Development of joint Australia New Zealand Food Standards

As part of the process of the Review of the
Food Standards Code

Review of Health and Related Claims
Full Assessment Report
Proposal P153

and

Pilot for Management Framework for Health Claims
Draft Inquiry Report
Proposal P170

August 2000

The Authority should receive written submissions no later than 25 October 2000

Submissions on both matters should be sent to:

The Project Manager - Proposal P153
Australia New Zealand Food Authority

at one of the following addresses:

PO Box 7186
Canberra Mail Centre ACT 2610
Australia

or

PO Box 10559
The Terrace
Wellington 6036
New Zealand

Submissions will be placed on the Authority’s public register (unless a claim of commercial confidentiality is made and accepted by the Authority) and will therefore be open to public scrutiny.
### TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>ii</td>
</tr>
<tr>
<td>Information for submitters</td>
<td>vi</td>
</tr>
<tr>
<td>1. Executive summary</td>
<td>1</td>
</tr>
<tr>
<td>1.1 Policy context</td>
<td>1</td>
</tr>
<tr>
<td>1.2 Background</td>
<td>2</td>
</tr>
<tr>
<td>1.3 Stakeholder views on health claims</td>
<td>3</td>
</tr>
<tr>
<td>1.3.1 Arguments submitted against health claims</td>
<td>3</td>
</tr>
<tr>
<td>1.3.2 Arguments submitted in support of health claims</td>
<td>4</td>
</tr>
<tr>
<td>1.4 The current regulation of nutrition, health and related claims</td>
<td>4</td>
</tr>
<tr>
<td>1.4.1 Nutrition messages and nutrition content claims</td>
<td>4</td>
</tr>
<tr>
<td>1.4.2 Health claims</td>
<td>4</td>
</tr>
<tr>
<td>1.5 Theoretical continuum of nutrition and health-related messages on food labels</td>
<td>5</td>
</tr>
<tr>
<td>1.6 Proposed definitions</td>
<td>5</td>
</tr>
<tr>
<td>1.7 Options for the review of the current regulations</td>
<td>6</td>
</tr>
<tr>
<td>1.7.1 The proposed substantiation framework for health claims</td>
<td>10</td>
</tr>
<tr>
<td>1.7.2 The proposed substantiation framework for nutrition function claims</td>
<td>10</td>
</tr>
<tr>
<td>1.7.3 Education</td>
<td>11</td>
</tr>
<tr>
<td>1.7.4 Monitoring</td>
<td>11</td>
</tr>
<tr>
<td>1.7.5 Enforcement</td>
<td>12</td>
</tr>
<tr>
<td>1.8 The broader context</td>
<td>12</td>
</tr>
<tr>
<td>1.9 Resourcing Issues</td>
<td>13</td>
</tr>
<tr>
<td>2. Public comment</td>
<td>14</td>
</tr>
<tr>
<td>2.0 Public comment</td>
<td>14</td>
</tr>
<tr>
<td>2.1 Problem</td>
<td>15</td>
</tr>
<tr>
<td>2.2 Objective</td>
<td>15</td>
</tr>
<tr>
<td>3. Background</td>
<td>16</td>
</tr>
<tr>
<td>3.1 Current regulation of nutrition, health and related claims</td>
<td>16</td>
</tr>
<tr>
<td>3.1.1 Nutrition messages and nutrition content claims</td>
<td>16</td>
</tr>
<tr>
<td>3.1.2 Health claims</td>
<td>16</td>
</tr>
<tr>
<td>3.2 Health claims prior to P153</td>
<td>16</td>
</tr>
<tr>
<td>3.3 P153 - Health and Related Claims</td>
<td>17</td>
</tr>
<tr>
<td>3.3.1 Submissions in response to P153</td>
<td>18</td>
</tr>
<tr>
<td>3.4 The folate pilot</td>
<td>18</td>
</tr>
<tr>
<td>3.5 Related issues</td>
<td>21</td>
</tr>
<tr>
<td>3.6 An international perspective on health claims</td>
<td>22</td>
</tr>
<tr>
<td>4. Health claims policy</td>
<td>23</td>
</tr>
<tr>
<td>4.1 Introduction</td>
<td>23</td>
</tr>
<tr>
<td>4.2 The public health environment in Australia and New Zealand</td>
<td>23</td>
</tr>
<tr>
<td>4.2.1 Australia</td>
<td>23</td>
</tr>
<tr>
<td>4.2.2 New Zealand</td>
<td>25</td>
</tr>
<tr>
<td>4.3 Health claims in Australia and New Zealand - the advantages and the disadvantages</td>
<td>26</td>
</tr>
<tr>
<td>4.3.1 The advantages of health claims</td>
<td>26</td>
</tr>
<tr>
<td>4.3.2 The disadvantages of health claims</td>
<td>28</td>
</tr>
<tr>
<td>4.4 Implications for a health claims system in Australia and New Zealand</td>
<td>30</td>
</tr>
<tr>
<td>5. Relevant provisions</td>
<td>32</td>
</tr>
<tr>
<td>6. Options including regulation impact statement</td>
<td>34</td>
</tr>
<tr>
<td>6.1 Options and regulation impact statement</td>
<td>36</td>
</tr>
<tr>
<td>6.1.1 Issue / objective</td>
<td>36</td>
</tr>
</tbody>
</table>
INFORMATION FOR SUBMITTERS

REGULATION IMPACT ANALYSIS

The Authority develops food regulation suitable for adoption in Australia and New Zealand. It is required to consider the impact, including compliance costs to business, of various regulatory (and non-regulatory) options on all sectors of the community which includes the consumers, food industry and governments in both countries. The regulation impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the Australian Guide to Regulation (Commonwealth of Australia 1997) and New Zealand Code of Good Regulatory Practice.

