06/03
18 December 2002

DRAFT ASSESSMENT REPORT

APPLICATION A424

FORTIFICATION OF FOODS WITH CALCIUM

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
12 February 2003
(See “Invitation for Public Submissions” for details)
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 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 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.

INITIAL ASSESSMENT
- Comment on scope, possible options and direction of regulatory framework
- Provide information and answer questions raised in Initial Assessment report
- Identify other groups or individuals who might be affected and how – whether financially or in some other way

DRAFT ASSESSMENT
- Comment on scientific risk assessment; proposed regulatory decision and justification and wording of draft standard
- Comment on costs and benefits and assessment of regulatory impacts

MINISTERIAL COUNCIL
- An IA report is prepared with an outline of issues and possible options; affected parties are identified and questions for stakeholders are included
- Applications accepted by FSANZ Board
- IA Report released for public comment

PUBLIC INFORMATION
- Those who have provided submissions are notified of the Board’s decision

FINALE ASSESSMENT
- Public submissions collated and analysed
- A Draft Assessment (DA) report is prepared using information provided by the applicant, stakeholders and other sources
- A scientific risk assessment is prepared as well as other scientific studies completed using the best scientific evidence available
- Risk analysis is completed and a risk management plan is developed together with a communication plan
- Impact analysis is used to identify costs and benefits to all affected groups
- An appropriate regulatory response is identified and if necessary a draft food standard is prepared
- A WTO notification is prepared if necessary
- DA Report considered by FSANZ Board
- DA Report released for public comment

PUBLIC ASSESSMENT
- Comments received on DA report are analysed and amendments made to the report and the draft regulations as required
- The FSANZ Board approves or rejects the Final Assessment report
- The Ministerial Council is notified within 14 days of the decision

If the Ministerial Council does not ask FSANZ to review a draft standard, it is gazetted and automatically becomes law in Australia and New Zealand.

The Ministerial Council can ask FSANZ to review the draft standard up to two times.

After a second review, the Ministerial Council can revoke the draft standard. If it amends or decides not to amend the draft standard, gazetral of the standard proceeds.
INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared a Draft Assessment Report of Application A424; and prepared a draft variation to the Food Standards Code.

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

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in Section 10 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the Food Standards Code (Code) from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

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

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

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

Submissions should be received by the Authority by: 12 February 2003. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or 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 enquiries and requests for information.
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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ, formerly ANZFA) 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 joint 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 crispbread/cracker type biscuits.

A total of 28 submissions were received in response to the Initial Assessment Report. The Australia New Zealand Food Authority (ANZFA) to FSANZ transitional requirements for an application at full (draft) assessment stage have been followed and no additional submissions have been received.

Regulatory Problem

Vitamins or minerals are not permitted to be added to [general-purpose] foods unless the addition of that 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. There is not currently any permission for the addition of calcium to any of the food products requested by the applicant.

Objective

To determine whether the Code should be amended to permit the voluntary fortification of the food products requested in the application with calcium. Any such amendment would need to be consistent with the objectives set out in section 10 of the FSANZ Act.

Background

Regulatory principles for the voluntary vitamin and mineral addition to general purpose foods were developed by ANZFA previously and were derived from the Codex General Principles for the Addition of Essential Nutrients to Foods (Codex General Principles) developed by the Codex Alimentarius Commission.

Issues

FSANZ has recently clarified and elaborated the regulatory principles for addition of vitamins and minerals to foods. This clarification and elaboration was undertaken in order to:

• provide a basis for decision making in relation to relevant applications until such time as the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) develops policy on the matter; and

• respond to calls from submitters for a review of the regulatory principles (and Standard 1.3.2) in order to address the perceived inequity of vitamin and mineral permissions.

This application has been assessed against the (clarified and elaborated) regulatory principles for addition of vitamins and minerals to foods.
Issues considered in the Draft 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; an assessment of the risk of nutrient deficits or imbalances; a consideration of potential effectiveness; 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, as requested by the applicant, and approve the voluntary addition of calcium to the food products requested by the Applicant.

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, matters raised by submitters and the Regulatory Impact Statement (RIS). 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 under Option 2.

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

Consultation

A total of 28 submissions were received in response to the Initial Assessment Report released in December 2001. Of these submissions, 12 submitters unconditionally supported Option 2 and 8 submitters opposed the application in its entirety. Other submitters either: supported limited permissions (variation of Option 2); declined to support either option; or thought the application should not be assessed in isolation of a review of Standard 1.3.2 – Vitamins and Minerals, and the regulatory principles underpinning the Standard.

Conclusion and Statement of Reasons

FSANZ recommends the approval of the application to permit the voluntary addition of calcium to fruit and/or vegetable juices, fruit and/or vegetable drinks, fruit cordial, soups and crispbread/cracker-type biscuits for the following reasons:
• Calcium is considered to be potentially eligible for voluntary fortification (subject to risk assessment) because, in accordance with the regulatory principles for the addition of vitamins and minerals to foods, more than one population subgroup in both Australia and New Zealand has a customary intake below 30% of the Estimated Average Requirement (EAR) 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 are consistent with general dietary guidance.

• 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 to all the proposed foods.

• 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 permission to voluntarily add calcium is taken up by industry.

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

It is recommended that all food categories requested by the applicant be granted a permission to voluntarily add calcium to a level that allows a ‘good source’ content claim (at least 25% of the Recommended Dietary Intake (RDI) per reference quantity) to be made.

The proposed drafting for an amendment to Standard 1.3.2 – Vitamins and Minerals, is at Attachment 1 of the Draft Assessment Report.

1. Introduction

1.1 Subject of the Application

Food Standards Australia New Zealand (FSANZ, formerly ANZFA) 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 joint 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 crispbread/cracker type biscuits.

1.2 Transitional Requirements

This application reached Initial Assessment stage under the operation of the Australia New Zealand Food Authority Act 1991 (ANZFA Act), and will be finalised in accordance with the provisions of the Food Standards Australia New Zealand Act 1991 (FSANZ Act).

FSANZ has therefore been required to:

1. give the applicant the opportunity to (by 29 July 2002) request deferral of consideration of the application in order to provide any additional information;
2. give notice under section 13A or 14 of the FSANZ Act; and

3. review the initial assessment having regard to any new submissions received in response to the above notice as well as any written policy guidelines that have been notified by the Ministerial Council.

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. Standard 1.3.2 of Volume 2 regulates the addition of vitamins and minerals to [general purpose] foods (with some exceptions such as special purpose foods e.g. infant formula), and the claims, which 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 however, there is no permission for the voluntary addition of calcium to the products proposed by the applicant. Certain vitamins and minerals other than calcium are permitted to be added to biscuits. However, it should be noted that this permission is only relevant to biscuits containing not more than 200 g/kg of fat and not more than 50 g/kg of sugar. The applicant has not requested any change to the sugar and fat restrictions on the fortification of biscuits as part of this application and so in effect, the application applies only to cracker type, crispbread type and some savoury biscuits (hereafter referred to as crispbread/cracker-type biscuits). A request for the review of the prohibition on fortification of sweet biscuits is the subject of another application currently being considered by FSANZ, Application A430 – Fortification of Sweet Biscuits.

The Table to clause 3 of Standard 1.3.2 sets reference quantities for products that may have vitamins or minerals added within this context. Reference quantities of 200 mL for fruit/vegetable juice, fruit drink, fruit cordial and 35 g for crispbread/cracker type biscuits have been set. These reference quantities have been used throughout this assessment.

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). Some fruit drinks have also appeared on the Australian market, which carry claims for 25% of the RDI for calcium per 200 mL serving. The source of calcium is stated as ‘whey powder’.

2.2 Requested amendment to Standard 1.3.2

The applicant requests an amendment to Standard 1.3.2 to permit the voluntary addition of permitted calcium salts specified in the Schedule to Standard 1.1.1 to the proposed products so as to allow a maximum claim per reference quantity of 25 percent of the RDI.

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1 As specified in the Schedule to Standard 1.1.1 of the Code, unless stated elsewhere in the Code.
In order to do this, an amendment to the Table to clause 3 of Standard 1.3.2 of the Code would be required. There are no vitamins and minerals currently permitted to be added to soups and as such, there is no reference quantity set for soups. The applicant has proposed a reference quantity for soup of 200 mL. This reference quantity has been used throughout the assessment. Soup and vegetable drinks are new food categories in the Table, all other food categories have reference quantities set in Standard 1.3.2. The applicant has not requested approval of any additional forms of calcium and as such, no additional forms of calcium will be considered as part of this assessment process.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the Food Standards Australia New Zealand Act 1991. 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 as follows:

1. Assess (with the assistance of public submissions) the net benefits to the community of permitting a range of foods to be fortified with calcium in terms of public health and safety impacts on consumers, industry, public health professionals and governments.

2. Ensure adequate information be 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 Volume 1 of the 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. 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 developed by ANZFA in 1995 and derived from the Codex General Principles for the Addition of Essential Nutrients to Foods (Codex General Principles) developed by the Codex Alimentarius Commission. These regulatory principles were reviewed in 1999 as part of the development of joint Australia New Zealand food regulation.

Some industry submitters to the Initial Assessment Report for Application A424 indicated that a review of the regulatory principles pertaining to the voluntary addition of vitamins and minerals to foods is required, as well as a review of Standard 1.3.2 – Vitamins and Minerals in order to address the perceived inequity of permissions for different food categories across the Standard.

In June 2002, the FSANZ Board granted an extension of six months to the statutory timeframe for the assessment of Application A424. This extension was based on the need to clarify and elaborate FSANZ’s regulatory principles for the addition of vitamins and minerals to foods in order to provide a basis for future decision making in relation to relevant applications and proposals until such time as the ANZFRMC develops policy on this matter. The Food Regulation Standing Committee (FRSC) has recently commenced work on new policy guidelines in relation to food fortification on behalf of ANZFRMC however, in accordance with the FSANZ Act, this Application has to be assessed within the statutory timeframe and cannot be delayed pending guidance from ANZFRMC.

FSANZ has clarified and elaborated its regulatory principles pertaining to the addition of vitamins and minerals to foods, and those pertaining to general-purpose foods are at Attachment 2. These regulatory principles have been used as the basis for decision making with respect to Application A424.

This clarification and elaboration of the regulatory principles should in part address the concerns of submitters outlined above. FSANZ is not planning to review Standard 1.3.2 as this is outside the scope of this Application. The regulatory principles provide sufficient detail to guide manufacturers and regulators on the addition of vitamins and minerals to foods.

5. Relevant Issues

5.1 Regulatory Principles for Addition of Vitamins and Minerals to Food

The Regulatory Principle pertaining to the voluntary fortification of general purpose foods is relevant to this application and is stated in boxed text below. Consideration of the addition of all vitamins and minerals to any food/nutrient combination will be made in the context of a risk assessment framework.
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:
      i) added sugars\(^2\); 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.

5.2 Assessment of A424 against the Regulatory Principle 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 in terms of a risk framework.

5.2.1 Eligibility of Calcium for Potential Fortification

FSANZ has assessed the adequacy of calcium intakes of the total population and population subgroups by reference to the EAR for calcium established by the United Kingdom. An EAR is a value that represents the median requirement for the dietary intake of a particular nutrient in a given population group.

