Opportunities for how food products are labelled fall within FSANZ's regulatory responsibilities. The proposed health claims framework is currently exploring the potential impact of various claims on consumers' purchasing and consumption patterns.

5.2.2.4 Proposed Health Claims Framework

FSANZ's consumer research (TNSSR, 2005) has shown that health claims can influence consumers' intent to purchase food products. Consumers perceive products with a health claim to be healthier and report that they are more likely to purchase a product with a health claim.

The TNS report, at Attachment 4, notes that health claims can increase a product's market share. However, this impact is most likely to occur amongst consumers who already purchase this type of product and consumers are unlikely to switch to a different product category because of the health claim.

Under the proposed health claims framework, FSANZ is currently examining the possibility of developing generic disqualifying criteria to apply to general level health claims[43]. The proposed generic disqualifying criteria are based on nutrient profiling to prevent foods containing large amounts of saturated fat, sugar and salt from being able to make general level health claims.

[43] An example of a general level health claim is: *this food is a source of calcium and when consumed as part of a healthy diet is good for strong bones and teeth.*

These disqualifying criteria would only apply to general level health claims and not nutrition content claims[44]. Thus, the proposed health claims framework may only allow 'source' and 'good source' claims to be made on the nominated food vehicles of this Application.

As this Review precedes the finalisation of the health claims framework, details of the compositional disqualifying criteria cannot be specified at the time of writing and the potential impact on the nominated food vehicles predicted. However, FSANZ is mindful of the potential influence of health claims on consumers food choices and so will seek to ensure that the generic disqualifying criteria help prevent the increased consumption of foods high in sugar, fat and salt.

5.2.3 Conclusion

Based on the above information, it is unlikely that this voluntary fortification permission would promote consumption patterns inconsistent with nutrition polices and guidelines and result in the increased consumption of foods high in sugar, salt and fat.

Consumer research indicates that the majority of consumers would substitute a fortified product for its unfortified counterpart and thus the dietary impact would be neutral. Due to the different consumer perceptions of the role of water, milk and juices in the diet and their different consumption times, there is less probability of substitution between these beverage categories. There is little or no evidence that directly links the consumption of fortified juices/drinks to a decrease in milk and/or water consumption.

Since communication of voluntary fortification will mainly be through labelling claims, the proposed health claims framework will seek to minimise the risk of claims resulting in the increased consumption of foods high in sugar, fat and salt.

5.3 Provision of adequate information to enable informed choice

One of the Policy Guideline's 'Specific Order' Policy Principle is that *the fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.*

Some stakeholders have expressed concern that this Application may mislead consumers by:

- fortified foods being perceived as being 'healthier' than their counterparts;
- consumers underestimating the level of risk-increasing nutrients due to the presence of claims about beneficial nutrients in the same product; and
- the calcium in fortified products being less effective for bone health in comparison to calcium in dairy products.

[44] An example of a nutrition content claim is: *this food is a source of calcium.*

5.3.1. *Perception of fortified foods being 'healthier'*

There is a risk that fortified foods may be considered 'healthier' than their counterparts, for example fortified orange juice as being nutritionally superior to whole oranges. The use of labelling statements, such as warning and advisory statements, have been suggested to help mitigate this risk and to assist consumers in making informed choices. Advisory statements, such as 'fortified orange juice is not a substitute for milk and should be limited to one serve a day', have been suggested.

As indicated in Section 5.2, it is likely that consumers will substitute fortified juices for their unfortified counterparts, rather than other beverages such as water and milk. On this basis, the risk of increasing rates of obesity and dental caries due to increased sugar intakes would be the same for both unfortified and fortified sweetened beverages. Thus the need for a labelling statement would apply to all sweetened beverages, including both fortified and non-fortified juices/drinks, soft drinks and cordials.

FSANZ's labelling risk management framework for decision-making is outlined below:

High risk
Where the risk to public safety is potentially life threatening and it can reasonably be assumed that the general population or the specific target group is unaware of the potential safety risk, a prescribed labelling statement is needed to alert consumers of the risk. Warning Statements are required where the risk to public health and safety is high and awareness of the potential risk is low.

Medium risk
Advisory statements are provided where the general population or a sub group of the population are largely unaware of a potential, but non life threatening risk to public health and safety and need advice about that risk.

Low risk
Where a risk to public health and safety is determined to be low because the likelihood of an adverse event occurring is rare and the consequences minor, it should be sufficient to rely on general labelling provisions and existing food law to manage the risk. An education initiative could be used to raise awareness of and promote the use of general labelling information (FSANZ, 2002).

FSANZ has assessed the potential risk to public health and safety as a result of this Application as being low and as a consequence has reaffirmed its position that no specific labelling statements are currently required. FSANZ believes that the general labelling provisions outlined in Section 5.3.2 will be sufficient to inform consumers.

FSANZ supports and acknowledges the role nutrition education can play in providing information in relation to the role of calcium-fortified products in the overall diet and believes this approach is consistent with level of risk identified.

5.3.2 Labelling requirements

Under current labelling requirements, an added vitamin or mineral must be listed in the ingredient list and if a nutrition content claim is made in relation to a food, the nutrient is required to be listed in the Nutrition Information Panel on the label.

'Source' or 'good source' calcium claims for fortified foods can be made provided that a reference quantity of the food contains at least 10% or 25% of the RDI respectively for calcium. The above requirements would provide consumers with factual information as to the amounts of fortificant in the food. These labelling requirements are also in accordance with the additional policy guidance for voluntary fortification which states *there should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods.*

5.3.3 *Claims misleading consumers*

There is concern that consumers may underestimate the level of risk-increasing nutrients due to the presence of claims about beneficial nutrients in the same product. As discussed in Section 5.2.2.4, FSANZ is aware of this risk and since communication of voluntary fortification will mainly be through labelling claims, the proposed health claims framework will address these issues.

5.3.4 *Effectiveness of calcium-fortified products*

Some stakeholders have expressed concern that the added forms of calcium may be less effective in protecting bone health when compared to the calcium in dairy foods, resulting in consumers being misled.

However, FSANZ's assessment as outlined in Section 5.1.8, shows that the forms of added calcium, in the context of the overall diet and physiological status of the person, are likely to have a similar impact on bone and dental health as traditional sources of calcium. Thus the risk of consumers being misled because of different impacts of added calcium compared to natural sources is minimal.

5.3.5 Conclusion

FSANZ has assessed the potential for consumers to be misled by this Application and concluded that the risk is low. However, to further reduce these risks, FSANZ proposes:

that the health claims framework will seek to ensure that the presence of claims on fortified foods will not mislead consumers; and
to support education initiatives to help raise awareness of general labelling information and the role of fortified food in the diet.

6. Review Options

Three options were considered in this Review:

1. re-affirm approval of the draft variations to Standard 1.3.2 of the Code as notified to the Ministerial Council; or

2. re-affirm approval of the draft variations to Standard 1.3.2 of the Code subject to any amendments FSANZ considers necessary; or

3. withdraw approval of the draft variations to Standard 1.3.2 of the Code as notified to the Ministerial Council.

7. Conclusion and recommendation

The Second Review concludes that the preferred review option is Option 1. This re-affirms the approval of the draft variations to Standard 1.3.2 of the Code as notified to the Council. This decision permits the voluntary addition of calcium to fruit- and vegetable juices/drinks, soups and savoury biscuits as outlined in the draft variations at Attachment 1.