Consideration of the Regulatory Impact for this proposal concludes that based on the assessment of the issues, there is insufficient justification for a total prohibition of health claims and that, in the interests of providing for informed choice by consumers, there is scope for claims linking a particular food to health/disease outcomes to be provided on food labels. Similarly, within the context of a comprehensive management framework, such claims bear the potential to support national public health and nutrition initiatives.

ANZFA is also of the view, in the interests of public safety, that any permitted health claims should be subjected to rigorous substantiation (on a claim by claim basis) and a robust management framework therefore, permission for health claims should be contained within legislation.

The preferred option is therefore that, the current provisions be amended with the inclusion of exemptions to the prohibition on health claims under certain conditions.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

This matter will be notified to the WTO as a Technical Barriers to Trade (TBT) notification because, although the provisions addressed by the proposal are voluntary, they represent a significant departure from the current provisions.
FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint Australia New Zealand Food Standards Code which will provide compositional and labelling standards for food in both Australia and New Zealand.

Until the joint Australia New Zealand Food Standards Code is finalised the following arrangements for the two countries apply:

• Food imported into New Zealand other than from Australia must comply with either the Australian Food Standards Code, as gazetted in New Zealand, or the New Zealand Food Regulations 1984, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand Food Regulations 1984.

• Food imported into New Zealand from Australia must comply with either the Australian Food Standards Code or the New Zealand Food Regulations 1984, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.

• Food imported into New Zealand from Australia must comply with either the Australian Food Standards Code or the New Zealand Food Regulations 1984, but not a combination of both.

• Food imported into Australia from New Zealand must comply with the Australian Food Standards Code. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the New Zealand Food Regulations 1984 or Dietary Supplements Regulations 1985.

• Food manufactured in Australia and sold in Australia must comply solely with the Australian Food Standards Code, except for exemptions granted in Standard T1.

In addition to the above, all food sold in New Zealand must comply with the New Zealand Fair Trading Act 1986 and all food sold in Australia must comply with the Australian Trade Practices Act 1974, and the respective Australian State and Territory Fair Trading Acts. Any person or organisation may apply to ANZFA to have the Food Standards Code amended. In addition, ANZFA may develop proposals to amend the Australian Food Standards Code or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the Food Standards Code.

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a full assessment of the proposal, prepared a new joint Australia New Zealand food standard and will now conduct an inquiry to consider the new draft standard and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.
Submissions providing more general comment and opinion are also invited. However, in order that full assessment of such views may be possible, any comments in support or otherwise of the proposal should be presented in conjunction with supporting information. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

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 confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* 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.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Proposal P153** at one of the following addresses:

<table>
<thead>
<tr>
<th>Australia New Zealand Food Authority</th>
<th>Australia New Zealand Food Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>PO Box 7186</td>
<td>PO Box 10559</td>
</tr>
<tr>
<td>Canberra Mail Centre ACT 2610</td>
<td>The Terrace WELLINGTON 6036</td>
</tr>
<tr>
<td>AUSTRALIA</td>
<td>NEW ZEALAND</td>
</tr>
<tr>
<td>Tel (02) 6271 2222 Fax (02) 6271 2278</td>
<td>Tel (04) 473 9942 Fax (04) 473 9855</td>
</tr>
</tbody>
</table>

Submissions should be received by the Authority by **25 October 2000**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.
REVIEW OF HEALTH AND RELATED CLAIMS

1. Executive summary

The current regulations relating to the prohibition on health and related claims in Australia and New Zealand are ambiguous and are being interpreted inconsistently between government, industry and consumers. This situation has consequently led to difficulties in the enforcement of health and related claims. The current prohibition of health and related claims is also inconsistent with the principles of the review of the joint Code. However these issues need to be balanced against concerns amongst some stakeholder groups that health claims may harm consumers.

The Australia New Zealand Food Authority therefore has before it a proposal to review the current regulations relating to the prohibition on health claims in Australia and New Zealand in order to:

1. clarify the intent of the legislation and ensure that it is clear and enforceable; and
2. determine whether the current prohibition on health claims in Australia and New Zealand should be lifted and if so, under what policy framework should a health claims system be allowed to proceed.

This review is part of the broader development of the joint *Australia New Zealand Food Standards Code* (hereafter referred to as the joint Code). Any standard resulting from this review will become Standard 1.2.7 – Health, Nutrition and Related Claims About Food, in the joint Code.

1.1 Policy context

In developing or reviewing food standards, ANZFA must have regard to the objectives outlined in Section 10 of the Australia New Zealand Food Authority Act 1991. These are discussed further in the context of this proposal in Section 14. The objectives are:

- protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;
- the promotion of fair trading in food;
- the promotion of trade and commerce in the food industry; and
- the promotion of consistency between domestic and international food standards where these are at variance.