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\(^2\) 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.
An RDI by contrast, 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. At the time of this report, no EARs had been established for Australian or New Zealand populations and only the United States and the United Kingdom have established EARs for their populations. The EARs established by the United Kingdom were chosen for use over EARs established by the United States since Dietary Reference Values produced by the United Kingdom are generally more compatible with Australian RDIs. The EARs for calcium established by the United Kingdom are provided at in Table 1. FSANZ has concluded that 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. For more detail on the rationale for this method of establishing nutrient inadequacy or further explanation refer to Attachment 2.

Percentages of respondents to the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey with intakes below the United Kingdom EAR for calcium were determined. Submitters to the Initial Assessment Report suggested that the dietary intake assessment should more specifically target adolescents, young women and women over 65 years. As such, narrower subgroups have been incorporated into the assessment.

There were a number of population subgroups with 30% or more of respondents whose calcium intake was below the EAR for calcium (Table 1). In Australia, more than 30% of the respondents within the following subgroups consumed less than the EAR for calcium: males 11-12 years and 13-15 years; and females 11-12 years, 13-15 years, 16-18 years, 19-24 years, 25-44 years, 45-64 years and 65+ years. In New Zealand, more than 30% of the respondents within the following subgroups consumed less than the EAR for calcium: males 15-18 years, 45-64 years and 65+ years; and all female age groups (only respondents 15 years and over were surveyed). For New Zealand, 33.9% of all respondents consumed less than the EAR. The results are summarised in Table 1 below and the percentages of subgroups where more than 30% of the subgroup do not meet the EAR are presented in bold text.

In its report titled “The burden of brittle bones”, Access Economics reports that in 2001, nearly two million Australians have osteoporosis-related conditions. Osteoporosis is a multifactorial disease with calcium intake being one relevant factor (refer to Attachment 3 for more detail on osteoporosis). However, increasing the calcium intake of the population is consistent with national dietary guidance. A description of the roles, sources, intake, bioavailability and nutrient interactions, risks of excess intake, the recommended daily intake and deficiency in the context of osteoporosis are provided in Attachment 3.

Conclusion

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

- more than one population subgroup in both Australia and New Zealand has a customary intake below 30% of the EAR; and
• calcium intake is one of several factors associated with osteoporosis, a disease of public health significance.

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

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>UK EAR for calcium (mg)</th>
<th>% Respondents below EAR – Australia</th>
<th>% Respondents below EAR - New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>275</td>
<td>7.1</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>275</td>
<td>7.5</td>
<td>na</td>
</tr>
<tr>
<td>4-6 years</td>
<td>Male</td>
<td>350</td>
<td>9.9</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>350</td>
<td>17.5</td>
<td>na</td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>425</td>
<td>11.8</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>425</td>
<td>22.6</td>
<td>na</td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
<td>750</td>
<td>37.0</td>
<td>na</td>
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<td></td>
<td>Female</td>
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<td>34.0</td>
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<td>13-15 years</td>
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<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>625</td>
<td>44.7</td>
<td>na</td>
</tr>
<tr>
<td>16-18 years (Australia)</td>
<td>Male</td>
<td>750</td>
<td>29.8</td>
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</tr>
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<td>39.4</td>
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<td></td>
<td>Female</td>
<td>625</td>
<td></td>
<td></td>
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<tr>
<td>19-24 years</td>
<td>Male</td>
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<td>19.0</td>
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<td>525</td>
<td>36.9</td>
<td>36.4</td>
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<tr>
<td>25-44 years</td>
<td>Male</td>
<td>525</td>
<td>22.1</td>
<td>22.4</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>525</td>
<td>34.8</td>
<td>37.2</td>
</tr>
<tr>
<td>44-64 years</td>
<td>Male</td>
<td>525</td>
<td>24.1</td>
<td>32.8</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>525</td>
<td>32.2</td>
<td>35.8</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>525</td>
<td>27.8</td>
<td>35.6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>525</td>
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<td>33.9</td>
</tr>
<tr>
<td>Adjusted 2nd day</td>
<td>525</td>
<td>18.8</td>
<td></td>
<td>na</td>
</tr>
</tbody>
</table>

5.2.2 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. The risk of distortion of consumer’s diets as a result of increased consumption of inappropriate foods (due to the presence of content claims) is also assessed.

A wide range of foods are proposed for calcium fortification as part of this application including beverages, soups and biscuits. Some of the beverages being considered as part of this application contain reasonably high amounts of sugar from both natural and added sources. While juices contain mainly natural sugars, fruit drinks and, in particular, fruit based cordials, contain added sugars. The dietary guidelines recommend taking care to: consume only a moderate amount of sugars and foods containing added sugars; limit saturated fat and moderate total fat intake; and choose foods low in salt.3

The products being considered are low in fat (for biscuits this is by virtue of the limit on fat for biscuits permitted to have added vitamins and minerals in Standard 1.3.2) and generally low in salt with the exception of some soups and vegetable juices.

Assessment of candidate foods against compositional criteria

The compositional 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 which had been proposed for appropriate use of health claims.

The compositional criteria to be applied to candidate foods for voluntary fortification were included in Section 5.1 of this report and are also included below for ready reference:

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

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

i. added sugars; and
ii. any ingredient comprising more than 75% triglyceride; and

b) contain no more than 800 mg sodium per manufacturer’s serve size; and

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.

Candidate foods must meet all of the compositional criteria a), b) and c) in order to be eligible for fortification. It is worth noting that the limits on sugar and fat are stated in terms of ingredients or added sugar- and fat-ingredients (recipe based) rather than on the total sugars 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 contains, 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.

An assessment of the foods proposed for fortification as part of Application A424 is provided in tabular form below.

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4 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.
Table 2: Assessment of food categories proposed for calcium fortification against compositional criteria (✓ = meets criteria, ± = some products will meet criteria while others will not)

<table>
<thead>
<tr>
<th>Food</th>
<th>Sugar &amp; Fat Content (no more than 25%)</th>
<th>Sodium (no more than 800 mg)</th>
<th>At least 5% of RDI for one vitamin or mineral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Juice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Vegetable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drinks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Vegetable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fruit Based Cordial</td>
<td></td>
<td></td>
<td>±</td>
</tr>
<tr>
<td>Soups</td>
<td></td>
<td>±</td>
<td>✓</td>
</tr>
<tr>
<td>Crispbread/cracker-type biscuits</td>
<td>✓</td>
<td></td>
<td>±</td>
</tr>
</tbody>
</table>

FSANZ recognises that in some cases, only some products in a particular food category will meet the compositional criteria while other products may not (indicated by the symbol ± in the table above) however, a permission for voluntary fortification may be granted (subject to a risk assessment) if the majority of products in the food category meet the criteria. FSANZ recognises that:

1. most biscuits in the category being considered will meet criteria c), i.e. they will contain at least 5% of the RDI for at least one vitamin or mineral per manufacturer’s serve size for example, niacin and/or thiamin and/or phosphorous and/or iron;
2. most soups will meet criteria b), i.e. they will contain less than 800 mg sodium per manufacturer’s serve size; and
3. most fruit based cordials will meet criteria a), i.e. they will contain no more than 25% combined fat and sugar by ingoing weight by virtue of the directions for preparation and use, and most fruit based cordials will meet criteria c), i.e. they will contain at least 5% of the RDI for at least one vitamin or mineral per manufacturer’s serve size by virtue of the natural vitamin C content.

One submitter argued that crispbread/cracker-type biscuits are inappropriate foods to contain added calcium because they ‘often have a high fat content’. However, the biscuits proposed to be fortified with calcium are those already permitted to claim the presence of certain vitamins and minerals under Standard 1.3.2. This group of biscuits is restricted by their fat and sugar content, containing not more than 200 g/kg fat and not more than 50 g/kg sugar. Therefore, the biscuits being considered as part of this application are crispbread and cracker-type biscuits only and must contain no more than 20% fat.

Fruit and vegetable juices, fruit and vegetable drinks, fruit based cordial, soups and crispbread/cracker-type biscuits are, subject to a risk assessment, all eligible foods categories for voluntary fortification based on these criteria. Although added sugar is the major ingredient of fruit based cordial concentrate by ingoing weight, once made up according to directions, the sugar content (fruit cordial contains no or negligible fat) is likely to be less than 25% of the final product based on the recommendation to make up the drink as 1 part cordial concentrate to 4 parts water. The reference quantity proposed by the applicant for soup of 200 mL has been accepted as a realistic serve size.
The Applicant has sought permission for the addition of calcium to vegetable drinks. At present, vegetable drinks are not defined in the Food Standards Code however, the Applicant has requested that a voluntary permission be granted to vegetable drinks containing at least 25% vegetable juice. An analysis of food composition data for vegetable juices was performed in order to ascertain whether vegetable drinks of a 200 mL serving size containing at least 25% juice would meet the compositional criteria to be applied to candidate foods for voluntary fortification. This analysis is reported in Table 2. For four different vegetable juices analysed: carrot; celery; mixed vegetable; and tomato, all criteria would be met for a drink containing the respective juice. In relation to the criteria requiring the food to contain at least 5% of the RDI per manufacturer’s serve prior to fortification, based on the composition of the juices, the following drinks would meet the criteria: carrot drink, vitamin A and vitamin C; celery drink, magnesium and vitamin C; mixed vegetable drink, vitamin A, folate and vitamin C; and tomato drink, vitamin A and vitamin C.

Conclusion

All foods requested by the applicant are considered to be eligible for voluntary fortification (subject to risk assessment) since the food categories are consistent with general dietary guidance.

Risk of potentially increased consumption of inappropriate foods

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 fortified product, which does not meet the Codex definition of a substitute food, being substituted for natural source of the vitamin or mineral. 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.

In the Initial Assessment Report, ANZFA raised a concern that calcium-fortified fruit juices, fruit drinks and fruit based cordial might be substituted for milk, particularly by low income earners and children (purchased by the parents because the children do not like the taste of milk or dairy products). This concern was confirmed as an issue for some submitters from the nutrition/public health sector.

However, the experience in the USA during the last 15 years has shown that calcium-fortified beverages have gained an approximate 25% market share which has remained stable, but they are substituted for unfortified beverages rather than for milk. The beverages proposed in this application are considered to be sufficiently different in nutrient profile, taste and use (e.g. milk on breakfast cereal) from milk and dairy products to avoid the risk of inappropriate substitution.
The products proposed for fortification with calcium are not intended for promotion as substitutes for dairy, but are intended to provide an alternative choice, in addition to calcium supplements or other calcium-fortified foods, for those already not consuming dairy products. Milk and dairy products are also consumed for reasons other than calcium such as taste and the suitability of milk with breakfast cereal.

Nevertheless, some risk management options have been developed and assessed given the concern expressed by public health professionals in submissions of potential inappropriate substitution. These risk management options are discussed in the following section of this report.

5.3 **Assessment of the impact of calcium fortification of the proposed products on calcium intake 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.*

5.3.1 **Risk of Excess Calcium Intake**

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. 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.

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 a voluntary permission is being considered, information on the market share of the proposed fortified product in Australia and 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:

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• no permission for the nutrient addition granted;

• limited range of food or amount of the nutrient permitted (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.

The dietary intake assessment presented in the Initial Assessment Report for this application was only able to be conducted based on unadjusted 24 hour recall survey data which has been shown to overestimate the nutrient and food consumption of high consumers. A small sample (10%) of those surveyed for the NNS recorded a second day’s intake. FSANZ now has adjustment figures that can be applied to the one-day intake estimate to take into account the effect of second day intakes.