Attachments

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Ministerial Council's Policy Guideline - *Fortification of Food with Vitamins and Minerals*
3. Market Trends for Fortified Juices and Milk
4. TNS Social Research – Analysis of Fortification of Foods with Calcium

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ATTACHMENT 1

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.3.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from the* Table to clause 3, *the entry for* Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugar, *substituting* -

Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugars	35g	thiamin	0.55 mg (50%)
		riboflavin	0.43 mg (25%)
		niacin	2.5 mg (25%)
		vitamin B6	0.4 mg (25%)
		vitamin E	2.5 mg (25%)
		folate	100 µg (50%)
		calcium	200 mg (25%)
		iron	3.0 mg (25%)
		magnesium	80 mg (25%)
		zinc	1.8 mg (15%)

[1.2] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Fruit juice, reconstituted fruit juice, concentrated fruit juice –

calcium	200 mg (25%)

[1.3] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Tomato juice, concentrated tomato juice –

calcium	200 mg (25%)

[1.4] *inserting in the* Table to clause 3, Columns 3 *and* 4, *under the entry for* Vegetable juice –

calcium	200 mg (25%)

[1.5] *omitting from the* Table to clause 3, *the entry for* Fruit drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit; fruit drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit, *substituting –*

Fruit and/or vegetable drinks containing at least 250 mL/L of the juice, puree of comminution of the fruit and/or vegetable; fruit and/or vegetable drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit and/or vegetable	200 mL	folate vitamin C carotene forms of vitamin A calcium	refer to clause 8 refer to clause 8 refer to clause 8 200 mg (25%)

[1.6] *inserting in the* Table to clause 3 -

Composite products

Soups, prepared for consumption in accordance with directions	200 mL	calcium	200 mg (25%)

ATTACHMENT 2

Policy Guideline
Fortification[1] 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
   (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:

[1]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.

(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:

- 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.
- Be required only if it is assessed as the most effective public health strategy to address the health problem.
- Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
- 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.
- 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

Assessment of alternative strategies – consideration must be comprehensive and include for example assessment of voluntary fortification and education programs.

Requirement to label – no mandatory requirement to label as fortified however, consideration should be given, on a case by case basis, to a requirement to include information in Nutrition Information Panel.

Monitor/Review – any agreement to require fortification should require 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 sub-clinical 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[2]).

  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.
- 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.

[2] 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.

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 3

Market Trends for Fortified Juices And Milk

1. New Zealand

A leading Australasian drinks company produces a premium range of fortified juices for the New Zealand market. This product range includes a fortified orange juice called *Citrus Tree* that contains added calcium and folate. Currently in New Zealand such beverages can be manufactured to the New Zealand *Dietary Supplements Regulations 1985* (NZDSR)[45].

Citrus Tree is presented as a two-litre chilled product containing 80 mg/100 ml (10% RDI per 250 ml serve) of calcium and so can make a 'source' claim for calcium. Although these products have been on the market for several years, the product line has not grown significantly. The company reports that the public are not prepared to pay a premium for the added functionality of these juices and so the cost is borne by the manufacturer. Although these products are lined priced with standard juice, they have not significantly increased in market share after the past few years (*personal communication Frucor, New Zealand*).

In New Zealand supermarkets, total fruit juice/drinks annual sales to June 2004 were 89,917,840 litres, of which only 1,852,768 litres (2%) were from calcium-fortified products. Almost 100% of calcium-fortified juices are sold through the supermarkets. This compares with milk and cream sales in supermarkets for the same period of 181,320,000 litres and an estimated total fresh milk market in New Zealand, in 2003, of 358,100,000 litres. Thus, calcium-fortified juice represents only 1% of the volume of supermarket sales and only 0.5% of the estimated total milk sales.

2. Australia

Orange juices with additional sources of calcium have been on the Australian market since 1999. Originally whey powder was added to increase the calcium content of juice but recently this has been replaced with a seaweed extract[46].

In 2003 Australia's largest fruit juice manufacturer launched a chilled, premium brand orange juice with added calcium. The two-litre product contains 200 mg/200 ml of calcium and so can make a 'good source' claim. Sales data from the past two years indicate that this product has achieved a relatively stable market share of approximately 6% of their product range (*personal communication Berri, Australia*).

3. United States (US)

In the mid-1980s, calcium-fortified juices were introduced onto the US market. Coca-cola released calcium-fortified *Minute Maid* category and PepsiCo launched *Tropicana Pure Premium* and *Tropicana Essentials* lines. US sales of calcium-fortified orange juice have grown dramatically since then and were estimated to be worth nearly $US1 billion in 2003 (American Beverage Association, 2004).

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[45] http://www.legislation.govt.nz/browse_vw.asp?content-set=pal_regs

[46] The calcium-rich seaweed can be added to orange juice as an ingredient and therefore does not require permissions to be listed in Standard 1.3.2 – Vitamins and Minerals of the Code.

Due to the market dominance of major multinational drink companies there is considerable investment in product development, marketing and distribution. Calcium-enriched juices are now well established and are viewed as mainstream with no price premium and a wide choice of brands.

While sales of fortified juices have increased, this has not coincided with a decrease in milk consumption. A US study examining trends in children's' beverage consumption from 1987-98 concluded that there was no significant decline in children's milk consumption during this time period (Park *et al.*, 2002). In 2002, the American Dairy Association and Dairy Council reported that overall milk sales had increased and that milk drinking among 13- to 17- year-olds had increased by 3% in 2001 and 6.8% in 2002 (American Beverage Association, 2004).

4. United Kingdom (UK)

Calcium-fortified juices have been on the UK market since PepsiCo launched *Tropicana Plus Calcium* in 1999. This product is actively advertised as a substitute with milk with the words 'as much calcium as milk' and a side-by-side image of a glass of orange juice and a glass of milk on the package with the words '38% of the RDI'. It is important to note that comparative claims, as mentioned above, are currently prohibited in Australia and in New Zealand. Thus, it would not be possible to directly compare the calcium content of fortified orange juice with milk in Australian and New Zealand.

As a general trend, milk consumption in the UK has steadily declined by 38% between 1974 and 2003/4. However the introduction of calcium-fortified juices onto the market has not increased the rate of decline in milk consumption. Just after the release of *Tropicana Plus Calcium*, the 2000 UK National Food Survey reported that household consumption of milk and cream (including yoghurts and dairy desserts) rose by 4%, mainly due to an increase in liquid milk consumption.

5. Germany

The market for fortified juices was created in 1994 with the launch of ACE products (fortified beverages with antioxidant vitamins A, C and E). These beverages are usually orange, carrot or lemon flavoured with a typical juice content of 30%. During 1994, the market for ACE beverages grew from virtually zero to four million litres. After high levels of promotional activity, the market grew steadily reaching over 300 million litres in 2002, with a value of about $44.8 billion (Hilliam, M., 2003).

From 1992 to 1997, the per capita consumption of liquid milk decreased by 10% from 71.7 kg to 64.5 kg per capita in Germany. In contrast to this declining trend in milk consumption, German dairy operators in 2003 reported increases in the production of consumer milk by 2.7% in 2003 (Milch & Markt, 2004) and 0.4% in 2004 (Milch & Markt, 2005). A recent study examining consumption trends of dairy foods in children and adolescents between 1986 and 2001 reported that consumption of milk products remained relatively constant during this time (Alexy *et al.*, 2003).

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ATTACHMENT 4

ANALYSIS OF FORTIFICATION OF FOODS WITH CALCIUM RESEARCH

A RESEARCH REPORT

Prepared For:
FOOD STANDARDS AUSTRALIA NEW ZEALAND

Client Contact:
Ann Hunt
Catherine Deeps

TNS Consultants:
Ashley Moore
Angela Southwell
Julia Zelenska
Brigid van Wanrooy

90174

August, 2005

TNS Social Research
65 Canberra Ave
Griffith ACT 2603
t +61 2 6295 2900
f +61 2 6295 2988
e canberra.au@tns-global.com

tns social research

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Executive summary

PURPOSE OF THE RESEARCH

This report evaluates the findings from research conducted by Dairy Australia into the impact of calcium-fortified juice/drink products on the consumption of milk products. A limited literature review into the issues related to the Dairy Australia research was also conducted. This report has been compiled using existing data and previous research, no primary research was conducted.