Consistent with these statutory objectives and the policies of ANZFA, the development of the joint Code will, where possible:

- reduce the level of prescriptiveness of standards to facilitate innovation by allowing wider permission on the use of ingredients and additives, but with consideration of the possible increased need for consumer information;
- develop standards which are easier to understand and make amendment more straightforward;
- replace standards which regulate individual foods with standards that apply across all foods or a range of foods;
- consider the possibility of industry codes of practice as an alternative to regulation; and
- facilitate harmonisation of food standards between Australia and New Zealand.
The development of the joint Code is also being carried out in accordance with the competition policy guidelines established by the Council of Australian Governments (COAG) in 1995. These generally require that the impact of regulation on competition should be minimised, and require an assessment of the impacts on all affected sectors of the community. This is provided in the form of the Regulation Impact Statement (see Section 6).

1.2 Background

There is an extensive background to health claims in Australia, New Zealand and internationally, particularly during the 1990s, of which this proposal is a culmination. The issue of health claims was first formally raised in Australia in a paper on functional foods prepared by the [then] National Food Authority in 1993. This led to the preparation of a Concept Paper on Health and Related Claims in 1996, and the raising of P153 in 1997. The Preliminary Assessment report for P153 proposed a range of elements that should be addressed in the management of health claims (regulation, education, monitoring and substantiation).

In order to provide further information about how such elements should be applied in managing health claims, a further proposal (P170) was raised in 1998 to conduct a trial of a pilot health claim. The claim chosen for the trial was the relationship between increased peri-conceptional folate consumption and reduced risk of babies developing neural tube defects (hereafter referred to as the folate pilot). The folate pilot commenced in November 1998 and is due to cease in August 2002. The folate pilot involved: making a temporary amendment to the health claims prohibition to permit the claim to be made; establishing the claimed relationship through a process of scientific substantiation; establishing eligibility criteria for foods to carry the claim; undertaking education and monitoring activities; and working with industry through a co-regulatory approach to enforce the regulations. While the activities associated with the folate pilot have finished, the claim is still permitted to be used until August 2002.

Codex is also currently reviewing its policy on health claims on food and is at step 3 of the Codex process. This is further discussed in Attachment 6.
Table 1. Chronological background of the Review of Health and Related Claims.

<table>
<thead>
<tr>
<th>Year</th>
<th>Paper / Proposal / Application</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>Discussion paper</td>
<td>Discussion on health claims within the context of functional foods</td>
</tr>
<tr>
<td>1996</td>
<td>Concept paper</td>
<td>Discussion paper on the concepts of health and related claims</td>
</tr>
<tr>
<td>1997</td>
<td>P153</td>
<td>Preliminary Assessment paper for Review of Health and Related Claims</td>
</tr>
<tr>
<td>1998</td>
<td>P170, P184, P192, P201, P208, P214, P218, P221</td>
<td>Proposals for recommending variation to Standard A1(19) to enable a pilot of a health claim management framework; and to list those foods eligible to carry a folate/NTD claim.</td>
</tr>
<tr>
<td>1999</td>
<td>A399</td>
<td>Application to amend Standard A1(19), separate to P153</td>
</tr>
</tbody>
</table>

1.3 Stakeholder views on health claims

There are a wide range of views on the relative benefits and risks of health claims. Unfortunately, there is limited data in the published literature to verify some of these views, which has made it difficult to determine the way forward for health claims. Generally, the following arguments have been made in support for, and against, health claims:

1.3.1 Arguments submitted against health claims

- The total diet is more important than individual foods. Diet related problems are multifactorial.
- There is concern about ongoing validity of claims and liability issues.
- Inappropriate encouragement of health claims may lead to over use of fortified products with the potential for nutrient imbalance or overload.
- Health claims have the potential to undermine the total diet, reduce the visibility and effectiveness of government health promotion schemes and may increase the promotion of packaged food.
- There is no evidence to show that health claims affect public health either positively or negatively.
- Health claims will not be suitable for all groups within the population and may lead to increased food costs.
- Health claims, in isolation, will be counterproductive to health.

---

1 P169, Representational Issues – Claims About Food, included claims about tooth decay, slimming claims and endorsements. At Full Assessment, it was decided that these issues should be considered as part of P153.
1.3.2 Arguments submitted in support of health claims

- A relaxation of the current prohibition on health claims would provide manufacturers with a secure environment to commit resources for product development.
- Health claims are an important means of communicating useful information about diet and disease to consumers and may impact positively on the community;
- Allowing health claims would permit agencies to target dietary advice to specific community groups.
- There are links between foods and health which have already been substantiated and which should be allowed on labels.
- Health claims systems are working successfully overseas.
- The current regulations are not in keeping with the more flexible approach adopted by modern regulatory practice.

1.4 The current regulation of nutrition, health and related claims

Currently in Australia and New Zealand there are three recognised levels of messages or claims regarding nutrition on food packages or in associated advertising. These are nutrition content claims, nutrition messages and health claims.

1.4.1 Nutrition messages and nutrition content claims

Nutrition messages and nutrition content claims are currently regulated as ‘nutrition claims’ under Standard A1(13) of the Food Standards Code and regulation 2(1) of the New Zealand Food Regulations 1984.

1.4.2 Health claims

Standard A1(19) of the Food Standards Code and the New Zealand Medicines Act currently regulate the use of health claims in Australia and New Zealand, respectively. The Relevant Provisions are given in Section 4. Specifically, the current regulations prohibit:

- a claim of therapeutic or prophylactic action or a claim described by words of similar import;
- the word "health" or any words of similar import as a part of or in conjunction with the name of the food;
- any statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person; and
- the name or a reference to any disease or physiological condition.
1.5 Theoretical continuum of nutrition and health-related messages on food labels

The types of nutrition and health-related claims that relate to food occur in a continuum. This continuum is demonstrated below:

1.6 Proposed definitions

The following definitions are being proposed in Standard 1.2.7 Review of Health, Nutrition and Related Claims About Food.