Based on the 24 hour recall data available at Initial Assessment, it appeared that there was a potential for the 95th percentile of males aged 15-24 years in Australia to exceed the UL for calcium (2500 mg/day) if the products proposed in this application were fortified with calcium, with an estimated intake of 3080 mg. The second day adjustment factor determined by the Australian Bureau of Statistics (ABS) applies to 16-24 years males and so this is the age group investigated at Draft Assessment. The one-day unadjusted 95th percentile intake for Australian males aged 16-24 years was 2950 mg/day, slightly lower than the 15-24 year age group. The adjusted 95th percentile calcium intake for males aged 16-24 years was 2545 mg/day, which is approximately equal to the UL for calcium, which is 2500 mg/day.

Some submitters suggested that further refinement of the dietary modelling scenarios, in which 100% of product is assumed to be fortified, be made to take into account uncertainties and limitations of the data. A more realistic estimate of uptake of any voluntary permission to add calcium to the proposed products was taken to be 25% of the total market rather than assume total uptake by both manufacturers and consumers. This was based on the US market, in which fortified fruit juice has 25% of the market share for fruit juice. Refinement is possible only for the fruit juice model based on the market data available however, this further modelling provides some indication of the likely market conditions in Australia and New Zealand. The estimated 95th percentile calcium intake based on unadjusted 24 hour recall data of males aged 16-24 years when 25% of juices were fortified was 2857 mg/day, as compared with 2953 mg/day when 100% of juices were assumed to be fortified.

**Conclusion**

The dietary intake assessment suggests that there would be negligible risk of excess calcium intake based on the addition of calcium at the levels requested to all the proposed foods. While the adjusted 95th percentile intake for males aged 15-24 years was approximately equal to the UL for calcium, this assumes 100% uptake of the permission to voluntarily add calcium to the proposed products. Information available (e.g. NNS data) suggests that this pattern of high calcium consumption of young adult males is not continued through the life cycle.
5.3.2 Risk of Nutrient Deficits or Imbalances

Some submitters have expressed concern that should substitution of calcium-fortified beverages for milk occur, there will be nutritional implications for certain sub-groups of the population. Specifically, concern that children and ovo-lacto vegetarians would be at risk of deficiencies in riboflavin and vitamin B12, present in the nutritional profile of milk, if substitution occurs over a long term.

Dietary modelling prepared for the Initial Assessment Report was used to estimate possible impacts on the intake of protein, vitamin A and riboflavin, should some calcium-fortified products substitute for flavoured milk. The model used assumes that parents will allow a child (aged 6-12 years) to substitute calcium-fortified fruit cordial for milk as a drink and a source of calcium. It was assumed that there would be a 50 percent decrease in milk consumption, substituted by a 50 percent increase in calcium-fortified fruit cordial consumption. Based on this substitution scenario, the estimated intakes of protein, vitamin A and riboflavin were all slightly lower than before substitution, but still substantially greater than their respective RDIs (268 percent, 180 percent and 142 percent of the RDI respectively).

Vitamin B12 intake based on this substitution scenario was not included in the dietary modelling at initial assessment however, some submitters believed that the impact of the substitution scenario on vitamin B12 intake should also be estimated. This modelling substitution scenario could not incorporate vitamin B12 as data is not included in the database. Submitters from the public health and nutrition professions also believed that ovo-lacto vegetarians should be included in this modelling. It is not possible to include ovo-lacto vegetarians in this modelling since this group cannot be selected out from the NNS, the closest approximation of this group is non-dairy consumers, which includes participants in the NNS that did not consume dairy on that particular day only but do consume dairy products on a regular basis.

5.3.3 Potential Dietary Impact

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.

The potential dietary impact of calcium fortification of the proposed products was presented in the Initial Assessment Report with post-fortification intake data presented in terms of an increase in the percentage of the total population and subgroups of the population meeting the RDI. In this Report, the data is presented as a change in the percentage of the population or subgroup of the population meeting the respective EAR for calcium as this was the indicator used to establish inadequacy of calcium intake (refer to Attachment 4). The analysis that is presented below at best represents the potential effectiveness.
Fortification of all the proposed products has the potential to increase the dietary intake of calcium for population subgroups such that for those 18 subgroups in Australia and New Zealand with 30% or more of the subgroup not meeting the EAR prior to fortification, only one of these subgroups has at least 30% of the subgroup not meeting the EAR after fortification (Table 3). It should be noted that this is a ‘best-case’ scenario in terms of potential effectiveness since dietary modelling assumes that: there will be 100% uptake of the permissions to fortify by industry; and consumers will purchase the product. Nevertheless, fortification of these products provides the potential for an increase in calcium intake for those target population subgroups. For example, prior to fortification, 47.2% of Australian females aged 16-18 years had a calcium intake below the EAR whereas after fortification only 25.2% of this subgroup had a calcium intake below the EAR.

In order to obtain a more realistic estimate of the potential impact of fortification on calcium intakes, 25% of juices were assumed to be fortified with calcium in accordance with the US experience of 25% market share for calcium fortified fruit juice. Based on this model, the potential impact on calcium intake is reduced slightly such that 20.3% of the total population in Australia are predicted to have an intake below the EAR (compared with 18.2% based on the ‘best-case’ scenario described above) and 26.9% of the total population in New Zealand are predicted to have an intake below the EAR (compared with 25.4% based on the ‘best-case’ scenario).

A detailed account of the potential effectiveness of fortification is discussed in the Dietary Intake Assessment at Attachment 4.

Table 3: Percentage of respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) after fortification*

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Australia</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>1.2</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>3.3</td>
<td></td>
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<tr>
<td>4-6 years</td>
<td>Male</td>
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</tr>
<tr>
<td></td>
<td>Female</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>4.4</td>
<td>na</td>
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<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
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<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>14.9</td>
<td></td>
</tr>
<tr>
<td>13-15 years</td>
<td>Male</td>
<td>19.2</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>24.7</td>
<td></td>
</tr>
<tr>
<td>16-18 years</td>
<td>Male</td>
<td>16.3</td>
<td>na</td>
</tr>
<tr>
<td>(Australia)</td>
<td>Female</td>
<td>25.2</td>
<td></td>
</tr>
<tr>
<td>15-18 years</td>
<td>Male</td>
<td>na</td>
<td>30.3</td>
</tr>
<tr>
<td>(New Zealand)</td>
<td>Female</td>
<td>28.5</td>
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<td>19-24 years</td>
<td>Male</td>
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</tr>
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</tr>
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<td>25-44 years</td>
<td>Male</td>
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<td>45-64 years</td>
<td>Male</td>
<td>17.3</td>
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<td>65+ years</td>
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<td>Total Population</td>
<td>24 hour recall</td>
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</tr>
<tr>
<td></td>
<td>Adjusted 2nd day</td>
<td>6.7</td>
<td>na</td>
</tr>
</tbody>
</table>

*Assuming all proposed products in the application are fortified with calcium.
5.4 Risk Management

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 as follows:

*In general, claims to the effect that the 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% of the RDI respectively for the particular vitamin or mineral and the food is a ‘claimable food’.*

All foods proposed for calcium addition in this application will be included in the Table to Clause 3 of Standard 1.3.2 and are thus all ‘claimable foods’ as defined in Standard 1.3.2, clause 1.

In addition to submitter’s concerns related to the inappropriate substitution of calcium-fortified foods for milk, submitters have raised the possibility for increased consumption of calcium-fortified foods on the basis of a ‘content claim’.

Submitters from the public health/nutrition sector indicated their concern that a ‘good source’ claim displayed on the product label of calcium-fortified products may 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 overnutrition, undernutrition, and dental caries in the population. In addition, 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.

Based on market share data in the US, there is no evidence that there will be an overall increase in consumption of fruit juices, drinks and cordials, but that people will substitute the calcium-fortified juice for the unfortified juice. If however, there was an increase in overall consumption of these products, there would be an increase in sugar consumption which is not consistent with the dietary guideline relating to sugar consumption, “Eat only moderate amounts of sugars and foods containing added sugars”.

Two studies into how consumers use content claims suggest that there may be changes in purchasing based on the information provided in content claims however, these studies do not provide any insight into whether a consumer purchasing a product with a content claim may substitute this product for something else. The results of a copy test of nutrient content claims and food health claims in advertising6, the “Halo Effect Component” was described where, respondents on average underestimated the level of risk-increasing nutrients (such as sodium, saturated fat, or cholesterol) in products that also contained claims about beneficial nutrients (such as fibre or calcium) when only quantitative written information about the risk-increasing nutrients was provided. The results of another study7 suggest that the presence of added value information (i.e. new information such as a content claim) is an important condition for whether or not a claim will have an impact.


This implies that consumers are less likely to look at a Nutrition Information Panel (and therefore assess the quantities of other nutrients) of a product if it bears a nutrient content claim on the front.

One submitter 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. It is also acknowledged that good hygiene practices such as regular brushing of teeth and inclusion of fluoride in the water supply are important in protecting teeth and it is anticipated that if these practices continue, dental health will be protected even in the case of an increased consumption of fruit juices and drinks.

In response to the concerns raised regarding bioavailability, this complex issue 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. While it is acknowledged that this is an important issue, FSANZ does not have the capacity to assess the bioavailability of calcium in each product because of, among other reasons, a lack of data in relation to the bioavailability of calcium in particular foods. FSANZ recognises that various calcium salts also have different bioavailabilities in different foods however,

5.4.1 Options for Risk Management

Although the food/nutrient combinations have been assessed as eligible for voluntary fortification in section 5.2 of this report, risk management strategies were considered to address the concerns raised by consumers, mainly in relation to fruit cordial. The most feasible risk management option was to permit voluntary fortification and the content claim in accordance with clause 6 of Standard 1.3.2 (stated in section 5.4), but require an advisory statement. In the Initial Assessment Report the following question was posed:

Do submitters think that, should this application be accepted, words to the effect that the food is not a dairy/milk substitute should apply?

A large proportion of submitters commented on this question. Some submitters from the nutrition/public health sector expressed the view that, subject to granting a permission for the voluntary addition of calcium, the advisory statement should be required. Submitters from industry generally did not support the inclusion of such a statement. The reason given was that consumers would not necessarily make the connection between the calcium-fortified products and dairy products. One submitter pointed out that the inclusion of an advisory statement could however, work in the opposite way to which it was intended, for example, some individuals who had not made the connection between calcium-fortified juice and milk, may consider consuming the product as a substitute for milk or dairy based on the advisory statement.

In addition, some submitters opposing this statement argued that products with permissions to claim the presence of calcium are not required to display such a statement e.g. breakfast cereals and soy beverages. In response to this argument, soy beverages are a substitute for milk based on nutritional equivalence, therefore, such an advisory statement would be misleading.
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 the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, or when guidance about use of a food is needed to protect public health and safety.

In response to the first criteria, that the general public or the sub-population is exposed to a significant potential risk to health but the risk is not life threatening, the risk is identified as:

- potential substitution of calcium-fortified fruit cordial for milk based beverages as a source of calcium; and
- potential for subsequent nutrient deficits (other than calcium) or imbalances based on such substitution; and/or
- increased consumption of calcium-fortified fruit cordial (regardless of substitution) which are high in sugar.

It should be noted that these are potential risks.

In relation to the second criteria, that guidance about use of a food is needed to protect public health and safety, it would be difficult to argue that an advisory statement related to these beverages is required because:

- the risks listed above are not sufficiently likely; and
- guidance about the use of a food may be more appropriately and effectively catered for by public health/nutrition education.