METHODOLOGY

The research was conducted by TNS Social Research (TNSSR) and involved a four stage process:

- Initial re-analysis of the data provided by FSANZ. This analysis was conducted prior to the researcher reviewing any of the reports or supporting documentation from Dairy Australia or FSANZ, so in essence the initial data analysis can be considered a 'blind' review.
- Review of the findings from the Dairy Australia research, and the subsequent assessment reports from FSANZ and response from Dairy Australia.
- Comparison between the TNSSR conclusions from the initial review of the data and the findings from Dairy Australia.
- A limited literature review, including some of the literature mentioned in the Dairy Australia research, to evaluate the validity of the findings relevant to the TNS review.

RESULTS

From the review of the data, which is based on consumers' intentions, for the population as a whole it is apparent that there is likely to be relatively little impact of calcium-fortified juice/drinks on the purchase of milk products. As noted in the Dairy Australia research, the proportion of those who would shift from a milk product to calcium fortified drinks is very small and in reviewing the data, it is clear that this proportion **does not represent a significant reduction in the consumption of milk**.

More specifically, based on the total number of respondents, **less than 2% of the population** would shift from a milk product to a calcium-fortified juice product. Further, almost all (approximately 90%) indicate that their current consumption of milk products would **remain at the same level**, regardless of the availability of calcium-fortified products (see Section 3.1). Due to high margins of error associated with these very small sample sizes it is not possible to draw any meaningful conclusions about the profile of those who may shift from milk to a calcium-fortified juice product or confirm their motivations behind shifting (see Section 3.2).

In addition to these findings, it is important to note that the Dairy Australia research is not able to identify the magnitude of the shift (i.e. how many serves a day would be replaced) or the degree to which specific milk products would be replaced and under what conditions this substitution would take place or for how long (see Section 3.2.4). This information would provide a greater insight into the true impact of any substitution behaviour.

It is also not possible to identify who, within the household, would shift from a milk product to a calcium-fortified juice/drink product. Essentially, the findings only represent households in general and the research does not provide information on which target groups would shift – which could have a considerable impact on the implications of a shift in consumption (i.e. shift may be considered more detrimental for one consumer group compared to another target group).

The limited impact of calcium-fortified juice/drinks observed within the Dairy Australia research is generally supported within the literature, where there is little or no evidence that directly links the increase in consumption of calcium-fortified orange juice to a decrease in the consumption of milk products.

While there is evidence to indicate that once a calcium-fortified fruit juice/drink is introduced to the market there is a considerable growth for this category, there is no evidence to suggest a significant impact on the milk market. Rather, the evidence suggests that it is a shift within category, as opposed to a shift between categories (see Section 4 Literature Review).

Indeed, in terms of consumers substituting milk with fruit juice, research commissioned by Campbell's has found this is unlikely to occur[47]. This is because these drinks are viewed differently by consumers and the drivers of consumption differ. Juices are perceived as "nutrition boosters"—having a supporting role for healthy living; whereas milk is perceived to have more specific functional benefits in 'preventing' and 'protecting'. However, the research does not explore whether calcium-fortified orange juices may be perceived in this way. The research identifies that the drivers of consumption of milk are varied and can not be substituted by juices or water, such as in cereal or cooking.

While there may be relatively little impact on overall milk product consumption with the introduction of calcium-fortified juice/drink products, it is important to examine the overall health effects of any shift in consumption. Re-analysis of the findings indicates that in most instances, **the shift can be considered a positive trend from a health perspective**. The research shows that there are a greater proportion of respondents who shift from a "soft drink" to one of the calcium-fortified juice products, when compared to the shift from milk to these products (see Section 3.3).

[47] Research conducted by Julie Dang & Associates, commissioned by Campbell's.

While these findings do indicate that there is relatively little impact on milk consumption by calcium-fortified juice/drinks it is important to comprehensively explore the factors that influence whether such a shift could occur, such as price, branding and labelling. Further research concentrating on the Australian and New Zealand market would assist in drawing a more definitive conclusion.

The literature indicates that the consumption of functional foods is increasing and that this is largely driven by a concern for health and well-being, as these products present a healthier alternative to the consumer[48]. According to the Food Marketing Institute, consumers are more willing to use functional foods than dietary supplements[49].

In addition to the attitudinal drive, consumers' perceptions of food products, particularly in relation to their health and well-being, will ultimately rest on the products' branding and labelling. Consumers' perceptions are heavily influenced by visual aids which attempt to influence the consumer's emotional response to the product. As highlighted above, products such as calcium-fortified orange juice appeal to consumers' concern for health and well-being; claims presented on the packaging of such products are aimed at eliciting such a response.

Given these findings, and based on the data provided in the Dairy Australia research, it is not possible to draw the conclusion that there will be a significant impact on the dairy market as a result of the introduction of calcium fortified juice products. It is more apparent that the impact of the introduction of these forms of fortified products will be within category (i.e. juice categories) as opposed to between categories (i.e. between dairy and fruit juice). However, consideration should be given to the evidence that there are other factors at work when consumers make purchase decisions, which have not been measured (e.g. price, branding and food labels) in the Dairy Australia research.

[48] "Health concerns continue to drive functional food", *Nutra Ingredients* Europe website.
[49] Leighton, P. "The bright future of functional foods and beverages", *Nutraceauticals World* website, accessed 4 July 2005, http://www.nutraceuticalsworld.com/Nov021.htm

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an application to permit the addition of calcium to fruit and vegetable juices, fruit and vegetable drinks, soups and crispbread/cracker biscuits. In 2003 FSANZ invited written submissions from the public, in particular, to comment on the potential costs and benefits of the proposed change to the *Food Standards Code*.

In July 2005, FSANZ commissioned TNS Social Research (TNSSR) to review a research report that was submitted to FSANZ by Dairy Australia regarding calcium-fortified juice/drinks. The main finding of the report was that calcium-fortified fruit juice and fruit drink will appeal to a 'small but significant group' of consumers, causing concern that this will lead to the substitution of milk.

To review the findings of the report, TNSSR has taken the following steps:

- **Re-analysed** the data submitted by Dairy Australia. This data pertains to findings associated with the fortification of juice/drinks with calcium.
- **Compared and contrasted** conclusions based on our analysis of the data with the findings from Dairy Australia – noting any differences in conclusions drawn.
- **Conducted a (limited) literature review** to evaluate the validity of the findings. This literature review has concentrated on open-source material relevant to the TNSSR findings.

This report details the core differences in findings and interpretation between the initial Dairy Australia research and the TNSSR review, as well as the reasons for and implications of these differences. Also included within this report is relevant information drawn from the literature review.

2. Methodology of the Dairy Australia research

The overall aims of the Dairy Australia research of calcium-fortified juice/drinks were to determine:

- The proportion of consumers who would consider a calcium-fortified fruit juice, fruit drink or fruit juice-based cordial as a substitute for milk for:
  - themselves
  - their teenage children
  - their pre-teenage children
- The characteristics of consumers who would consider a calcium-fortified juice/drink as a substitute for milk.

The questionnaire was included as part of the Newspoll telephone omnibus survey conducted over a weekend in early 2003. In total there were **n=1200** respondents aged 18 years and over.

A copy of the key questions used in the Newspoll questionnaire can be found in Appendix 1.

2.1 Limitations of this survey approach

One of the key difficulties faced in conducting any form of consumer research is that it is difficult to assess and account for all aspects that may go toward making a purchase decision. While there maybe a number of approaches used to gather this form of information, all have limitations and restrictions that need to be taken into account when reviewing the findings.

It is important to note that criticisms about the methodology in this section are not specific to the Dairy Australia research. These are issues that are generally faced in all small-scale surveys on consumer behaviour. However as mentioned above, while it is not unique, it must be taken into account when interpreting the findings.

The key issue in terms of methodological approach with the Dairy Australia research is that the testing and questioning is conducted in an artificial environment. In particular, this survey was conducted:

- Over the telephone, with
- No visuals of the products, and
- Devoid of other key drivers of purchase, including:
    - Time pressures
    - Packaging, branding and shelf location
    - Costing implications
    - Food labels.

The presence or absence of these drivers may have a considerable impact on intended purchase behaviour, particularly in the case of switching behaviour, where price, brand and food labels may have considerable impact on intention to switch.