**nutrition content claim** means a claim in relation to food which describes or indicates the presence or absence of a nutrient, energy content or biologically active substance in that food.

**nutrition function claim** means a claim in relation to food which describes the physiological role of a nutrient, energy content or biologically active substance in the food, in the growth, development, maintenance and other like functions of the human body.

**health claim** means a claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a -

(a) enhanced function claim;
(b) reduction of disease risk claim; and
(c) claim that a food is a slimming food or has intrinsic weight-reducing properties;
but excludes a –

(d) nutrition function claim; and
(e) nutrition content claim; and
(f) claim of therapeutic or prophylactic action.
**enhanced function claim** means a claim about the specific beneficial effects of a food or constituent of a food on the physiological, psychological or biological functions other than the role of the nutrient or biologically active substance in the normal growth, development, maintenance and other like functions of the human body.

**reduction of disease risk claim** means a claim in relation to food that a relationship exists between the consumption of a food or food constituent and the reduced risk of developing a disease or health related condition.

1.7 **Options for the review of the current regulations**

Despite the polarised views on health claims as outlined above, there appears to be strong support for a review of the current regulations relating to health claims. There are concerns that the current regulations are ambiguous, leading to inconsistent interpretation of the regulations between governments, industry and consumers, and difficulties in enforcement. These difficulties result in claims being made which to all intents and purposes may present as ‘implied health claims’, but do not contravene the letter of the law and therefore, may not technically be a breach of the regulations.

It is therefore considered important that the current regulations about health claims are reviewed. Within the context of this review, ANZFA is proposing that health claims be permitted as exemptions to the prohibition. In reaching this view, the following issues were considered:

- The folate pilot has demonstrated that, when introduced in the context of a comprehensive management framework, claims can contribute to an increase in awareness of the claimed relationship.
- The continued prohibition on claims is difficult to justify in the context of the principles of the development of the joint Code (refer section 1-policy context). However, because there are concerns that health claims may cause harm, ANZFA does not consider a blanket permission for health claims is appropriate. Instead, an approach that permits exemptions only after thorough consideration by experts, with appropriate levels of supporting education and monitoring, is proposed.
- Given the above, the introduction of a well managed, comprehensive health claims system may be able to support current and future public health nutrition priorities in Australia and New Zealand. For example, the majority of claims originally introduced in the United States were general claims that support broad-based dietary guidance.

A diagrammatic representation of the proposed options for the review of Health and Related claims is provided below. The preferred option is bolded.
Figure - Options for review of health claims regulations

Section 6 Options for the review of health claims regulations

A. No amendment to health claims regulations
B. Amended health claims regulations but no exemptions
C. Amended health claims regulations with exemptions
D. No regulation of claims in the joint Code

Section 7 Proposed revision of health claims standard for joint Code

Section 8 Options for management frameworks for health claims

Co-regulation with general approach to education and monitoring, placing the focus in the context of the changes to the Code as a whole.

Co-regulation with a more integrated approach to education and monitoring with the focus on incorporation into current public health initiatives

Sections 9-12 Detail of elements of the management frameworks for health claims

Regulation and Enforcement (Section 9)
Substantiation (Section 10)
Education and Communication (Section 11)
Monitoring and evaluation (Section 12)
Four options for the review of health and related claims are proposed (see Section 6), including:

A. No revision of the regulations – i.e. maintenance of the status quo;
B. A revision of the regulations to clarify their intent and scope, but with no permission for any exemptions to the prohibition on claims;
C. A review of the regulations to clarify their intent and scope, but with permission for exemptions to the prohibition on claims on a claim-by-claim basis; and
D. No regulation of health claims through the joint Code (reliance on general requirements in food and fair trading laws).

ANZFA’s preferred option is Option C. The regulations relating to the current prohibition on health claims are in need of review. Option A is not feasible as the current regulations are inconsistent, duplicatory and open to interpretation, creating difficulties for government, industry and consumers.

Option B is not desirable as the current regulations are also not in keeping with modern regulatory practice. One of the key principles underpinning the development of the joint Code has been the reduction of prescription to enhance innovation by industry. However, this needs to be balanced against the need to protect public health and safety and to ensure that consumers have adequate information with which to make informed food choices. For this reason, Option D should also not be considered, as it will not provide a system that protects consumers against unsubstantiated claims and ensure public confidence in the system.

In the interests of providing for informed choice by consumers, ANZFA considers there is scope for claims linking a particular food to health/disease outcomes to be provided on food labels and, that such claims bear the potential to support national public health and nutrition initiatives. However, permissions for health claims should be subject to rigorous substantiation and managed within the context of a comprehensive framework.

Option C shares the responsibility for a health claim system and allows some flexibility in relation to the practical implementation of a management framework.

As part of Option C, two frameworks have been proposed for managing exemptions to the general prohibition on health claims. A diagrammatic representation of these frameworks is provided below. Both frameworks are based upon a co-regulatory approach, as used in the folate pilot. The frameworks have the same approaches to regulation, enforcement and substantiation but differ in their recommended approaches to education and monitoring. Framework 1 proposes a general approach to education and monitoring, placing the focus on education and monitoring activities in the context of the changes to the joint Code as a whole. Framework 2 builds upon the elements in Framework 1, and proposes a more integrated approach to education and monitoring with the focus on incorporation into current public health initiatives. Detailed information on each of the framework elements is outlined in Sections 9-12. Framework 1 is being recommended on the basis that it meets all the essential elements of a framework for managing health claims while being sustainable in terms of the resources required to manage the framework.
**Framework 1:** Co-regulation using a system similar to that tested in the folate pilot, with the focus of education and monitoring on protection of public health and safety.