In order to require an advisory statement in relation to calcium-fortified fruit cordial, FSANZ would need to have some evidence the risks outlined in relation to the first criteria are likely to occur, i.e. that substitution of calcium-fortified beverages for milk beverages or an increase in consumption of calcium-fortified beverages are likely to occur as a result of a voluntary permission accompanied by a label.

FSANZ has conducted database searches over the period of time in which calcium-fortified juice has been available in the US and has not identified any research supporting the potential risks outlined above. At this point in time, in the absence of any such evidence that these consumption patterns are likely to occur, FSANZ does not propose to require an advisory statement in relation to the consumption of calcium-fortified non-dairy beverages.

5.4.2 Education

Most submitters from the public health/nutrition sector did not believe that calcium-fortified non-dairy products 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.

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.
Nutritionists often recommend consumption of calcium supplements where calcium intake is possibly not adequate. These calcium-fortified products could be recommended as alternative choices to calcium supplements for those that may not have an adequate calcium intake.

FSANZ recognises that nutrition education may become more complex as a result of extended permissions for voluntary fortification however, education is seen as a realistic and effective risk management tool in the context of the appropriate consumption of fortified products.

5.5 Additional Issues Raised by Submitters

5.5.1 Inappropriateness of Juice for Infants

One submitter pointed out that neither undiluted juice nor cow’s milk are appropriate foods for infants. Infants are defined in the Code as persons under 12 months of age and there is a separate standard in the Code that addresses foods for infants, Standard 2.9.2 – Foods for Infants which is a special purpose standard. The current application does not apply to foods for infants, i.e. there is no request to add calcium to fruit juices for infants, and as such it is not considered.

5.5.2 Integrity of the 100% juice market

One submitter raised concerns regarding ensuring the integrity of the market for 100% fresh juice with no additions. By way of example, if a juice carries a “100% juice” label and it has calcium added, a claim of “100% juice” could be misleading.

The Australian Competition and Consumer Commission (ACCC) has previously concluded that juice can only be labelled as “100% juice” if the product is constituted from freshly squeezed juice product and not made from or blended with reconstituted juice. The ACCC concluded that labelling a juice made from concentrate (which may include the addition of additives, vitamins or minerals) as “100% juice” was potentially misleading or deceptive.

5.6 Reference to sugar in Standard 1.3.2

In Standard 1.3.2, Table to clause 3, column 1, certain vitamins and minerals are permitted to be voluntarily added to:

- Biscuits containing not more than 200 g/kg fat and not more than 50g/kg sugar

A reference to ‘sugar’ is provided in Standard 2.8.1 – Sugars, clause 2 as follows.

“A reference to ‘sugar’ elsewhere in this Code is, unless otherwise expressly stated, a reference to –

a) white sugar; or
b) caster sugar; or
c) icing sugar; or
d) loaf sugar; or
e) coffee sugar; or
f) raw sugar.”

In Standard 2.8.1, clause 1, a definition is provided for ‘sugars’ which is much broader than the definition for ‘sugar’. In Standard 2.8.1, clause 1:

\textit{sugars} means -

\begin{enumerate}
\item hexose monosaccharides and disaccharides, including dextrose, fructose, sucrose and lactose; or
\item starch hydrolysate; or
\item glucose syrups, maltodextrin and similar products; or
\item products derived at a sugar refinery, including brown sugar and molasses; or
\item icing sugar; or
\item invert sugar; or
\item fruit sugar syrup;
\end{enumerate}

derived from any source, but does not include -

\begin{enumerate}
\setcounter{enumi}{7}
\item malt or malt extracts; or
\item sorbitol, mannitol, glycerol, xylitol, polydextrose, isomalt, maltitol, maltitol syrup or lactitol.
\end{enumerate}

It was not intended that the description of biscuits in column 1 of Table to clause 3 of Standard 1.3.2 pick up the meaning of ‘sugar’ rather than ‘sugars’ and this was probably the result of the separate development of Standards 1.3.2 and 2.8.1 and the impact of Standard 2.8.1 on Standard 1.3.2 was possibly not fully considered. Therefore, it is proposed to replace the reference to ‘sugar’ in the description of biscuits in Standard 1.3.2 with ‘sugars’ to reflect the original intent.

6. Regulatory Options

There are two options for addressing this application.

6.1 Option 1 – No approval

Maintain the \textit{status quo} by not amending the Code to approve the addition of calcium to fruit and vegetable juices, fruit drinks, fruit cordial, soups and crispbread/cracker-type biscuits.

6.2 Option 2 – Approval

Amend the Code, as requested by the applicant and approve the addition of calcium to fruit and vegetable juices, fruit drinks, fruit cordial, soups and crispbread/cracker-type 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 which carry claims for 25% of the RDI for calcium per 200 mL serving. The source of calcium is stated as ‘whey 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.
   - High consumers of calcium, in particular, young adult males who may be at risk of exceeding safe upper levels of calcium intake.

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 which currently provides food sources of calcium for those individuals who, for whatever reason, do not consume dairy products.
   - The calcium supplement industry which 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

Consumers

- There was very little 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.

- Those consumers currently taking calcium supplements due to lack of suitable dietary choices would need to continue to do so.

- 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 $1.9 billion per annum in health costs and a further $5.6 billion in indirect costs, representing 1.2% of GDP in 2000-2001 or $389 for every Australian. This estimate of the total cost is an increase on the total cost of $60 million per annum estimated by the Australian Institute of Health and Welfare (AIHW) in 1993-94 which was presented in the IAR. Calcium inadequacy is one of several factors that contribute to osteoporosis.

Public health professionals

Benefits

- The current health/nutrition education messages around 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 remain consistency with nationally endorsed guidelines for healthy eating.

- Additional strategies such as reorienting the health system, creating support 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.

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 identified domestic markets and to export to identified international markets.

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

Costs

- Assuming a link between inadequate calcium intake and osteoporosis (or the prevalence of fractures) in the community, there is a flow on cost to governments of sustaining the public health costs. The health costs associated with osteoporosis, as reported by Access Economics, in “The Burden of Brittle Bones”, are currently a cost to the government. Calcium inadequacy is one of several factors that contribute to osteoporosis.

7.2.2 Option 2: Approval

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 $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 these costs would be absorbed by the manufacturer. This means that the choice available to consumers would not be denied by prohibitive prices.

**Costs**

- As indicated by the dietary intake assessment, fruit juices, fruit drinks and fruit-based cordial are consumed by a large proportion of the population. 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, drinks or cordial for milk as an alternative calcium sources is unlikely to occur. However, should substitution occur for young children, the potential exists for symptoms resulting from malabsorption of carbohydrate and dental problems to occur.

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

**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. One submitter from this sector suggested that the promotion of milk and dairy products as the main source of calcium would remain however, in the same way as dietitians recommend calcium supplements for those clients not obtaining adequate calcium from their diet, they could recommend additional/alternative food sources of calcium should a voluntary permission be granted. Another submitter from this sector indicated that soup [and biscuits] are complex foods and the promotion of these foods as alternative sources of calcium would not be inconsistent with general dietary guidance.

**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. Most 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 of dairy.
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.

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 have 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 $939 million of which crispbread, rice crackers and crackers contribute 10%, 10% and 8% respectively. Fruit juice and drinks markets are worth $738 million; of which 66% is juice and 34% is drink. The cordial market is worth $204 million and the market for soups is worth $361 million. It is anticipated that growth in the calcium-fortified citrus cordials and 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 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.

- 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 which 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. This has not been confirmed by submissions.

**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) have deduced that, if successfully increasing calcium intake through this fortification measure such that 10% fewer people developed osteoporosis, a future health dividend of $190 million per annum based on year 2000 costs could be anticipated. Even a conservative 1% reduction delivers $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 to the IAR 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 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 these 28 submissions, 12 submitters unconditionally supported Option 2 (amend the Code as requested by the applicant and approve the addition of calcium to the proposed products), eight submitters opposed the application in its entirety (support for Option 1 – maintain the status quo by not amending the Code to approve the addition of calcium to the proposed products), one submitter declined to commit support to either option until the release of the draft assessment, two submitters supported Option 2 for some of the products proposed only, and five submitters expressed the view that this application should not be assessed in isolation and recommended a comprehensive review of Standard 1.3.2 – Vitamins and Minerals of the Code and the regulatory principles underpinning this standard. Of the five submitters who requested a review of Standard 1.3.2, one supported Option 2 and the other four supported Option 1 in the absence of such a review.

The specific issues raised by submitters were addressed in detail in section 5 of this report.

No additional submissions were received in response to the section 13A or 14 notice required under the ANZFA to FSANZ transitional provisions.

Public submissions are sought on this Draft Assessment Report. Comments that would be useful would cover the options, impacts, conclusion and recommendations.

Wherever comment is provided, please provide your rationale and where possible, supporting evidence.

As a member of the World Trade Organization (WTO), Australia is 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. It is not anticipated that the proposed amendment to the Code resulting from this application will have a significant impact on trade therefore, it is not considered necessary that any notification be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Transitional Issues

In accordance with the transitional requirements for an application which has reached initial assessment prior to the commencement of the FSANZ Act, the initial assessment has been reviewed. No relevant policy guidelines have been notified by the Ministerial Council and no additional submissions were received in response to the notice given under section 13A or 14.
10. Conclusion and Recommendation

FSANZ recommends the approval of the application to permit the voluntary addition of calcium to fruit and/or vegetable juices, fruit and/or vegetable drinks, fruit cordial, soups and crispbread/cracker-type biscuits for the following reasons:

- Calcium is considered to be potentially eligible for voluntary fortification (subject to risk assessment) because, in accordance with the regulatory principles for the addition of vitamins and minerals to foods, more than one population subgroup in both Australia and New Zealand has a customary intake below 30% of the Estimated Average Requirement (EAR) 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 generally are consistent with general dietary guidance.

- 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 to all the proposed foods.

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

It is recommended that all food categories be granted a permission to voluntarily add calcium to a level that allows a ‘good source’ content claim (at least 25% of the RDI per reference quantity) to be made.

The proposed drafting for an amendment to Standard 1.3.2 – Vitamins and Minerals, is at Attachment 1 of the Draft Assessment Report.

11. Implementation and review

Following the consultation period for this document, the Final Assessment of the Application will be completed. Following the preparation of the Final Assessment Report and consideration by the FSANZ Board, a notification will be made to the Ministerial Council and it is anticipated that the notification will be made by the end of the 2nd quarter 2003. Subject to the outcome of the Ministerial Council process, an amendment to Standard 1.3.2 – Vitamins and Minerals would come into effect upon gazettal.

It should be noted that the ANZFRMC has commenced development of policy on food fortification. The scope of this policy development has not yet been established.
FSANZ does not propose to develop and implement an evaluation strategy designed to track the uptake of permissions to voluntarily fortify products with calcium as a result of this Application. However, it is expected that the next National Nutrition Survey will pick up calcium-fortified products on the market.

ATTACHMENTS

1. Draft variation to Standard 1.3.2 – Vitamins and Minerals of the Code
2. Regulatory principles for the Addition of Vitamins and Minerals to Food
3. Calcium – Roles, sources, intake and deficiencies
4. Dietary Intake Assessment
5. Summary of submissions to the IAR
DRAFT VARIATION TO STANDARD 1.3.2

To commence: On Gazettal

[1] **Standard 1.3.2 of Volume 2 of the 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 -*

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

[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 | refer to clause 8 |
| 200 mL | vitamin C | refer to clause 8 |
| 200 mL | carotene forms of vitamin A | refer to clause 8 |
| 200 mL | calcium | 200 mg (25%) |

[1.6]  *inserting in the Table to clause 3, Columns 3 and 4, under the entry for Fruit cordial, fruit cordial base –*

| 200 mL | calcium | 200 mg (25%) |

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

**Composite products**

| 200 mL | calcium | 200 mg (25%) |

| Soups, prepared for consumption in accordance with directions | 200 mL | calcium | 200 mg (25%) |
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\textsuperscript{8}.