2.2 Research for the future

In reviewing the methodology, TNSSR would suggest two key modifications that would enhance the results, these being:

- The inclusion of stimulus material (packaging/product mock-ups), as it is well documented that packaging and labelling of a product can have a significant impact on people's consumption patterns. Therefore, to accurately understand consumers' behaviour is important to replicate as many factors as possible that will influence these patterns.
- A focus on the main grocery buyer in the household. Specifically, it is well understood that the person within the household who can be defined as the main grocery buyer has the most control over purchasing decisions for the household. Given this, targeting the main grocery buyer in the household would assist in getting a more accurate measure of purchasing behaviour.

3. Data Analysis of the Findings

The key research aims and objectives of the report for the Australian Dairy Corporation have been listed previously in Section 2 above.

Given that these objectives tap into the core information requirements of both Dairy Australia and FSANZ, it is essential that the information gathered in the survey provides insight into these objectives. TNSSR reviewed the findings of the survey to ensure that the information met these objectives. The findings are presented below.

3.1 Objective 1 – Identification of who would substitute

The following section examines the conclusions drawn in the Dairy Australia research, with regard to Objective 1, and reviews the validity of these conclusions.

3.1.1 Possible questionnaire influences on findings

In reviewing the findings from the Dairy Australia research, it is apparent that the structure and order of the questions may have had an influence on the ability of the research to gather information related to the first objective.

Specifically, question F3, F7 or F11 was asked first:

> "*Could you please tell me the sex and age of those members of your household, including yourself, who would be likely to drink fruit juice/fruit drink/fruit juice-based cordial with added calcium*?"

and then followed by question F4, F8 or F12:

> *"And what type of drink or drinks would calcium-fortified fruit juice/fruit drink/fruit juice-based cordial replace?"*

While this is a legitimate way to measure **household** consumption and switch behaviour, given that question F4, F8 and F12 are single response only, this question does not provide a measure of this behaviour for the specific household members – as required in the research objective. Essentially, substitution figures are related only to household in general, with all members of the household included in the final statistic.

In addition, it is not possible to identify the age, gender and other demographics of potential shifters due to the questions being asked of the household, as opposed to the individual drinkers. This weakens the findings from the survey, as in some cases, shifting behaviour is more negative for certain demographic types (e.g. children or women), when compared to other groups.

To address some of these concerns related to the first hypothesis, TNSSR would suggest the following revisions to the questionnaire in future research:

- Gather a base-line measurement of current juice drinking behaviour by including a question at the beginning of the questionnaire assessing whether a household currently consumes any juice/fruit drink/fruit juice-based cordial – to determine any potential changes in overall juice/fruit drink/fruit juice-based cordial consumption.
- Ensure that questions F4, F8, F12 (regarding substitution) be asked as a multiple response for each member of the household to ensure that information on how substitution would be made is available.

3.1.2 Influence of the sampling methodology

In addition to the question order having an affect on the validity of the results, it is possible that the sampling methodology may have an influence on the conclusions that can be drawn. Specifically, respondents included in questions F4, F8 and F12 (measure of replacement) are both main grocery and non-main grocery buyers. Given that questions F4, F8 and F12 refer directly to purchase behaviour, a significant proportion of the sample (the non-grocery buyers) are being asked to make an assumption about a behaviour that they do not currently exhibit. The results show that there are clear differences in potential behaviour for these two groups.

3.2 Objective 2 – Overall size of shift

The following section examines the conclusions drawn in the Dairy Australia research, with regard to the second objective that examines the characteristics of consumers who would consider a calcium fortified drink as a substitute for milk, and reviews the validity of these conclusions.

3.2.1 Possible questionnaire influences on findings

The wording of question F2 may have had a prompting effect on respondents, influencing them to indicate that they would switch from milk to one of the calcium-fortified juice/drink types.

Specifically, question F2 has a clear reference to milk:

> *"Thinking now about fruit juice with added calcium. One glass of this new fruit juice contains the same amount of calcium as one glass of milk. It would be the same price as other fruit juices. How likely would you be to buy this new fruit juice with added calcium, either for yourself or other members of your household. Would you say that you…?*

While this is a legitimate statement, it is plausible to assume that this reference creates a concrete link between the juice and milk, with regard to calcium. This prompting may have increased the number of respondents who linked the calcium-fortified fruit juice/drink options to the substitution of milk.

In addition, in accordance with the current *Food Standards Code*, comparative references are not permitted, and as a result no manufacturer is permitted to explicitly place this link on packaging. This means that this is not a valid argument for the inclusion of this reference to milk.

3.2.2 Calculation of potential for shift

One of the key conclusions from the Dairy Australia research is that *"in all cases, a small but significant group will buy the new calcium-fortified beverages and replace either regular milk, modified/low fat milk or flavoured milk"*[50]. Specifically, the research report indicates that 5.8% of respondents would substitute one of these forms of milk for calcium-fortified fruit juice, 12.2% would substitute for calcium-fortified fruit juice cordial, and 6.1% would substitute for calcium-fortified fruit juice-based cordial.

However, there are some important aspects that need to be considered before the conclusion of "a small but significant group" can be reached.

First, it is important to consider that the figures quoted on page 10 of the report are not based on the total population – rather these findings are based on a very small subpopulation of the sample.

Specifically, the base for this question is only those respondents who:

1. Would buy the calcium-fortified fruit juice/drink product; and
2. Would buy this as a replacement for one of the milk products mentioned.

There are two key impacts of this small sample population (fruit juice n=18, fruit juice drink n=21, fruit juice cordial n=12) on the interpretation of the overall findings of shift behaviour:

1. The shift figures may actually be more relevant based on the total population – as this provides a truer indication of the shift trend in the population as a whole; and
2. The base sizes for these populations are very small and incur a very high margin of error, which reduces any conclusions based on these groups.

[50] Issues Research – Calcium Fortified Drinks. Sandra Beanham and Associates. 2003

Recalculation of the figures based on the total population

As noted above, it may be more relevant to identify the proportion of "shifters" within the total population, as this provides a clearer understanding of overall population trends, as opposed to trends within a subgroup.

Once these findings are recalculated on the total base (n=1200), the figures quoted in the report represent a very small percent of the total sample, and given the weighting of the sample to reflect the general population, represent a very small proportion of the general community.
Table 1 below shows this recalculation and figures 1-3 highlight the percentages for each subgroup.

In all cases a very small group of respondents would replace either regular milk, modified/low fat milk, or flavoured milk with new calcium-fortified fruit juice/drink products. Almost all (98%) respondents would maintain their current behaviour with regard to milk consumption, with between 1.3% and 1.8% of all respondents (see Table 1 below) stating they would substitute a milk product for one of the three calcium-fortified juice types tested.

This finding does not support the conclusion that there is a 'significant proportion' of consumers who will shift from milk to a calcium-fortified juice type product.