<table>
<thead>
<tr>
<th>Regulatory mechanism; Compliance and enforcement</th>
<th>Substantiation and qualification</th>
<th>Education and communication + Monitoring and evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(see Section 9)</td>
<td>(See Section 10)</td>
<td>(See Sections 11 and 12)</td>
</tr>
</tbody>
</table>
| A co-regulatory approach would be adopted whereby the prohibition on claims remains, with exemptions, and a code of practice developed in conjunction with industry to support the regulations. | Applications for claims submitted for approval would need to be accompanied by supporting evidence, for review and assessment by ANZFA. | Education and monitoring activities would be largely funded by industry and supported by the public sector and possibly non-government organisations. The focus of the public sector in both the education and monitoring elements of the framework would be to:  
  - ensure adequate information is available to the public on the health claims system;  
  - ensure that health claims are protective of public health and safety; and  
  - place education and monitoring of claims in the context of all the other changes to the label that will result from the joint Code. |
| Enforcement through the code of practice management committee and state/territory and New Zealand governments. |                                       |                                                         |

**Framework 2:** As for Framework 1 but with a more comprehensive approach to education and monitoring.

<table>
<thead>
<tr>
<th>Regulatory mechanism; Compliance and enforcement</th>
<th>Substantiation and qualification</th>
<th>Education and communication</th>
<th>Monitoring and evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(See Section 9)</td>
<td>(See Section 10)</td>
<td>(See Section 11)</td>
<td>(See Section 12)</td>
</tr>
<tr>
<td>A co-regulatory approach would be adopted whereby the prohibition on claims remains, with exemptions, and a code of practice developed in conjunction with industry to support the regulations.</td>
<td>Applications for claims submitted for approval would need to be accompanied by supporting evidence, for review and assessment by ANZFA.</td>
<td>Education and communication as for Framework 1, but with the focus on a more integrated approach, linking education on health claims into current public health initiatives and an increased focus on education on individual claims.</td>
<td>Monitoring and evaluation as for Framework 1, but it would also extend into exploring the impact of health claims on health outcomes. As for education, there would be a focus on linking monitoring and evaluation strategies to current national monitoring initiatives.</td>
</tr>
<tr>
<td>Enforcement through the code of practice management committee and state/territory and New Zealand governments.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1.7.1 The proposed substantiation framework for health claims
The substantiation necessary for health claims would be the same under framework 1 and framework 2. The following diagram summarises the process that would occur. Guidelines for the substantiation of claims have been developed and these are available from ANZFA.

1.7.2 The proposed substantiation framework for nutrition function claims
Nutrition function claims will be required to meet the same substantiation requirements as health claims. However, instead of submitting the evidence to ANZFA in an application, the sponsor would be required to “hold” the evidence. This means the food industries are required to carry out their own substantiation to ensure that the totality of the scientific evidence is “convincing” and therefore supports the nutrition function claim, however this information will only be required to be produced on request. If requested, the food industry will have to produce copies of the references on which they based their substantiation before the end of a two week period.
1.7.3 Education

Two approaches to education are being proposed to accompany health claims if they are permitted. Under framework 1 (preferred approach), there would be a general approach to education placing the focus on changes to the Code as a whole. Under framework 2, there would be a more integrated approach to education with the focus on incorporation into current public health initiatives. The activities that would occur under the 2 approaches are summarised below.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Responsibility</th>
<th>Included in Approach 1?</th>
<th>Included in Approach 2?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Information about the food labels and its changes as a result of the joint Code</td>
<td>ANZFA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Information about the health claims system as a whole – how it operates; how claims are substantiated; how to make a complaint etc</td>
<td>ANZFA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Information about each individual claim that is approved – the relationship between the food/component and disease; sources of the component; importance of dietary variety; links to food selection guides etc</td>
<td>Governments; non-government organisations; industry (preferably in partnership)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Linking the information on individual claims into broader, ongoing national public health nutrition strategies in both countries</td>
<td>As above</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Information about individual claims in relation to specific foods</td>
<td>Industry</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

NB Strategies that would occur under Approach 1 are bolded. Strategies 1-5 would all occur under Approach 2. Approach 1 is ANZFA’s preferred approach.

1.7.4 Monitoring

Two approaches to monitoring are being proposed to accompany health claims if they are permitted. Under framework 1 (preferred approach), monitoring of health claims would occur as part of the proposed monitoring and evaluation of the joint Code in Australia and New Zealand. However, before any “monitoring” as such occurs, there needs to be uptake of claims by industry and products carrying claims widely available in the marketplace. The types of monitoring that would then need to occur can be grouped as:

1. Surveys to determine the food industry’s response to changes to the joint Code. In particular there would be a need to determine:
   - The impact the changing compositional requirements as a result of deregulation have had on the food supply.
• The impact of label changes on composition of products.
2. Assessment of whether products comply with the eligibility criteria for health claims and contain levels of the nutrient/active ingredient in the amount stated and necessary to see the desired effect.
3. Consumer surveys to determine consumer understanding of the label changes which would be an integral part of determining the success or otherwise of the joint Code.