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.

\textit{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.

\textsuperscript{8} 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 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:

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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.

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’ 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.

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10 This Regulatory Principle was modified from the Codex General Principle of restoration

11 ‘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

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At the time of this report, no EARs had been established for Australian or New Zealand populations, although several Australian RDIs\textsuperscript{14} 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

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\textsuperscript{14} 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. 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\(^{15}\), 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\(^{16}\) 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.


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:

\[
\text{a food which is designed to resemble a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles.}
\]

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\(^\text{17}\); 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.

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\(^{17}\) 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; 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 Food Standards Code and to inform FSANZ’s internal decision-making processes.
ATTACHMENT 3

CALCIUM

The Role of Calcium

The role of calcium in the diet involves: the protection of the calcium in the bones; the regulation of cardiac and skeletal muscle contraction; the regulation of certain enzymes; assistance in nerve transmission. Low calcium intake has been implicated as a determinant of pre-eclampsia (a hypertensive disorder of pregnancy) and several other chronic conditions including colon cancer and hypertension. Conversely, a high calcium intake is known to decrease the risk of hypertension, colon cancer, adverse affects of kidney exposure to lead, and also to aid the prevention of kidney disease.

Sources of Calcium

The main food sources of calcium for the Australian and New Zealand populations as indicated by the Australian 1995 National Nutrition Survey and the New Zealand 1997 National Nutrition Survey respectively are shown in Table 1 below.

<table>
<thead>
<tr>
<th>Country</th>
<th>Food</th>
<th>Contribution to Calcium Intake (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Milk, regular</td>
<td>18.9</td>
</tr>
<tr>
<td></td>
<td>Cheese, regular</td>
<td>8.5</td>
</tr>
<tr>
<td></td>
<td>Milk, reduced fat (&lt;2 per cent fat)</td>
<td>7.7</td>
</tr>
<tr>
<td></td>
<td>White bread and rolls</td>
<td>5.5</td>
</tr>
<tr>
<td></td>
<td>Milk, low fat (&lt;1 per cent fat)</td>
<td>3.3</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Milk regular</td>
<td>18.3</td>
</tr>
<tr>
<td></td>
<td>Milk, trim</td>
<td>13.3</td>
</tr>
<tr>
<td></td>
<td>Cheese (&gt;30 per cent fat)</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>Cheese (20-30 per cent fat)</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>Milk, calcium enriched</td>
<td>3.0</td>
</tr>
<tr>
<td></td>
<td>White bread and rolls</td>
<td>2.7</td>
</tr>
</tbody>
</table>

The calcium in these foods may be present as:

- naturally occurring calcium, of which the most commonly recognised sources are dairy products such as milk (primarily cows), yoghurt and cheese;
- fortificant calcium such as found in breakfast cereals, soymilk and soy yoghurt. In some countries (for example the United States), fortification of food products that are not natural sources of calcium is more prevalent and extends to products such as apple and orange juices; and
calcium salts of food additives, as permitted by Standard 1.3.1 of the Code. For example, the relatively large contribution of bread as a food source of calcium can be attributed to the use of calcium propionate as a food additive, which is permitted to be added to up to 4000 mg/kg in the Code.

Calcium supplements may also contribute to total calcium intake although, there is no detailed quantified information relating to calcium supplement intake in the Australian or New Zealand populations. According to the National Nutrition Survey Selected Highlights, Australia 1995 \(^7\), 29 percent of men and 18 percent of women consumed a nutrient supplement on the day prior to the survey. Of these men, 3.8 percent consumed a calcium supplement, while 12.1 percent of the women consumed a calcium supplement. In New Zealand, 2 percent of the population used a calcium supplement in a one-year period, with calcium supplement use peaking in the 65-74 years age group (9 percent). Overall, dietary supplements contributed less than one percent of total dietary calcium intake for the New Zealand population\(^6\).

**Bioavailability and Nutrient Inter-actions**

Calcium bioavailability refers to the fraction of dietary calcium that can be absorbed by the intestine and used for physiological functions, particularly bone mineralisation, or to limit bone loss. The actual bioavailability will vary somewhat between individuals and may be influenced by both dietary and non-dietary factors including: the source and solubility of the calcium, an adequate intake of vitamin D, physiological adaptation, level of physical activity, hormones and drugs. Calcium from milk and dairy products appears to be better absorbed than other sources of calcium due to the lactose-induced enhancement of calcium absorption.

Calcium absorption and intake are inversely related, declining from 45% at intakes of 200 mg/day to 15 at intakes above 2000 mg/day. In women, absorptive efficiency falls with age, declining 2.2% at the time of the menopause and then 0.21% each year thereafter\(^a\). Efficiency of absorption varies throughout the lifespan, being highest in infancy, rising again in early puberty and mid-to late pregnancy, and declining with age\(^b\). Changes in calcium intake lead to up- or down-regulation of absorption\(^c\).

These factors have implications for the efficacy of use of different calcium salts of food additives in fortified foods. Furthermore, supplemental or fortificant calcium taken with food may also affect the absorption of other nutrients, such as iron, magnesium and phosphates.

**Recommended and actual consumption of calcium**

Data from the Australian National Nutritional Survey 1995 indicate that females consume the Recommended Dietary Intake (RDI) for calcium only in the age groups 2-3 years, 4-7 years and 16-18 years. Similarly, New Zealand data (collected for those aged 15 years and above) indicate that for women, the daily median intake of calcium from food falls short of the RDI for calcium. Australian males do not meet the RDI for calcium in the 12-15 years and 65+ years age groups, while the only group of New Zealand males that does not meet the RDI for calcium is the 15-18 years age group. The mean calcium intakes for the Australian and New Zealand populations in comparison with the RDI are provided in Table 2.
The mean daily calcium intake of women aged 20-94 years who participated in a ‘Geelong Osteoporosis Study’ over the years 1994-97 was estimated by a calcium-specific food-frequency questionnaire to be 663 mg per day. This is lower than the figures documented in the 1995 National Nutrition Survey, which reported a mean daily intake of 748.6 mg for women over the age of 19 years. The study also suggested that 14 percent of women consume less than the minimal requirement of 300 mg/day and therefore are at risk of bone loss.

Although the 1997 New Zealand National Nutrition Survey did not obtain data for children under 15 years of age, some studies detailing the calcium intake of New Zealand children are available. A study by the New Zealand Department of Health indicated that 45 percent of girls and 30 percent of boys aged 10-11 years had calcium intakes that fell below 70 percent of the recommended dietary intake. In a further study, 55 percent of boys and 59 percent of girls aged 13-15 years had a calcium intake below 70 percent of the RDI.

**Apparent consumption data for calcium**

According to apparent consumption of foodstuffs and nutrients data in Australia for 1997-1998, the dietary calcium supply available for consumption is only 6 percent in excess of the RDI. This means that the RDI for calcium is only just provided by the food supply. Apparent consumption data should be interpreted with some caution as it is based on production figures and therefore does not account for wastage. Comparable apparent consumption data for New Zealand does not appear to be available.

**Upper tolerable intake level (UL) for calcium**

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 no 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. 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.

The UL established for calcium by the Food and Nutrition Board, Institute of Medicine in the US is 2.5g/day.

**Table 2: A comparison of the mean calcium intakes of the Australian and New Zealand populations with the age and gender specific RDIs**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Australian Mean Daily Calcium Intake (mg)</th>
<th>New Zealand Mean Daily Calcium Intake (mg)</th>
<th>RDI (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3</td>
<td>867</td>
<td>N/A</td>
<td>700</td>
</tr>
<tr>
<td>4-7</td>
<td>831</td>
<td>N/A</td>
<td>700</td>
</tr>
<tr>
<td>8-11</td>
<td>938</td>
<td>N/A</td>
<td>800</td>
</tr>
<tr>
<td>12-15</td>
<td>1096</td>
<td>N/A</td>
<td>1200</td>
</tr>
<tr>
<td>16-18 (NZ:15-18)</td>
<td>1280</td>
<td>957</td>
<td>1000</td>
</tr>
<tr>
<td>19-24</td>
<td>1101</td>
<td>938</td>
<td>800</td>
</tr>
<tr>
<td>25-44</td>
<td>989</td>
<td>959</td>
<td>800</td>
</tr>
<tr>
<td>45-64</td>
<td>886</td>
<td>864</td>
<td>800</td>
</tr>
</tbody>
</table>
Calcium deficiency in the context of osteoporosis

Osteoporosis is a metabolic bone disease characterized by low bone mass and deterioration of bone tissue that leads to bone fragility and increased risk of fracture. Strategies to prevent or delay osteoporosis include maximising peak bone mass in teenagers and slowing the rate of adult bone loss, especially in peri- and postmenopausal women\textsuperscript{15}. Having an optimal amount of bone deposited during adolescence is the most effective strategy for decreasing the risk of osteoporosis later in life because a substantial part of bone accretion occurs between the ages of 11 and 16 years\textsuperscript{16}.

The skeleton contains 99\% of the calcium in the body, while the remaining 1\% exists as serum calcium. In the case of negative calcium balance, where losses of calcium in the urine, faeces or skin are greater than the intake and the fraction of the intake absorbed by the intestine; skeletal reserves will be used to maintain serum ionised calcium\textsuperscript{17}. Serum ionised calcium is maintained and closely guarded within a well-defined narrow normal range by the interaction of calcium regulating hormones. These hormonal mechanisms result in bone resorption to bring the serum calcium back to within the normal range, but at the price of bone loss. Negative calcium balance over a prolonged period places the individual at a greatly increased risk of osteoporosis.

Low calcium intake is one factor contributing to loss of bone mass and estimates of dietary calcium may be useful in identifying individuals at risk of calcium insufficiency but should not be over-simplistically viewed as the ‘solution’ to osteoporosis. Additional factors contributing to loss of bone mass include excessive alcohol consumption, vitamin D status, cigarette smoking, amenorrhoea (absence of menstrual periods), menopause (either early onset or surgically induced), inactivity, a high sodium intake, anorexia nervosa or bulimia and the use of certain medications such as corticosteroids and anticonvulsants\textsuperscript{18}.

More women suffer from osteoporosis than men because of the hormonal changes that occur at menopause. One in every two women over the age of 70 suffers a fracture related to osteoporosis\textsuperscript{19}. It is estimated that the proportion of women with osteoporosis increases from 15 percent in those aged 60-64 years up to 71 percent in those over 80 years of age. The incidence is much lower in men, ranging from 1.6 percent of those aged 60-64 years up to 19 percent for those aged over 80 years\textsuperscript{20}. There is a lack of data in relation to the incidence of osteoporosis in the New Zealand population, it is assumed to be similar to that of Australia.
The burden of disease associated with osteoporosis is largely caused by fractures of the hip, vertebrae and wrist. Hip fracture in older people is associated with long term disability and a decline in health status. Between 6 percent and 40 percent will die within one year, while half of the survivors will have long-term disability. 