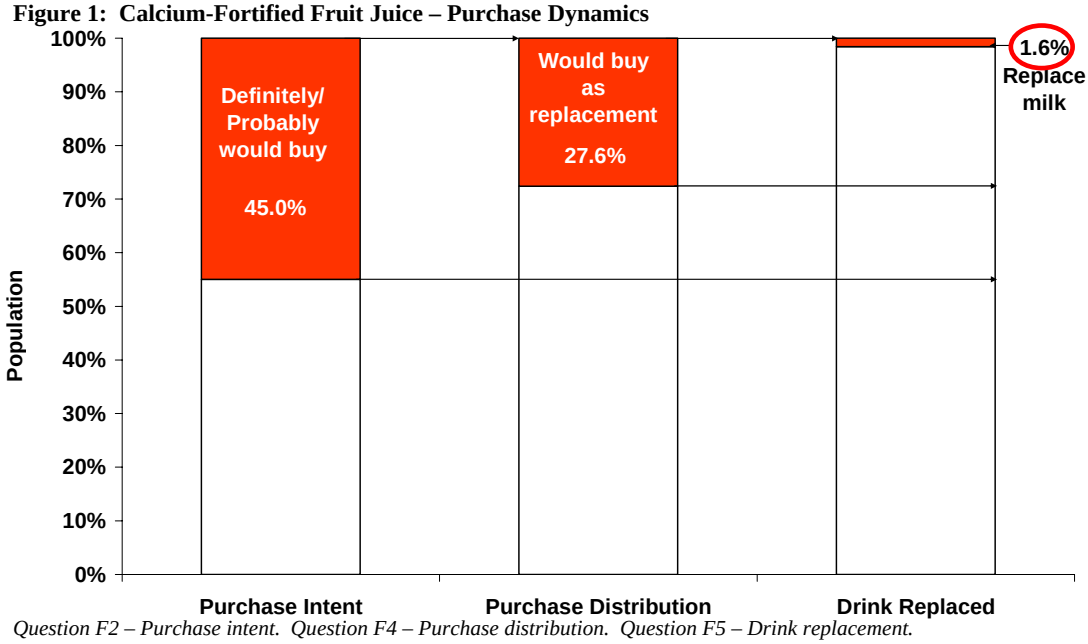
More specifically, in the Dairy Australia research, the word "significant" is not being used to represent a statistically significant finding, rather a finding that is worth noting. However, given the very small proportion of the total population that would shift from juice to dairy is very small, this result can not be considered particularly noteworthy.

Table 1: Proportion of milk substitution for calcium-fortified products

	Milk substitution (% of households)
Calcium-fortified fruit juice	1.6
Calcium-fortified fruit drink	1.8
Calcium-fortified fruit juice-based cordial	1.3

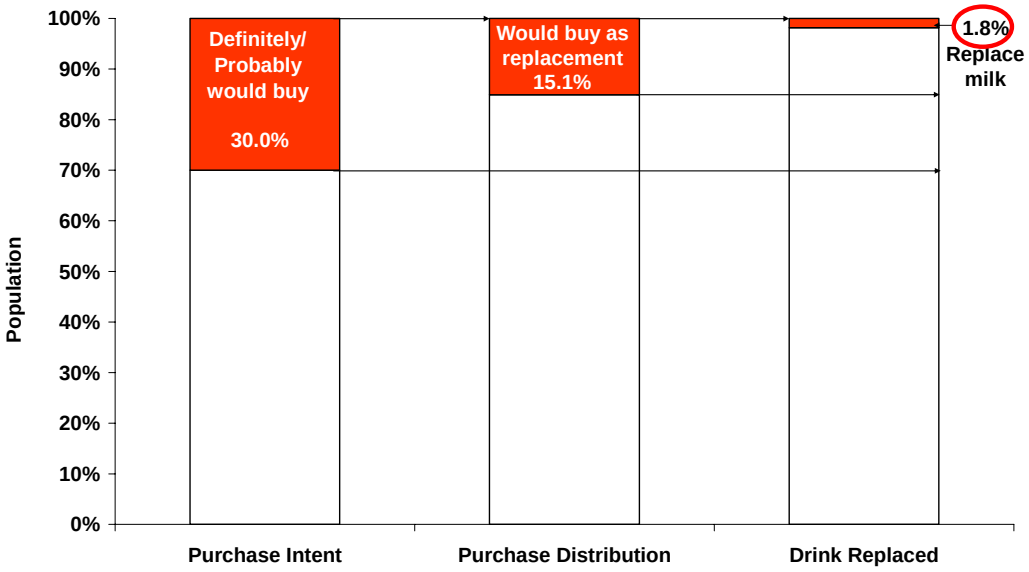
Question F5, F9 and F13: And what types of drinks would [fortified product] replace…?
Base: All respondents (n=1200)

Figure 1: Calcium-Fortified Fruit Juice – Purchase Dynamics



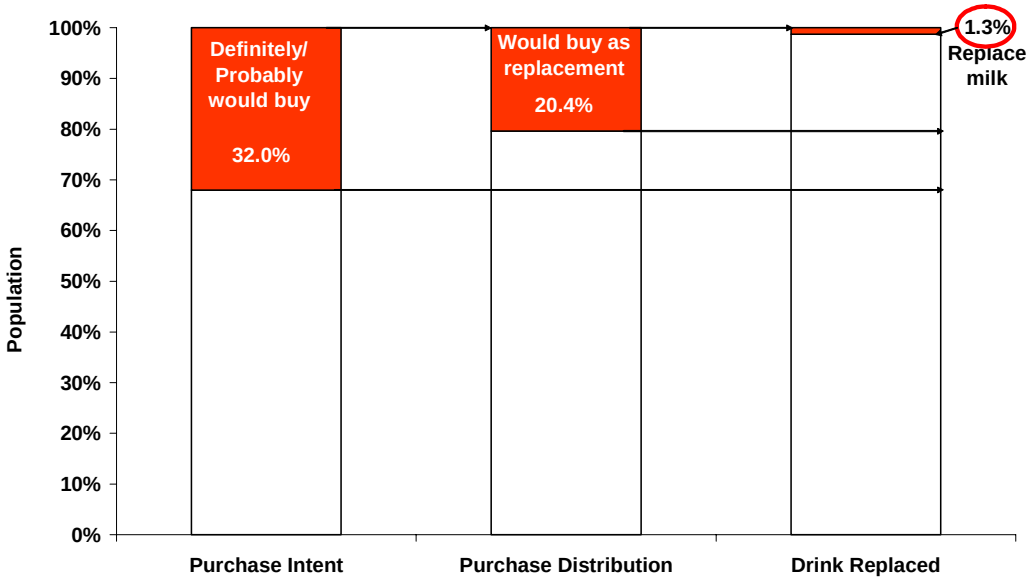
Question F2 – Purchase intent. Question F4 – Purchase distribution. Question F5 – Drink replacement.
Base: All respondents (n=1200)

Figure 2: Calcium-Fortified Fruit Juice Drink – Purchase Dynamics



Question F6 – Purchase intent. Question F8 – Purchase distribution. Question F9 – Drink replacement.
Base: All respondents (n=1200

Figure 3: Calcium-Fortified Fruit Juice-Based Cordial – Purchase Dynamics



Question F10 – Purchase intent. Question F12 – Purchase distribution. Question F13 – Drink replacement.
Base: All respondents (n=1200

Implications of small base sizes

As noted above, and in the Dairy Australia research, the base sizes for those who would shift from a milk product to a fruit juice product are very small and as a result, incur very high margins of error on a sample of n=1200, as highlighted in Table 2 below.

Table 2: Sample sizes/margins of error of respondents who would buy calcium-fortified juice/drink product as a replacement

	Sample size	Margin of error
Calcium-fortified fruit juice	18	22.9
Calcium-fortified fruit drink	21	21.2
Calcium-fortified fruit juice-based cordial	12	28.2

Question F5, F9 and F13: And what types of drinks would [fortified product] replace…?
Base: Those who would buy product as a replacement.

This means that figures related to each of these product types may be correct within a minimum of +/-20%. Indeed, the high standard error and small sample sizes indicate that most of the findings are based on statistically insignificant differences.

While results in the report have been footnoted with caution, the margin of error essentially means that any further analysis of these subgroups (e.g. demographic analysis as carried out in the report) will not yield any meaningful results and calls into question any conclusions made regarding these groups.

3.2.3 Impact of shift on milk purchase

In addition to the issues mentioned above, the Dairy Australia research concludes that the *"net effect for fortified fruit juice and fruit juice cordial will be a reduction in dairy food consumption".* Essentially, the report finds that on balance across the range of juice products, fewer milk products will be consumed. This conclusion is based on Table 3 below.

However, it is important to consider that these response categories are not mutually exclusive. This means that one respondent could be counted up to three times in this analysis (for example they say more to calcium-fortified fruit juice, calcium-fortified fruit drink and calcium-fortified fruit juice-based cordial). The reverse is also true (say fewer to all three). Given that the survey is analysing purchase behaviour for one type of product (juice) it is not appropriate to count respondents more than once in this analysis as it is plausible to assume that they would generally only buy one juice product or the other.