Under framework 2, all strategies identified under framework 1 would occur, but in addition monitoring would incorporate strategies to evaluate if health claims are of any public health benefit. This would involve exploring whether health claims have any impact on health outcomes. Framework 1 is ANZFA’s preferred approach for monitoring of health claims, should they be permitted.

1.7.5 Enforcement

It is proposed to establish a code of practice to support the health claims system, and form a Code of Practice Management Committee to oversee the code of practice. Under this model, complaints made would in the first instance be referred to the management committee for resolution. If the management committee were unable to resolve the complaint, the complaint would be referred onto the jurisdiction in which the product is manufactured for further action.

1.8 The broader context

The international experience of health claims, and recent experience with the folate pilot, demonstrates that health claims have not been shown to conclusively result in either positive or negative health-related outcomes. It is therefore essential that should the current prohibition be lifted, any system for the use of health claims be based on sound principles that support public health activities in Australia and New Zealand.

The following set of principles is therefore proposed as the foundation for a health claims system in Australia and New Zealand.

Health claims must:

• be consistent with the objectives of the ANZFA Act; COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies and the 1995 New Zealand Regulatory Principles and other legislation;
• be developed and managed on a whole of government and whole of industry approach to ensure consistency of policy and application across all portfolios and levels of government and across all food industry sectors;
• be truthful, not misleading and unambiguous;
• be consistent with national nutrition guidelines, nutrition policies and national health policies of Australia and New Zealand;
• be based on rigorous scientific assessment of the health benefits of the nutrient(s) or food(s) within the context of the food about which the claim is made;
• be appropriate and realistic: the amount of food to be consumed to obtain the claimed benefit should be appropriate within the context of a normal diet;
• be stated within the context of the total diet;
• have clear qualifying/disqualifying criteria for eligibility of use;
• include key components of information as determined for each individual claim;
• be accompanied by appropriate consumer education;
• be monitored and evaluated at regular intervals;
• be enforceable; if the claimed effect is attributed to a constituent of the food, methods must be available to assess the presence of the constituent in the amount claimed; and
• be part of a transparent system for dealing with complaints.

Health claims consistent with these principles may contribute to public health nutrition priorities in both countries (such as diabetes mellitus, coronary heart disease and some cancers). In addition, a carefully designed and managed health claims system, such as that described in Section 8, will ensure that public health and safety is protected.

1.9 Resourcing Issues

The approach proposed above needs to be considered in relation to respective roles and responsibilities. ANZFA clearly has a key role in ensuring that the way in which claims are regulated protects public health and safety, and that consumers receive adequate information about claims to make informed choices.

The proposed approach also needs to be considered in the context of resourcing. ANZFA has limited resources, and these resources need to be allocated to the development and maintenance of the joint Code as a whole. Health claims, should they be permitted, will form just one component of this activity.

Given the potential public health impact of claims, there may be a role for other parts of government to be involved in different elements of the management framework. Similarly, given the benefits that may accrue to industry through the use of claims in the marketing of products, consideration needs to be given to their role in supporting and resourcing the proposed health claims management framework. Other agencies, such as those in non-government organisations, may also have an interest in participating in educational or monitoring activities in relation to specific claims.

Given ANZFA’s existing and projected budgetary situation, if health claims are permitted in the future, and if adequate resources from other sources to support the proposed framework are not forthcoming, ANZFA may need to consider alternative ways in which to manage health claims.

Two potential options, both of which would require amendments to the ANZFA Act, include

- Increasing ANZFA’s cost recovery capacity to enable ANZFA to recoup the costs associated with substantiating health claims, and with the education and monitoring undertaken in support of claims.
- Limiting the number of permitted health claims and their implementation. Applications received for health claims may need to be limited to a certain number per year, and prioritised according to national health priorities in both countries.

A further option is also possible without requiring amendments to the ANZFA Act. Under this option, ANZFA could focus its efforts on ensuring public health and safety are protected.
through the substantiation process and place very minimal effort in the areas of education and monitoring.

2.0 Public comment

ANZFA is seeking comment on the following issues in this report in particular. Such comment should include evidence in support of the considered view(s).

- What are the relative benefits and risks of health claims? (refer Section 4.2)
- If health claims are permitted, what policy principles should be applied to a health claims system? (refer Section 4.4)
- Noting the current regulations on claims in Australia and New Zealand, is there a need to revise these? (refer Section 6.1)
- If a revision is to occur, should the focus be solely on retaining the prohibition on claims, or should some exemptions to the prohibition be permitted? (refer Section 6.1)
- Are there any other advantages and disadvantages of the options given in Section 6.1?
- Is there agreement on the proposed scope and content of the new Standard 1.2.7 – Health, Nutrition and Related Claims About Food? (refer Section 7)
- If exemptions are to be permitted to the prohibition on claims, is a co-regulatory approach appropriate? (refer Section 8)
- Are the proposed elements of a management framework for health claims appropriate? (refer Sections 8)
- Is the proposed approach to each element of the management framework comprehensive enough to ensure that public health and safety is protected and that consumers have sufficient information to make informed choices? (refer Sections 9-12)
- Is the scientific substantiation process sufficient to protect public health and safety and ensure consumers receive adequate information? (refer Section 10)
- Are the safeguards against unsubstantiated claims adequate? (refer Section 9)
- Who should be responsible for resourcing the proposed health claims management framework? (refer Section 13.1)
- What options should be considered if inadequate resources are available to implement the proposed health claims management framework? (refer Section 13.1)
2. ISSUE AND OBJECTIVE

2.1 Problem

The current regulations relating to the prohibition on health and related claims in Australia and New Zealand are ambiguous and are being interpreted inconsistently between government, industry and consumers. This situation has consequently led to difficulties in the enforcement of health and related claims. The current prohibition of health and related claims is also inconsistent with the principles of the review of the joint Code. However these issues need to be balanced against concerns amongst some stakeholder groups that health claims may harm consumers.