Musculoskeletal disorders were the third leading cause of health system expenditures in Australia, with an estimated total expenditure of $3,002 million in 1993-94. Specifically, the total cost of osteoporosis was $60 million in 1993-94, the largest proportion of this expenditure was incurred by nursing homes, with expenditure at $22 million. There were fewer admissions to hospital as a result of disease associated with osteoporosis than other musculoskeletal disorders however, the average length of stay was longer than any other musculoskeletal disorder at 14.5 days. Health system costs rise steeply for older women to a total of $594 million for women aged 75 years and over. Nearly 60 percent of this $594 million results from nursing home costs attributable to disabling musculoskeletal disorders.

REFERENCES


DIETARY INTAKE ASSESSMENT

A424 – Addition of calcium to fruit and vegetable juices, fruit drinks, fruit cordials, soups and crispbread/cracker type biscuits

Summary

A dietary intake assessment was deemed necessary in order 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 any risk to consumers with high calcium intakes exceeding the upper safe level and the potential effectiveness of fortification of the proposed foods with calcium.

Dietary modelling indicates that a large number of population groups in Australia and New Zealand do not obtain adequate calcium intakes from their food consumption habits and the naturally occurring calcium content of foods. 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 the Upper Limit for calcium will be exceeded by high consumes of 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 of the population with large numbers of respondents not meeting their calcium requirements, even after fortification.

Background

The applicant is seeking a voluntary permission for calcium to be added to fruit and vegetable juices, fruit drinks, fruit based cordials, soups and crispbread/cracker type 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 be sufficient to provide not less than 25% of the Recommended Dietary Intake (RDI) of calcium per serve.

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 respective RDI, while females generally did not have adequate calcium intakes in relation to the 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.

**Dietary Modelling**

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 1995 and 1997 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.

\[
\text{Dietary intake} = \text{food nutrient concentration} \times \text{food consumption}
\]

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 modelling**

Assumptions made in the dietary modelling 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 modelling

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 overestimate 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. FSANZ has recently developed, with the Australian Bureau of Statistics (ABS) a procedure for taking into account second day nutrient intakes by the use of factors for adjusting the first day intake to gain a more accurate reflection of longer-term nutrient intakes. At present this approach is only adopted for Australia. However, the only groups (of relevance to this application) that have second day adjustment factors incorporated to date are the total population group (before and after calcium fortification) and the males aged 16 to 24 years age group (after fortification only) for Australia. FSANZ is still in the process of developing adjustment factors for other population sub groups. Therefore, calcium intakes are unadjusted for second day intakes for the other population groups included in the dietary modelling. Second day adjustments will have no impact on estimated mean calcium intakes, but would likely reduce estimated one-day 95th percentile calcium intakes and increase one-day 5th percentile intakes.

Dietary modelling 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 Upper Level (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.

Assessing the Potential Effectiveness of Fortification

In order to determine whether or not fortification is estimated to increase calcium intakes in the groups with low calcium intakes, estimated dietary calcium intakes before and after fortification were compared to Estimated Average Requirements (EARs) for calcium, set by the United Kingdom. The EARs vary depending on age and sometimes gender. The age and gender 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

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

**Scenarios for dietary modelling**

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

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.

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\(^{18}\) (Australia only); and
- Non-dairy consumers\(^{19}\) (Australia and New Zealand).

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

**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 serve will provide no less 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 gender 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 serve sizes were provided by the applicant and are 200 mL for fruit and vegetable juices and drinks, 200 mL for fruit based cordials, 200 mL for soups and 35 g for crispbread/cracker type biscuits. These serve sizes are based on the reference quantities specified in Standard 1.3.2. The foods and proposed levels of fortification are shown below in Table 2.

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18 People of Asian ethnicity are those who were born in an Asian country and are now living in Australia
19 Non-dairy consumers were those who did not consume products such as milk, cheese, yoghurt, cream and frozen milk products.
Table 2: Proposed fortification levels of calcium in foods

<table>
<thead>
<tr>
<th>Food Name</th>
<th>Fortification Level (mg/100g)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruit &amp; Vegetable juices and drinks</td>
<td>100</td>
</tr>
<tr>
<td>Fruit based cordials (as consumed)</td>
<td>100</td>
</tr>
<tr>
<td>Soup</td>
<td>100</td>
</tr>
<tr>
<td>Crispbread/cracker type biscuits, low fat</td>
<td>571</td>
</tr>
</tbody>
</table>

* 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 NNS or 1997 NNS and also allows scenario calcium concentrations to be assigned to food groups. Scenario calcium concentrations were applied to fruit and vegetable juices, fruit drinks, fruit cordials, soups and savoury crispbread/cracker type biscuits not high in fat (i.e. 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 percentage of respondents with estimated pre-fortification calcium intakes below the EAR for calcium are shown in Table 3 for Australia and New Zealand. Estimated calcium intakes assuming all proposed products are fortified are also compared to EARs for all respondents in Table 4. Pre and post-fortification results for New Zealand Maori are listed in Table 5, Australians of Asian ethnicity in Table 6 and non-dairy consumers in Tables 7 (pre-fortification) and 8 (post-fortification).

Population groups with greater than 30% of respondents having a calcium intake less than the EAR are highlighted in the results (appearing in bold font in each table), in accordance with the rationale for establishing nutrient inadequacy explained in Attachment 2 to the Draft Assessment Report.

Pre-fortification 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.
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.

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.

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.

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.
Post-fortification calcium intake

General population

Fortification of all the proposed products reduced the percentage of respondents with estimated calcium intakes below the EAR for calcium. New Zealand males aged 15-18 years were the only age/gender group for Australia and New Zealand with over 30% of respondents having a post-fortification calcium intake less than the EAR. The percentage of respondents with estimated calcium intakes below the EAR for Australian females aged 16-18 years, fell from 47% before fortification to 25% assuming all 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.

The percentage of total respondents with an estimated post-fortification calcium intake below the EAR was 18% and 25% for Australia and New Zealand respectively. These levels are approximately 10% and 9% lower than pre-fortification estimates for Australia and New Zealand respectively. When adjustments were made to account for second day intakes (Australia only), just 7% of total respondents had an estimated post-fortification calcium intake below the EAR.

Market Share scenario - 25% of juices are fortified

When it was assumed that calcium-fortified fruit and vegetable juices would make up only 25% of the, the percentage of total respondents with an estimated calcium intake less than the EAR was 20% for Australia and 27% for New Zealand. These levels 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. Australian males aged 16-24 years had a post-fortification intake of 2950 mg/day assuming all the proposed products were fortified. When it was assumed only 25% of the total market of fruit and vegetable juices was fortified, this estimate was only reduced to 2855 mg/day. The estimated 95th percentile for New Zealand males aged 16-24 years was the same for each scenario (2655 mg/day).

New Zealand Maori

If all proposed products were fortified, just over 32% 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.
**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 gender groups had similar reductions, however, females aged 65 years and over still had a high percentage of respondents with estimated calcium intakes below the EAR (57%).

**Non-dairy consumers**

Fortification of all 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 56%, compared to 81% before fortification. The reduction was not as large for the total New Zealand population, falling from 86% to 67% after fortification. Only three population groups for Australia and New Zealand (Australian males and females 2-3 years and males 7-10 years) had less than 30% of respondents below the EAR after fortification.

Although the number of respondents in some of the age and gender 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 less 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 fortification.

**High consumers**

The dietary intake assessment for the Initial Assessment Report for this Application 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.

FSANZ can now adjust the one-day intake estimate 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 is the age group included here. The one-day unadjusted 95th percentile intake for Australian males aged 16-24 years was 2950 mg/day, slightly lower than the 15-24 year age group. The adjusted 95th percentile calcium intake for males aged 16-24 years was 2545 mg/day, which is approximately equal to the UL for calcium. This is likely still an overestimate as it is assumed that all proposed products are fortified with calcium and that respondents always consume the fortified version of the food.

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.
Modelling presented previously at Initial 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\(^{20}\) (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.

### Table 3: Percentage of respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) before fortification

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

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

\(^{20}\) 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.
Table 4. Percentage of respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) after fortification*

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Australia</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>1.2</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>3.3</td>
<td></td>
</tr>
<tr>
<td>4-6 years</td>
<td>Male</td>
<td>4.3</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>4.0</td>
<td></td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>4.4</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>7.8</td>
<td></td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
<td>19.1</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>14.9</td>
<td></td>
</tr>
<tr>
<td>13-15 years</td>
<td>Male</td>
<td>19.2</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>24.7</td>
<td></td>
</tr>
<tr>
<td>16-18 years (Australia)</td>
<td>Male</td>
<td>16.3</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>25.2</td>
<td></td>
</tr>
<tr>
<td>15-18 years (New Zealand)</td>
<td>Male</td>
<td>na</td>
<td>30.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>28.5</td>
<td></td>
</tr>
<tr>
<td>19-24 years</td>
<td>Male</td>
<td>12.2</td>
<td>16.6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>22.6</td>
<td>27.3</td>
</tr>
<tr>
<td>25-44 years</td>
<td>Male</td>
<td>14.8</td>
<td>16.7</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>24.4</td>
<td>28.3</td>
</tr>
<tr>
<td>45-64 years</td>
<td>Male</td>
<td>17.3</td>
<td>24.7</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>21.6</td>
<td>26.7</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>18.3</td>
<td>27.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>26.7</td>
<td>29.5</td>
</tr>
<tr>
<td>Total Population</td>
<td>Pre-fortification</td>
<td>18.2</td>
<td>25.4</td>
</tr>
<tr>
<td></td>
<td>Adjusted 2nd day</td>
<td>6.7</td>
<td>na</td>
</tr>
</tbody>
</table>

*Assuming all proposed products in the application are fortified with calcium.

Table 5. Percentage of Maori respondents in New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) before and after fortification*

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Pre-fortification</th>
<th>Post-fortification</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-18 years (New Zealand)</td>
<td>Male</td>
<td>51.7</td>
<td>37.9</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>50.0</td>
<td>43.8</td>
</tr>
<tr>
<td>19-24 years</td>
<td>Male</td>
<td>59.6</td>
<td>22.2</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>43.5</td>
<td>33.3</td>
</tr>
<tr>
<td>25-44 years</td>
<td>Male</td>
<td>26.9</td>
<td>19.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>39.1</td>
<td>30.2</td>
</tr>
<tr>
<td>45-64 years</td>
<td>Male</td>
<td>43.7</td>
<td>36.6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>48.5</td>
<td>38.2</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>54.5</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>63.2</td>
<td>57.9</td>
</tr>
<tr>
<td>Total Population</td>
<td>Pre-fortification</td>
<td>40.6</td>
<td>32.1</td>
</tr>
<tr>
<td></td>
<td>Adjusted 2nd day</td>
<td>6.7</td>
<td>na</td>
</tr>
</tbody>
</table>

*Assuming all proposed products in the application are fortified with calcium.
Table 6. Percentage of respondents of Asian ethnicity\(^+\) in Australia with intakes below the United Kingdom EAR for calcium (mg/day) before and after fortification\(^*\)

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Pre-fortification</th>
<th>Post-fortification</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4-6 years</td>
<td>Male</td>
<td>22.2</td>
<td>22.2</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>20.0</td>
<td>20.0</td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>10.0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12.5</td>
<td>0</td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
<td>33.3</td>
<td>33.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>50.0</td>
<td>50.0</td>
</tr>
<tr>
<td>13-15 years</td>
<td>Male</td>
<td>66.7</td>
<td>16.7</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>83.3</td>
<td>50.0</td>
</tr>
<tr>
<td>16-18 years</td>
<td>Male</td>
<td>75.0</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>66.7</td>
<td>50.0</td>
</tr>
<tr>
<td>19-24 years</td>
<td>Male</td>
<td>42.1</td>
<td>26.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>37.9</td>
<td>13.8</td>
</tr>
<tr>
<td>25-44 years</td>
<td>Male</td>
<td>42.1</td>
<td>27.6</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>48.7</td>
<td>35.0</td>
</tr>
<tr>
<td>45-64 years</td>
<td>Male</td>
<td>31.6</td>
<td>28.9</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>36.0</td>
<td>26.0</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>31.8</td>
<td>18.2</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>61.9</td>
<td>57.1</td>
</tr>
<tr>
<td>Total Population 2 years and above</td>
<td></td>
<td>41.9</td>
<td>29.0</td>
</tr>
</tbody>
</table>

\(^+\) 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 are fortified with calcium.