Given this non-exclusivity, **it is not possible to assume that there will be a net reduction in consumption.** To accurately calculate this change, the base size needs to be recalculated to represent all respondents who have said fewer at least once and more at least once, thereby removing the duplicity in responses. TNSSR did not have access to raw data to recalculate these figures and as a result, can not make a conclusion about dairy food losses or gains.

Table 3: Changes in consumption as a result of the introduction of calcium-fortified fruit juice/drink products

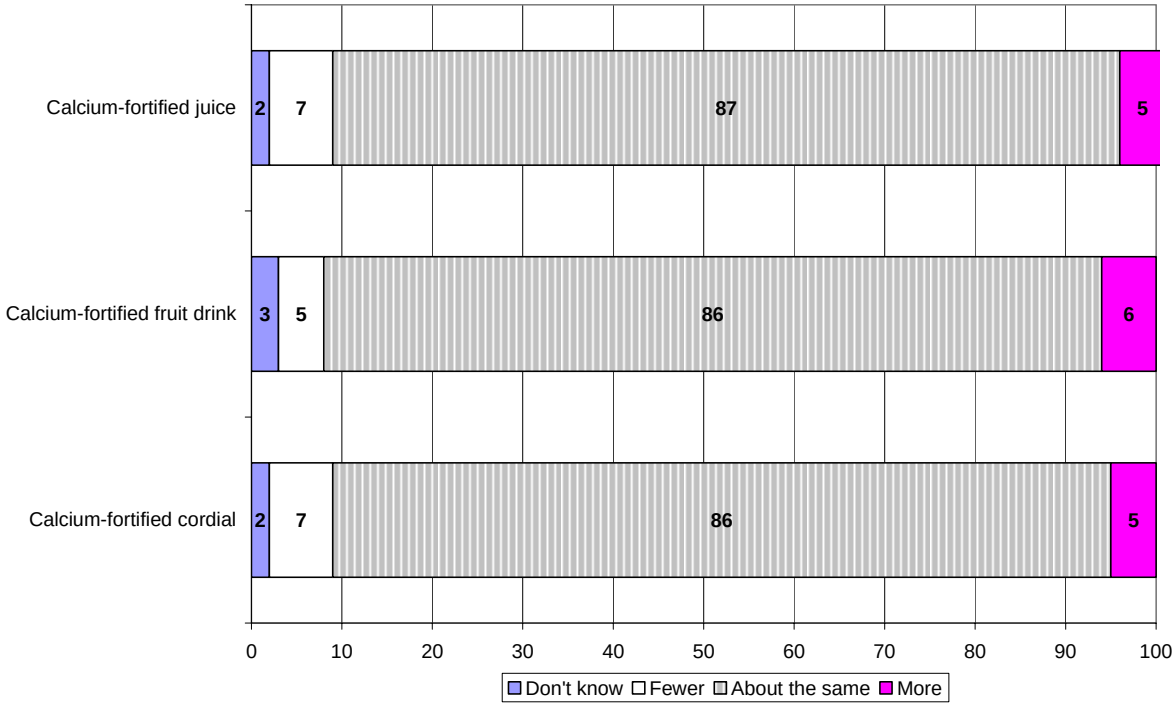
	More	Fewer	Net +/-
Calcium-fortified fruit juice	5.3	6.6	-1.3
Calcium-fortified fruit drink	6.2	5.0	+1.2
Calcium-fortified fruit juice-based cordial	7.1	5.2	-1.9

Question F4, F8 and F12: And would you buy [fortified product] with added calcium in addition to the drinks that you buy now, or as a replacement…?
Base: All respondents (n=1200)

It is also important to consider the large number of respondents who would remain at the same level of dairy consumption (Figure 4 below). Indeed**, almost 9 in 10 respondents would continue to use the same number of dairy products** regardless of there being a calcium-fortified juice/drink product available. In addition, the differences between increasing and decreasing of the dairy consumption are insignificant.

Given these findings, it is plausible to assume that the introduction of calcium-fortified juice/drink to the market **would not affect the consumption of dairy products**.

Figure 4: Changes in consumption of milk products as a result of calcium-fortified juice/drink products



Question F4, F8 and F12: And would you buy [fortified product] with added calcium in addition to the drinks that you buy now, or as a replacement…?
Base: All respondents (n=1200)

3.2.4 Degree of shift

When looking at shift behaviour it is important to consider not just the likelihood of a consumer shifting from milk to a calcium-fortified juice/drink product, but also the magnitude and frequency of this shift. For example:

- **The magnitude of the substitution**: Would the fortified fruit juice product replace milk entirely, or would it only replace milk to a certain degree (i.e. a reduction from five serves of dairy a day to four)? If a respondent were to substitute milk completely for juice this would have a considerably higher commercial and health impact than if it were only a very limited substitution.
- **The circumstances of substitution**: From a health, policy and impact perspective, it is important to understand under what circumstances substitutions would be made (i.e. would juice be substituted in all cases, including coffee, cereal etc). Again, this information has a considerable impact on the total volume of substitution and health implications of this substitution.

While it is important to measure these aspects, the research commissioned by Dairy Australia does not gather this information, and as a result, this needs to be taken into account when reviewing the findings. While it is possible that between 2% and 12% (depending on the base used) may substitute calcium-fortified products for milk, **the magnitude of this shift may be relatively small** depending on how the juice products are used and to what degree they are substituted for milk.

3.3 Impact of shift on health

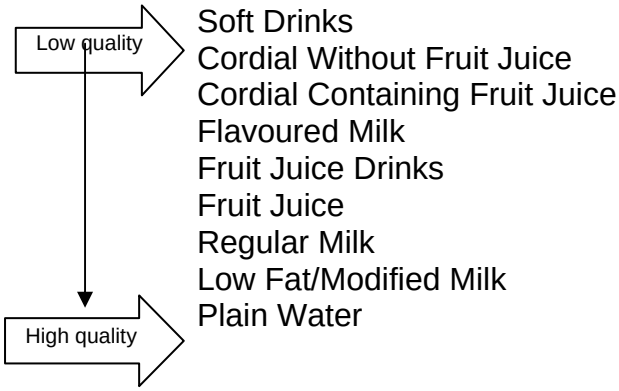
While it appears that there is relatively little impact on milk consumption with the introduction of calcium-fortified products, TNSSR reviewed the data in terms of direction of shift for health (either a positive shift or a negative shift) to further analyse if there was any negative impact of a change in consumption.

It is important to note that the example below represents one way that the beverages could be classified in terms of health (it is perfectly acceptable to have these beverages in a different order) and that this analysis is provided purely as a demonstration of the impact of the introduction of new juice products within this framework.

Positive shift (i.e. moving toward a more healthier choice):

A positive shift is defined as households which would replace a particular calcium-fortified fruit juice/drink for a "lower quality" drink (e.g. soft drink) or buy a calcium-fortified fruit juice/drink in addition to the drinks they usually buy, according to the categorisation below.

Figure 5: Categorisation of drinks



Possibly negative shift (i.e. moving toward a less healthier choice):

This shift is defined as households which would substitute a particular calcium-fortified fruit juice/drink for a "higher quality" drink (e.g. water). However, given that it is not possible to identify household members for whom this shift would be made, this shift can only be considered to be of 'possible' benefit as it may be more detrimental for some demographic groups to shift, when compared to other groups. Table 4 (overleaf) shows this analysis.

It is clear that the general trend with the introduction of calcium-fortified fruit juice/drinks can be considered a positive trend. For all three juice types, the vast majority of top of mind[51] results can be considered to be a positive shift (95% for calcium-fortified fruit juice, 72% for calcium-fortified fruit drink and 89% for calcium-fortified fruit juice-based cordial). This pattern is reflected in second mentions.

For calcium-fortified fruit juice and calcium-fortified fruit juice-based cordials there were very few negative trends (less than one in ten). However, approximately one third of shifts for calcium-fortified fruit drink could be considered to be negative. One important point is that shifts from soft drink to calcium-fortified drink are greater (8.8% juice; 5.2% drink; 7.1% cordial) than shifts from milk to calcium-fortified fruit juice/fruit juice-based cordial (3.5%, 3.9%) and about the same for milk to calcium-fortified fruit drink shift (6.2%).