2.2 Objective

1. To clarify the regulation of health and related claims and ensure that it is clear and enforceable; and
2. determine whether the current prohibition on health claims in Australia and New Zealand should be lifted and if so, under what policy framework should a health claims system be allowed to proceed.
3. BACKGROUND

3.1 Current regulation of nutrition, health and related claims

Currently in Australia and New Zealand there are three recognised levels of messages or claims regarding nutrition on food packages or in associated advertising. These are nutrition content claims, nutrition messages and health claims.

3.1.1 Nutrition messages and nutrition content claims

Nutrition messages and nutrition content claims are currently regulated as ‘nutrition claims’ under Standard A1(13) of the Food Standards Code and regulation 2(1) of the New Zealand Food Regulations 1984.

3.1.2 Health claims

Standard A1(19) of the Food Standards Code and the New Zealand Medicines Act currently regulate the use of health claims in Australia and New Zealand, respectively. The Relevant Provisions are given in Section 4. Specifically, the current regulations prohibit:

- a claim of therapeutic or prophylactic action or a claim described by words of similar import;
- the word "health" or any words of similar import as a part of or in conjunction with the name of the food;
- any statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person; and
- the name or a reference to any disease or physiological condition.

3.2 Health claims prior to P153

An initial review of the issues associated with the prohibition of health and related claims was undertaken by ANZFA with its consideration of functional foods in mid-1993. At that time, industry and medical researchers advised ANZFA that considerable advances were being made in assessing the health benefits of foods with certain functional properties. ANZFA hosted an international workshop and prepared a policy discussion paper on this matter, which generated much public interest and comment. A significant outcome of the workshop was recognition of the need to address the concept and regulation of functional foods within the broader context of health claims as the two matters were intimately linked.

ANZFA published a concept paper, which extended the initial consideration of functional foods into the context of diet and health, in February 1996. The paper outlined a conceptual framework, which detailed the characteristics of the different types of claims about nutrition and health in relation to food and also identified and explored the key issues involved in the regulation of health and related claims. The paper was circulated for public comment until mid-1996 and 59 submissions were received.

Comments reflected a diversity of viewpoints, ranging from claims being perceived as being primarily motivated by marketing objectives to being regarded as a legitimate vehicle for nutrition education.
ANZFA considered the issues raised by public comment in December 1996. It was considered that it may be possible that benefits could accrue to public health through the introduction of health claims by way of enhanced consumer awareness and understanding of how to choose a healthy diet. However, these benefits were considered only likely to accrue if they were recognised as an accurate portrayal of the situation and if they appeared in the context of a major nutrition education campaign. It was also recognised that to establish consumer confidence an appropriate scientific assessment and substantiation system would be required.

In April 1997, ANZFA and the [then] Australian Food Council agreed that a working group would be convened by ANZFA to provide a comprehensive report which outlined the scope of the key elements of a health claims system, the estimated cost of developing and maintaining each of the elements and the overall system, and an indication of the potential benefits which would accrue from health claims to the public, and to private interests.

Several sub-groups were established to determine the scope of work required to develop and implement a health claims system. Sub-groups were established on the following topics:

- Scientific substantiation of claims.
- Nutrition criteria for claimable foods.
- Communication effectiveness of claims.
- Monitoring and evaluation.
- Education framework.
- Promulgation of the regulation.

The outcomes of these working groups is discussed as part of Attachment 5.

3.3 P153 - Health and Related Claims

ANZFA considered a report from the above-mentioned working group in August 1997 and agreed to prepare a proposal to review standard A1(19) of the Food Standards Code and the relevant New Zealand medicines legislation. The Preliminary Assessment for P153 - Health and Related Claims was released for comment later that month.

ANZFA agreed that, should health claims be permitted in Australia and New Zealand, claims should only occur within a strong policy context and conceptual framework. The policy context for health and related claims outlined in P153 was such that a health claims framework would:

- Enhance public health;
- Improve the capacity of individuals to manage and enhance their own health;
- Avoid any increase in the risk of diet-related disease(s);
- Not compromise healthy diet principles; and
- Be developed and managed on a whole of government and whole of industry approach to ensure consistency of policy and application across all portfolios and levels of government and across all food industry sectors.

P153 proposed the following management framework for health claims:
a) *A regulatory mechanism* - the establishment of a food standard allowing different types of health claims, including:
- generic health claims open to all qualifying foods;
- generic health claims tailored to the requirements of specific products; and
- specific health claims for specific products.

b) *Substantiation and qualification* - case-by-case evaluation of proposed claims by ANZFA to ensure the proposed claim is:
- capable of appropriate and adequate substantiation;
- supported by nutritional criteria for qualifying or disqualifying attributes for foods on which the claim may be made; and
- effective in communicating its messages to consumers.

c) *Monitoring and evaluation* - the development of monitoring and evaluation programs to determine the impact of specific claims, and health claims generally, on public health, including dietary practices.

d) *Education and communication* - the coordination of national nutrition education campaigns including:
- education on healthy diet and lifestyle;
- information on how health claims and associated information may be used to select a healthy diet;
- education supporting dietary guidelines; and
- specific education associated with particular health claims.