Table 7: Percentage of non-dairy consuming respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) before fortification

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Australia</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>50.0</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>25.0</td>
<td></td>
</tr>
<tr>
<td>4-6 years</td>
<td>Male</td>
<td>66.7</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>84.2</td>
<td></td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>63.0</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>79.2</td>
<td></td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
<td>90.0</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>87.5</td>
<td></td>
</tr>
<tr>
<td>13-15 years</td>
<td>Male</td>
<td>92.3</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>100.0</td>
<td></td>
</tr>
<tr>
<td>16-18 years (Australia)</td>
<td>Male</td>
<td>84.6</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>90.9</td>
<td></td>
</tr>
<tr>
<td>15-18 years (New Zealand)</td>
<td>Male</td>
<td>na</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td></td>
<td>100.0</td>
</tr>
<tr>
<td>19-24 years</td>
<td>Male</td>
<td>66.7</td>
<td>87.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>90.9</td>
<td>93.8</td>
</tr>
<tr>
<td>25-44 years</td>
<td>Male</td>
<td>72.8</td>
<td>76.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>84.5</td>
<td>87.2</td>
</tr>
<tr>
<td>45-64 years</td>
<td>Male</td>
<td>77.2</td>
<td>82.4</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>85.7</td>
<td>80.8</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>76.7</td>
<td>83.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>96.4</td>
<td>96.3</td>
</tr>
<tr>
<td>Total Population 24 hour recall</td>
<td></td>
<td>81.0</td>
<td>85.8</td>
</tr>
</tbody>
</table>
Table 8: Percentage of non-dairy consuming respondents in Australia and New Zealand with intakes below the United Kingdom EAR for calcium (mg/day) after fortification*

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Sex</th>
<th>Australia</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-3 years</td>
<td>Male</td>
<td>0</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>16.7</td>
<td></td>
</tr>
<tr>
<td>4-6 years</td>
<td>Male</td>
<td>62.5</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>61.6</td>
<td></td>
</tr>
<tr>
<td>7-10 years</td>
<td>Male</td>
<td>25.9</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>45.8</td>
<td></td>
</tr>
<tr>
<td>11-12 years</td>
<td>Male</td>
<td>80.0</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>62.5</td>
<td></td>
</tr>
<tr>
<td>13-15 years</td>
<td>Male</td>
<td>76.9</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>58.3</td>
<td></td>
</tr>
<tr>
<td>16-18 years (Australia)</td>
<td>Male</td>
<td>46.2</td>
<td>na</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>60.6</td>
<td></td>
</tr>
<tr>
<td>15-18 years (New Zealand)</td>
<td>Male</td>
<td>na</td>
<td>40.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>64.3</td>
<td></td>
</tr>
<tr>
<td>19-24 years</td>
<td>Male</td>
<td>47.9</td>
<td>52.2</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>58.2</td>
<td>68.8</td>
</tr>
<tr>
<td>25-44 years</td>
<td>Male</td>
<td>51.0</td>
<td>54.0</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>59.2</td>
<td>74.4</td>
</tr>
<tr>
<td>45-64 years</td>
<td>Male</td>
<td>59.8</td>
<td>73.5</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>62.9</td>
<td>65.4</td>
</tr>
<tr>
<td>65+ years</td>
<td>Male</td>
<td>61.7</td>
<td>83.3</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>67.9</td>
<td>85.2</td>
</tr>
<tr>
<td>Total Population</td>
<td>24 hour recall</td>
<td>55.9</td>
<td>67.4</td>
</tr>
</tbody>
</table>

*Assuming all proposed products in the application are fortified with calcium.

**Conclusion**

Dietary modelling 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 utilisation of second day adjustment factors to gain a more realistic estimate of long-term nutrient intakes was only available for two population groups at the time this report was written. The adjusted intakes of the total Australian population greatly reduced the number of respondents with estimated calcium intakes below the EAR before and after fortification. The adjusted post-fortification intakes of Australian males aged 16-24 years 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 and it is considered unlikely that the UL will be exceeded from the diet alone on a long-term basis given the conservative nature of modelling assumptions.
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.
## SUMMARY OF SUBMISSIONS

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Preferred Option</th>
<th>Appropriate foods</th>
<th>Labelling</th>
<th>Health/nutrition Education</th>
<th>Costs and Benefits</th>
<th>Standard 1.3.2</th>
<th>Other Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Public Health</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dietitians Association Australia (DAA) – Sue Cassidy</td>
<td>Part Option 2</td>
<td><strong>Soup</strong> – already a complex food. <strong>Cracker biscuits</strong> – although fortification of these may not be very effective, there may be some benefit. Do not support juices, drinks or cordial b/c substitution for milk can affect riboflavin and protein status, dental erosion, weight gain, diarrhoea. ANZFA address the ‘loophole’ through which fruit juice products are making calcium claims</td>
<td>Soup is already a complex food and so fortification would not conflict with nutrition education messages. For juices, drinks and cordial education message would become more complex and may be difficult to reach children, minority groups and those with language difficulties.</td>
<td>Essential to integrity of Code that principles underpinning existing food standards be applied to all new applications.</td>
<td>Acknowledge that marketing/promotion of foods is a Trade Practices Issue but recommend ANZFA considers developing an approach that requires marketers of fortified products to only promote the products as an alternative rather than substitute.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>South Eastern Sydney area Health Service – Dian Tranter</td>
<td>Option 1</td>
<td>Concerns about undesirable increase in juice/drink/cordial consumption and/or substitution for dairy especially for children – diarrhoea, gastrointestinal</td>
<td>Fortification of juices is in conflict with Eat Well Australia. As fruit juices and drinks are not natural sources of calcium, fortified products may confuse consumers since only some products will be fortified. Problems for low income consumers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option</td>
<td>Location</td>
<td>Description</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>----------</td>
<td>-------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option 2</td>
<td>All foods</td>
<td>Nutrition education message will remain that dairy is the best source of calcium however, alternative products can be consumed in order to meet dietary requirements (rather than supplements).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option 1</td>
<td>If juice, drinks or cordial are substituted for milk this impacts on riboflavin, B12 status and protein intake especially for children, ovo-lacto vegetarians. Concerns about over consumption of juice such as diarrhoea.</td>
<td>Food labels are too small to adequately communicate information required. Consumer viewing a calcium content claim on juice would be unlikely to know that the riboflavin and vitamin B12 are lacking. Suggest a number of warning statements to be carried on juice, drink, cordial labels should the application be approved.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Allison Sigmund, Blacktown Mt Druitt Health**

**Central Sydney Area Health Service**

The relatively small benefit of more consumer choice is outweighed by potential disadvantages e.g. increase in dental decay from increased juice consumption. Dental caries costs $257-717 million in one year in Australia. The need for increased calcium in the food supply has not been identified. Cannot simply equate costs of osteoporosis with inadequate calcium intake. Fortification will only be effective if people eat fortified foods and in sufficient quantity and absorb and metabolise the calcium.
<table>
<thead>
<tr>
<th>Steward Truswell</th>
<th>Option 1</th>
<th>Current messages are consistent with obtaining calcium from dairy and supplements if necessary. Calcium fortification conflicts with 5 food groups message.</th>
<th>Negative impact on dairy industry – suffering under deregulation.</th>
<th>Nutrients should only be added to foods that are naturally a moderate source of the nutrient with the only exception be widespread nutritional deficiency – not the case with calcium status in Australia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arnott’s – Clarrie Ng</td>
<td>Option 2</td>
<td>Nutrient content claim and %RDI in product would enable consumers to make informed choices. In the absence of a calcium health claim, a nutrient content/structure-function claim can help consumers. A statement about the product not being a milk/dairy substitute could be confusing to consumers.</td>
<td>Acknowledge that dairy foods are and should remain to be the primary source of calcium and do not wish to position fortified biscuits as an alternative. Arnott’s are committed to working with health care professionals to ensure a consistent message about calcium including dietary and lifestyle factors that can counter calcium absorption e.g. caffeine, smoking, inactivity, sodium. Public health</td>
<td>Option 2 -Consumer research suggests that people would prefer these additional choices of calcium to be available. Those who do not currently consume dairy foods would benefit. Governments would benefit in terms of reduction in osteoporosis/osteoarthritis costs. Option 1 – concerns about the discrepancy between Aust and NZ i.e. placement of similar products under NZDSR. Support the assessment of this application under regulatory principle 2 underpinning Std 1.3.2.</td>
</tr>
</tbody>
</table>
professionals are aware the food supply is changing and should remain aware of the benefits of new products to consumers. It is vital to maintain consistent message.