However, although these changes represent a positive shift from a policy and overall health perspective, they may represent a negative trend from a commercial perspective (i.e. reduction in sales).

Table 4: Positive or negative shift trends

	Definitely positive shift (% of households – potential calcium-fortified drinkers)		Possibly negative shift (% of households - potential calcium-fortified drinkers)	
	First Mention[1]	Total Mentions[2]	First Mention[1]	Total Mentions[2]
Calcium-fortified fruit juice	95.7%	109.4%	1.5%	3.7%
Calcium-fortified fruit drink	71.8%	86.8%	23.3%**	30.4%**
Calcium-fortified fruit juice-based cordial	88.5%	99.0%	8.5%	15.7%

Question F5, F9 and F13: And what types of drinks would [fortified product] replace…?
Base: Variable base:
[1] Overall value less than 100% as "Other" responses hasn't been classified
[2] Overall value exceed 100% due to multiple responses of respondents

[51] Top of mind responses are those that were mentioned as a first mention in this multiple response question

3.4 Conclusions from the data analysis

Generally, from the review of the data, which is based on consumers' purchase intentions, it is indicative that there is relatively little impact of calcium-fortified fruit juice/drinks on the purchase of milk products for the population as a whole. As noted in the Dairy Australia research, the proportion of those who would shift from a milk product to a calcium-fortified juice product is very small and in reviewing the data, it is clear that this proportion **does not present a significant reduction in the consumption of milk.**

More specifically based on the total number of respondents, **less than 2% of the population** would shift from a milk product to a calcium-fortified fruit juice/drink product. Furthermore, almost all (90%) indicate that their current consumption of milk products would **remain at the same level**, regardless of the availability of calcium-fortified products. Due to high margins of error associated with these very small sample sizes it is not possible to draw any meaningful conclusions about the profile of those who may shift from milk to a calcium-fortified juice/drink or confirm their motivations behind shifting.

In addition to these findings, it is important to note that the Dairy Australia research is not able to identify the magnitude of the shift (how many serves a day would be replaced) or the degree to which specific milk products would be replaced and under what conditions this substitution would take place (see Section 3.2.4). This information would provide a greater insight into the true impact of any substitution behaviour.

It is also not possible to identify who, within the household, would shift from a milk product to a calcium-fortified fruit juice/drink. Essentially, the findings only represent households in general and the research does not provide information on which target groups are shifting. This could have considerable impact on the implications of a shift in consumption (i.e. shift may be considered more detrimental for one consumer group compared to another target group).

While there may be relatively little impact on overall milk product consumption with the introduction of calcium-fortified fruit juice/drinks, it is important to examine the overall health effects of any shift in consumption. Re-analysis of the findings indicates that in most instances, **the shift can be considered a positive trend from a health perspective**. The research shows that there is a greater proportion of respondent who shift from a "soft drink" to one of the fortified juice products, when compared to the shift from milk to these products.

4. Literature Review

Currently, little is known about the impact calcium-fortified orange juice/drinks will have on consumers' purchasing patterns. In particular, whether the addition of this product will lead people to decrease their consumption of calcium-containing milk products in favour of calcium-fortified fruit juices/drinks. The following issues require consideration:

- The growth of the consumption of calcium-fortified juice and the potential impact on the consumption of milk products.
- The factors that influence consumption of calcium-fortified juices/drinks, such as general perceptions of functional foods, branding and labelling, and pricing.

In addition to reviewing the data that was obtained in the survey, TNSSR conducted a limited literature review of articles included in the response to the FSANZ evaluation of the research by Dairy Australia and other literature related to the impact of calcium-fortified products on other categories.

4.1 Understanding growth in the calcium-fortified market

Generally, the literature provided by Dairy Australia is evidence of the growth of calcium-fortified orange juice/drink within the orange juice/drink market. There is no evidence that directly links the increase in consumption of calcium-fortified orange juice/drink to a decrease in the consumption of milk products.

An article in *New Nutrition Business*[52], notes that Tropicana calcium-fortified orange juice "is clearly targeted as a substitute for milk" but does not elaborate whether this substitution has in fact occurred. A statement of initial concern for the dairy industry is that, "The Tropicana brand grew no less than 96% in 1998, propelling 59% growth of the total category". In other words, partly due to their calcium-fortified orange juice, the Tropicana brand grew by almost 100 per cent, which lead to growth of the total category (although not specified, it is assumed they are referring to fruit beverages). However, this statement does not refer to the impact on the dairy industry or the consumption of milk.

Likewise, the statement from *Nutraceuticals World* that Tropicana's calcium-fortified beverages have driven sales up 173 per cent and build "a new category segment in the refrigerated juice business" is again pointing to the growing popularity of calcium-fortified products within the fruit beverage market but does not specify the implications beyond this limited market[53].

[52] "Pepsico aims for a healthier profile", *New Nutrition Business* website, accessed 4 July 2005. www.new-nutrition.com/newspage/pepsico03.htm

[53] Leighton, P. "The bright future of functional foods and beverages", *Nutraceauticals World* website, accessed 4 July 2005, http://www.nutraceuticalsworld.com/Nov021.htm

The use of sales percentages can sometimes give the impression that changes in sales volume are much more dramatic than they are, especially when a new product has entered the market. A new product will often start with relatively low sales, providing a low base number so that growth as a percentage of this base appears very high. When examining such data it is also useful to examine the actual sales volumes, which can give a clearer indication of the extent of sales. However, the article did not supply this information.

The *Beverage Daily* website highlights a report from the marketing firm Mintel, which finds fruit juice sales in the UK are being driven by a perception that it a healthier alternative to coffee and fizzy drinks[54]. A similar Mintel report on fruit juice and juice drinks in the US finds consumers are tending to steer away from these products due to high sugar and calorie content. The report concludes that "future product innovations, such as low calorie juice products and fortified juices, will be necessary to drive growth"[55]. Thus, it appears that the fruit juice industry is being driven by consumers perceptions about the health benefits of fruit juice due to an increasing demand for healthier alternatives. In this environment, calcium-fortification and product labelling are likely to play an important role in the consumption of fruit juice.

In terms of consumers substituting milk with fruit juice, research commission by Campbell's has found this is unlikely to occur[56]. This is because these drinks are viewed differently by consumers and the drivers of consumption differ. Juices are perceived as "nutrition boosters"—having a supporting role for healthy living; whereas milk is perceived to have more specific functional benefits in 'preventing' and 'protecting'. However, the research does not explore whether calcium-fortified orange juices may be perceived in this way. The research identifies that the drivers of consumption of milk are varied and can not be substituted by juices or water, such as on cereal or in cooking.

4.2 Influences on consumption of calcium-fortified orange juice/drink

Amongst the literature there is general agreement that the consumption of functional foods is increasing and that this is largely driven by a concern for health and well-being, and they present a healthier alternative to the consumer[57]. According to the Food Marketing Institute, consumers are more willing to use functional foods than dietary supplements[58].

[54] "Fruit juice and juice drinks – UK – November 2004" *Mintel* website, accessed 1 August 2005, http://reports.mintel.com/sinatra/reports/search_results/show&&type=RCItem&page=0&noaccess_page=0/display/id=4256#contents
[55] "Fruit juice and juice drinks – US – January 2005" *Mintel* website, accessed 1 August 2005, http://reports.mintel.com/sinatra/reports/search_results/show&&type=RCItem&page=0&noaccess_page=0/display/id=121091
[56] Research conducted by Julie Dang & Associates, commissioned by Campbell's.
[57] "Health concerns continue to drive functional food", *Nutra Ingredients* Europe website,
[58] Leighton, P. "The bright future of functional foods and beverages", *Nutraceauticals World* website, accessed 4 July 2005, http://www.nutraceuticalsworld.com/Nov021.htm

Consumers' perceptions of food products, particularly in relation to their health and well-being, will ultimately rest on the products' branding and labelling. The research by Dairy Australia was conducted over the phone and was unable to explore the impacts of visual aids in the promotion of products.

"*Debate all you will, it all comes down to how consumers perceive a product and whether it fulfils a desired benefit or need*"[59].

Consumers' perceptions are heavily influenced by visual aids which attempt to influence the consumer's emotional response to the product. As highlighted above, products such as calcium-fortified orange juice/drink appeal to consumers' concern for health and well-being; claims presented on the packaging of such products are aimed at eliciting such a response.

Previous research conducted by TNSSR and commissioned by FSANZ, has found that health claims clearly have an influence on consumers' intent to purchase food products[60]. Respondents were found to be more likely to purchase a product with a health claim than with no claim at all. Furthermore, graphic labels and brand names were also shown to be "powerful mechanisms for inferring health benefits"[61]. Health claims were also found to be a source of health information for consumers. Those who agreed that a product with a health claim had a health benefit were more likely to perceive this product as having a 'strong effect' on health impact compared to those products without a claim.

A comprehensive review of research (from Australia and overseas) on consumers' use of health claims found that there is general agreement that consumers perceive health claims to be useful, perceive that product to be healthier, and report that they are more likely to purchase a product with a health claim[62]. Furthermore, in the United States and Europe, there is evidence that health claims can increase the product's market share. However, research in Canada has found that the impacts of health claims are most likely to occur amongst consumers who already purchase that type of product, and that people are unlikely to switch to another product because of a health claim[63].

In addition to dietary preferences, health considerations and the impact of labelling, price also plays a significant role in consumer choices[64].

[59] ibid.
[60] TNSSR (2005) *Research On Consumers' Perceptions And Use Of Nutrition, Health And Related Claims On Packaged Foods And Associated Advertising Material,* A research report commissioned by FSANZ.
[61] ibid, p.6.
[62] Williams, P. (2005) "Consumer understanding and use of health claims for foods",
[63] National Institue of Nutrition. (1999) *Health Claims in Canada – Taking the Consumer Pulse.* Ottawa, National Institute of Nutrition. http://www.agr.gc.ca/misb/fb-a/nutra/index_e.php?s1=potent&page=intro
[64] Keller, J.L., Lanou, A.J., Barnard, N.D. (2002) "The consumer cost of calcium from food and supplements", *Journal of The American Dietetic Association*, Vol.102, No.11, pp.1669-1671.

A US study that recorded the costs and level of absorbable calcium of a variety of calcium-containing products found that calcium carbonate supplements were the least expensive source of calcium—approximately one-third of the cost of the least expensive food source of calcium[65]. The least expensive food source was a brand of calcium-fortified cereal. The study found that milk (skim and whole) and calcium-fortified orange juice concentrate (in it's frozen form) are comparable in cost, being the next least expensive items[66]. The researchers found that a 1 per cent increase in income or a 10 per cent decrease in dairy prices would be expected to have the impact of increasing calcium intake of 2.6 per cent.

4.3 Conclusions from the literature review

The research that explores the impact of calcium-fortified orange juice/drink on consumption patterns and the impact of health on consumers is limited. In most cases, tenuous conclusions can be drawn from the literature review.

Market information suggests that the growth in the consumption of calcium-fortified orange juice/drink is a result of decrease in other types of fruit beverages, in an otherwise stable market. The growth has come from consumers' movement towards purchasing 'health and well-being' products. One information source about whether a product promotes health and well-being is the labelling information displayed on the product. Consumers are more likely to purchase products with health claims than those without.

More research is needed about the different types and power of labelling and branding of calcium-fortified orange juice/drinks and the possible impact this could have on the consumption of milk products. For example, it would be expected that aggressive branding that directly compared calcium-fortified orange juice to milk would have a significant impact on consumers' consumption patterns.

There has been no evidence of shift away from milk directly to calcium-fortified orange juice/drink but it is important to comprehensively explore the factors that influence whether such a shift could occur, such as price, branding and labelling. Research conducted in Australia and New Zealand in these areas would assist a more definitive conclusion.

[65] ibid
[66] It is unclear why the study does not include calcium-fortified orange juice in its liquid, un-concentrated form.

Appendix 1

Key questions from the questionnaire

Question F2/F6/F10

Thinking now about a **[product]** with added calcium**.** One glass of this new **[product]** contains the same amount of calcium as one glass of milk. It would be the same price as other fruit juices. How likely would you be to buy this new fruit juice with added calcium either for yourself or other members of your household? Would you say that you...? **(read out 1-5)**

Definitely would buy.....1
Probably would buy 2
Might or might not buy.....3
Probably would not buy.....4
Or, defiantly would not buy.....5
Don't know.....6

Ask if would buy i.e. code 1-2 in F2/F6/F10. Code 3-6 Go to F6/F14

Question F3/F7/F11

Could you please tell me the sex and age of those members of your household, including yourself, who would be likely to drink **[product]?**

Males
0-4 years.....01
5-9 years.....02
10-12 years.....03
13-17 years.....04
18-24 years.....05
25-39 years.....06
40 years and older.....07

Females
0-4 years.....08
5-9 years.....09
10-12 years.....10
13-17 years.....11
18-24 years.....12
25-39 years.....13
40 years and older.....14
None/Don't know.....15

Question F4/F8/F12

And would you buy **[product]** in **addition** to the drinks you buy now or as a **replacement**?

In addition.....1
As a replacement.....2
Don't know.....3

Ask if replacement in code 2 in F4. Code 1,3 go to F6/F14

Question F5/F9/F13

And what type of drink or drinks would **[product]** replace? Which other drinks **(record first, second and other mentions.**

If do not mention two/three circle code 12 (none/ don't know) in all remaining columns).

If fruit juice

Is that fruit juice or fruit drinks containing at least 25 percent juice?

If cordial

Is that a cordial with fruit juice or without fruit juice?

If milk

Is that plain or regular milk, low fat milk or flavoured milk?

	First	Second	Other
Fruit juice	01	01	01
Fruit drinks, containing at least 25 percent juice	02	02	02
Cordial containing fruit juice	03	03	03
Cordial **without** fruit juice	04	04	04
Plain/ regular milk	05	05	05
Low fat or modified milks suck as skim, physical or tone	06	06	06
Flavoured milk	07	07	07
Drinking yoghurt	08	08	08
Soft drinks	09	09	09
Plain water	10	10	10
Other (specify)	11	11	11
None/don't know	12	12	12

Go to F6/F14

Question F14

Thinking of dairy products like milk, cheese, yoghurt and drinking yoghurt.

How often would you ... **[product]?** Would it be...? **(read out 01-09 as necessary)**
Repeat question for each product A-E.

	A	B	C	D	E
	Have milk with tea or coffee	Have milk with cereal	Drink a serve of milk where a serve is equal to 250 ml	Eat a serve of **any** type of cheese where a serve is equal to 2 cheese slices	Have a serve of yoghurt or drinking yoghurt where a serve is equal to 200 grams
4 times or more a day	01	01	01	01	01
3 times a day	02	02	02	02	02
Twice a day	03	03	03	03	03
Once a day	04	04	04	04	04
4-6 times a week	05	05	05	05	05
2-3 times a week	06	06	06	06	06
Once a week	07	07	07	07	07
Less often	08	08	08	08	08
Or, never	09	09	09	09	09
Don't know	10	10	10	10	10

Question F15

If you were to buy these new calcium added **[product]** do you think you or your household would eat or drink **more,** about the **same** or **fewer** dairy products on an average day than you do now?

More.....1
About the same.....2
Fewer.....3
Don't know 4

Question F16

Thinking now of **regular** milk, as far as you're aware, what are the main nutrients in regular milk, besides calcium? Which others?

Carbohydrates.....01
Magnesium.....02
Phosphorus.....03
Potassium.....04
Protein.....05
Riboflavin/vitamin B2.....06
Vitamin A.....07
Vitamin B12.....08
Zinc.....09
Other (specify).....10
None/don't know.....11