| National Foods Ltd – Jenny Robertson | 1. Support a review of Std 1.3.2  
2. If A424 is assessed in isolation of a review of Standard 1.3.2 – Option 1  
3. Subject to A424 being reviewed as part of a larger review of the entire Std 1.3.2, support larger body of work to review A424 and reserves judgement on the individual permissions proposed as per A424 until larger body of work is completed. | Educators would be required to advise of the risk of substituting calcium-fortified products or calcium supplements as nutritionally equivalent to dairy foods. Application must be considered in the context of the dietary guidelines. | Requests a review of Standard 1.3.2 and that A424 is not assessed in isolation but as part of this review.  
Suggest that ANZFA should raise a proposal to review Standard 1.3.2 and that A424 and A430 are considered as part of this review.  
Modelling should be based on a broader range of nutrients provided by dairy foods. There are an increased number of dairy products available than was in the 1995 NNS. Calcium-fortified foods and calcium supplements can help improve calcium intake however, these cannot correct poor dietary patterns of food selection.  
Concern about decisions and recommendations being based on anecdotal evidence. Need to explore the complexities of calcium metabolism. Further |
<p>| Australian Food and Grocery Council | Option 2 | Opposes the use of ‘not a milk/dairy substitute’ statement – there will be substitution of fortified products for similar non-fortified products. No concerns about making a nutrient content claim as the requirements for these claims are appropriately regulated. A content claim and entry in the NIP would adequately advise consumers. |
| Option 1 – present figures of the cost of osteoporosis currently and predictions for 2021. The public health burden of Option 1 is too great. If this burden were reduced by only a small amount by Option 2, favouring this option is justified. Unlikely that excess calcium intake will be a problem based on dietary modelling and US experience. On balance, dental health is unlikely to be compromised and calcium supplemented juices reduce the dental erosion. The potential cost savings to community of a decrease in incidence of osteoporosis outweighs the minimal, if any, cost to health/nutrition educators. People suffering from osteoporosis incur significant health costs. Overseas experience suggests consumers taking calcium supplements would prefer additional food alternatives. Figures are provided on the overall size of the markets. Fortification will provide |
| Complete revision of Std 1.3.2 together with the policy principles for the addition of vitamins and minerals to general purpose foods is required. | Need to refine modelling to reflect more likely market conditions e.g. US experience of ~25% market share. | Consider the health message is about calcium and not dairy products per se. Consistency of the message should remain and all that needs updating is the list of foods that are sources of calcium. Current public health education on the need for increasing consumption of calcium rich foods from the available choices has not rectified the deficit in calcium intake. Experience in US suggests a role for updating educational materials e.g. FDA/CFSAN calcium ‘score-card’ has been updated to include fortified foods. |
| Australian manufacturers with the same opportunities as NZ manufacturers. There may be some impact on the calcium supplement market in terms of self-medicators. Likely to be little or no additional enforcement costs since resources are likely to be reallocated as required. |
|-----------------|-----------------|-----------------|-----------------|
| Murray Goulburn – Wendy Morgan | Option 2. Preferred option was not clearly stated however, ‘it is reasonable that [people who choose to avoid dairy] have access to foods which provide one or more of the natural characteristics of dairy foods.' | Risk that some groups may substitute milk/dairy with calcium-fortified foods. A number of components in dairy important – CLA, butyric acid, vitamins A and D, Mg and P. | Advisory/warning statements on calcium-fortified drinks should apply when likely to be substituted for dairy. | Nutrition education should continue to promote the value of dairy foods for health, including bone health. Education should promote other calcium sources as secondary to dairy foods but useful in situations where dairy products are avoided or not available. Also important to overcome misconceptions in relation to lactose intolerance. |
| National Food Processors Assoc. – Peggy Rochette | Option 2 All foods. Supports expanding permission to include drinks with a juice content of less than 25%. | Do not support statement regarding substitution - US experience is that consumers will substitute calcium-fortified juice for similar unfortified products. No need to modify current labelling policy, which currently prohibits confusing or misleading labelling. | US experience shows health/nutrition educators including National Osteoporosis Foundation, American Dietetic Association, American Academy of Pediatrics and National Dental caries unlikely to develop since calcium fortification of acidic beverages reduces the erosive potential of juices. Option 2 provides great benefits in terms of reducing the cost of | Recommend including calcium hydroxide as an appropriate calcium salt. Provided references reporting calcium absorption from fortified juice |
| Nestlé Aust Ltd – Robyn Banks | Option 2 | All foods | No concerns with nutrient content claims. Do not support statement that product is not milk/dairy substitute. The product’s proposed cannot be confused with dairy. | Institutes of Health have readily embraced the availability of calcium-fortified juices and include in information material. Incorporating these products does not diminish role of dairy in the diet and a consistent message from industry and public sector will help consumers. | osteoporosis. Calcium-fortified juice 25% market share in US – both fortified and non-fortified products priced the same so no additional cost to consumer. Denial of request could be considered a trade barrier. | is greater than milk. |
| Food Technology Assoc VIC – | Option 2 | Do not support an advisory statement to the effect that the product is not a dairy/milk substitute | Permission to fortify foods will not be taken up by all manufacturers. Industry will consider from a cost and product suitability perspective. Should not be an increase in dental caries if good oral hygiene practices in place. Cost of Option 1 is no improvement in calcium status of population. The potential of Option 2 to decrease costs of osteoporosis outweighs any other costs. Option 2 should have no additional cost on nutrition educators as this message already encompasses soymilk (not natural source). | Support AFGC submission. |</p>
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<thead>
<tr>
<th>Name</th>
<th>Option</th>
<th>Concerns/Supports</th>
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<tbody>
<tr>
<td>David Gill</td>
<td></td>
<td>– strong negative connotation. Consumers would not easily understand the connection between nominated foods and dairy foods. Support nutrient content claim.</td>
</tr>
<tr>
<td>Australian Juice Assoc – Rolf Schufft</td>
<td>Option 2</td>
<td>Benefit to consumers of greater choice, helps alleviate low calcium intake. Australian manufacturers are at a disadvantage compared with NZ and US. Current value of juice exports from Australia $50M, great opportunity to expand. Calcium-fortified juices in US account for 35% total market.</td>
</tr>
<tr>
<td>Henry Jones Foods – John Darveniza</td>
<td>Option 2</td>
<td>Benefits to consumers – choice for consumers to obtain calcium from other food sources. Choice is important for those intolerant to dairy products, those susceptible to osteoporosis, those avoiding dairy on the basis of fat content and those who dislike dairy.</td>
</tr>
<tr>
<td>Dairy Farmers – Norm Reynolds</td>
<td>Option 1</td>
<td>Concerns about different nutritional profile of juice from milk. Infants and young children will be at risk of low intake of essential fat, protein and vitamins, excessive sugar intake. If approved, products should carry a warning statement to the effect that the products are unsuitable as a milk replacement for children. Need to properly understand the likely level of substitution of milk products and the level of misunderstanding of the population. The addition of calcium to juices, drinks and cordial does not specifically benefit non-dairy consumers since most have already substituted soy or rice milks. Appropriate to consider the application within the context of a review of Standard 1.3.2.</td>
</tr>
<tr>
<td><strong>Australian Dairy Corp – Richard Lange</strong></td>
<td><strong>Defer decision based on review of Standard 1.3.2</strong></td>
<td><strong>Fortified foods should be subject to the same rules regarding nutrient content claims as foods that are natural sources of the nutrient.</strong></td>
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<tr>
<td><strong>Consumers</strong></td>
<td><strong>Focus on Responsible consumption (FORK) – Ruth Kharis</strong></td>
<td><strong>Risk of people substituting dairy with calcium-fortified juice and therefore at risk of reduced riboflavin, B12, protein and vitamin A intake, dental health problems.</strong></td>
</tr>
<tr>
<td>National Council of Women Aust – Elaine Attwood</td>
<td>Non-committal. Propose to offer preferred option at Draft Assessment.</td>
<td>Excess juice consumption will result in high sugar intake – implications for dental health, absorption of Fe, Zn, Mg, P.</td>
</tr>
<tr>
<td>Government Department of Agriculture Fisheries and Forestry Australia – David Mortimer</td>
<td>Option 2</td>
<td>All foods</td>
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<tr>
<td>Health Department of WA – Virginia McLaughlin</td>
<td>Option 1</td>
<td>Strongly opposed to biscuits (based on misinterpretation that biscuits considered may be high in fat, sugars and sodium) and fruit based cordials (based on high sugar content and low nutritional value).</td>
</tr>
<tr>
<td>Environmental Health Unit, QLD Health – Kerry Bell</td>
<td>Option 1 (initial submission was part Option 2)</td>
<td>Initial submission - Support fruit and vegetable juices and drinks as these vehicles are predicted to be most</td>
</tr>
<tr>
<td>Australian</td>
<td>Effective in addressing the nutritional needs of the population. Revised submission – do not support juices, drinks, fruit cordial based on nutrition advice.</td>
<td>Milk in young children</td>
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<tr>
<td>New Zealand</td>
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<tr>
<td>Industry</td>
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<tr>
<td>Fonterra Co-op group – Shiromani Jayasuriya</td>
<td>Option 1</td>
<td>Fruit Juice is probably the most consistent with dietary guidelines. Substituting these products for dairy may result in low intakes of vitamin B12, and dental health problems. If</td>
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<td>Concerns about content claim since the calcium will have lower bioavailability – misleading to consumer. Support inclusion of a statement that the product is not a milk/dairy substitute.</td>
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<tr>
<td>New Zealand Dairy Foods Ltd – L Eyers</td>
<td>Option 1</td>
<td>Calcium fortification of beverages may displace milk having negative consequences on nutrient intake such as riboflavin, vitamin B12, thiamine, niacin, vitamin B6, vitamin A, Mg, P, K and Zn. Soups, biscuits and vegetable drinks may contain substances that inhibit calcium absorption.</td>
</tr>
<tr>
<td>New Zealand Juice Assoc – Bruce Cameron</td>
<td>Option 2</td>
<td>Do not support ‘not a dairy/milk substitute’. Significant enough</td>
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</table>
difference b/w juice and milk products that they will not compete – consumers are choosing b/w fortified and unfortified juice.  

market. Some incremental gains and substitution for non-fortified products. Industry will take up permission to the extent demanded by consumers. Fortified products unlikely to be priced higher – difference absorbed by manufacturer.  

presentation of the products is unlikely to change if positioned under food regulations.

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<td>Part Option 2 – soups and biscuits only</td>
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<td>Do not support addition of calcium to beverages as the products may be interpreted as milk substitutes. Juice, drinks and fruit based cordial are high in sugar. If fortification of</td>
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<tr>
<th>Heinz Wattie’s Australasia</th>
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<td></td>
<td>Suggest a review of the general principles underpinning addition of vitamins and minerals to general purpose foods</td>
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</table>

If there is an issue of public health and safety around calcium intake for the population or subgroups, ANZFA should look more broadly at the issue and how to appropriately address the issue.
| **Unilever Australasia** | **Option 2** | Do not support fruit-based cordial as an appropriate medium for fortification. | Support nutrition claim for calcium. An increase in awareness could prompt traditional food sources of calcium that do not currently declare calcium in NIP to volunteer this information. | Nutrition educators have role to play in assisting clients to meet their dietary recommendations for calcium by offering a number of food choices. Professionals should help educate clients and general public on the variety of fortified and supplemented products that would provide adequate without excessive intakes. | Support consideration of point 2 of underpinning principles for Std 1.3.2. Support widening permissions for addition of nutrients to foods. | Supports AFGC submission. Based on NNS tea supplied 30% of calcium intake at the highest levels of tea consumption due to the addition of milk however, there is now a trend toward drinking tea w/o milk. |
| **Nutrinova Australasia & PURAC Far East** | **Option 2** | All foods – beverages are particularly effective vehicles for fortification as the calcium is dissolved in liquid form accommodating better absorption. | Support nutrient content claim and entry in NIP as %RDI and believe inclusion will raise awareness. Do not think statement that products are ‘not a milk/dairy substitute’ should apply. | Health/nutrition educators can play a role in educating the public about the wider range of calcium containing products available. Need to convey the functionalities of calcium in the body in relation to bone and dental health. Educators need | Support for option 2 - Consumers are looking for alternatives sources of vitamins and minerals as evidenced by consumers buying these products in NZ and 25% market share for these products in the US. Consumers are not obtaining the RDI for calcium to a large extent. The consumer incurs the costs of osteoporosis to a |
The products will not be presented as a substitute. Such a statement would discriminate against these products in comparison with breakfast cereals. Believe statement would violate the promotion of fair trading practices in food, as it would favour dairy/milk products.

Information on factors affecting calcium absorption. Need to promote building bone density at an early age. Role of calcium in preventing dental caries and hypertension should be highlighted. Believe that public health profession accepts the need for non-traditional food sources of calcium in recommending calcium supplements.

Large extent. Provide figures for the current domestic market. Approval of application directly addresses trade issue relating to the products being produced in NZ under NZDSR. It was estimated by DoHA that in 2001 approximately A$700 million was spent to treat and prevent osteoporosis. If approved, growth is predicted at 15% over the first two years with incremental growth of 2-3% annually thereafter for fortified citrus juices, drinks and cordials. Prices are likely to equivalent or similar to unfortified products.