### 3.3.1 Submissions in response to P153

A total of 59 submissions were received in relation to P153. Of the 59 submissions received, 28 were from industry, 14 from government/regulatory bodies and 17 from consumers. In total, 50 submissions generally supported the review of health claims, however 11 of these submissions had some concerns. Twenty-seven of the submissions that generally supported the review were from industry, 11 from government/regulatory agencies and 12 from consumer groups. Many submitters held the view that health claims should only be permitted as specific exemptions to a general prohibition. A small number strongly advocated for the removal of all prohibitions with the only form of regulation for health claims being trade practices law. The majority of comments in response to the proposal were centred on three areas: the proposed management framework; policy issues; and resourcing issues.

A full summary of the submissions in response to P153 is at Appendix 1 of Attachment 3.

### 3.4 The folate pilot

In 1998, ANZFA considered conducting a health claims pilot project using a health claim linking the intake of peri-conceptual folate in women of child-bearing age with a reduced risk of neural tube defects (NTDs) in babies. The proposed pilot was viewed as a means of testing a proposed health claims management framework and therefore a way to guide future decisions arising from the full review of health and related claims being undertaken in P153.
The claim about folate was selected, in part, because the science linking folate intake to reduced incidence of NTDs had recently been reviewed by the Australian National Health and Medical Research Council. In addition to this the promotion of folate amongst women of child-bearing was a priority of the Department of Health and Aged Care in Australia.

On 30 March 1998, Ms Trish Worth, the [then] Parliamentary Secretary to Dr Michael Wooldridge, the Minister for Health, issued a formal direction to ANZFA in relation to ANZFA’s assessment of the folate pilot proposal (Proposal 170). The direction required ANZFA to consider the folate pilot as a matter of urgency and to truncate its assessment processes by omitting the usual public consultation steps. It required ANZFA to make a recommendation to the Australia New Zealand Food Standards Council (ANZFSC) by 1 May 1998.

To assist in developing the proposed management framework to be trialled in the folate pilot as shown in Figure 1 and in putting a recommendation to the ANZFSC, ANZFA conducted a series of working groups to address the following issues:

- Scientific substantiation of the link between folate and neural tube defects;
- Nutrition criteria for foods bearing a folate health claim;
- Education and communication supporting a folate health claim;
- Monitoring and evaluation of the folate health claim; and
- Regulatory and co-regulatory mechanisms for enforcement of a folate health claim.

Other key issues that were addressed in developing the folate pilot were in relation to resourcing the pilot; working with the States/Territories and New Zealand; building partnerships and strategic alliances with health professionals and community groups; and developing implementation plans for the education/communication and monitoring/evaluation strategies for the pilot.

**Figure 1: Proposed Management Framework For Health Claims**

<table>
<thead>
<tr>
<th>A regulatory mechanism</th>
<th>Substantiation and qualification</th>
<th>Education and communication</th>
<th>Monitoring and evaluation</th>
<th>Compliance and enforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A standard permitting different types of health claims, and supporting interpretative guidelines/industry code of practice.</td>
<td>Systems for establishing the substantiation, nutritional qualifying and disqualifying criteria and communications effectiveness of claims.</td>
<td>A coordinated national nutrition education campaign in support of health claims.</td>
<td>A system for managing health claims which would include ongoing programs for monitoring and evaluation.</td>
<td>A nationally coordinated co-regulatory system for compliance and enforcement.</td>
</tr>
</tbody>
</table>
On 30 June 1998, the Australia New Zealand Food Standards Council (ANZFSC) gave approval to conduct the folate pilot for a period of 18 months. The pilot was undertaken as a joint initiative between the Australian and New Zealand Governments and the food industry and had 2 objectives:

- the primary objective was to trial the use of a health claim within the context of an overall management framework; and
- the secondary objective was to address a significant public health problem.

The folate pilot was launched in November 1998, following amendments to the *Food Standards Code* and to the New Zealand medicines legislation. At this point, it became legal for foods and food products assessed by ANZFA and approved by ANZFSC, to carry a folate health claim.

The proposed health claims management framework outlined in Figure 1 was trialed in the folate/NTD health claims pilot with the following key activities undertaken as part of each component of the framework:

**The regulatory mechanism**
- changes to the Food Standards Code;
- pre-market approval of foods and food products; and
- a co-regulatory system working between Government and the food industry.

**Scientific substantiation**
- substantiation of the link between folate and neural tube defects using the NHMRC report that established that the risk of NTDs decreases as folate intakes increase and a meeting of independent experts to review scientific advancements since the NHMRC made its recommendations in 1994; and
- development of a set of nutritional criteria for foods that wish to carry a folate/NTD health claim by an independent expert group.

**Education and communication**
- establishment of partnerships with a range of health and community organisations;
- development of education/promotion materials;
- development of an ANZFA health claims logo; and
- a media campaign.

**Monitoring and Evaluation**
- a process evaluation of the proposed health claims management framework;
- outcome evaluation of:
  - sociocultural and biomedical outcomes of the pilot; and
  - the impact on the food supply.

**Enforcement and Surveillance**
- development of an Interim Code of Practice; and
- establishment of a Management Committee for the Interim Code of Practice.
The report of the process evaluation of the folate pilot (ARTD, 1999) found that the management framework provided a sound basis for the appropriate, effective and efficient management of the folate health claim within the current regulatory and public health environments in Australia and New Zealand. The executive summary of the process evaluation report is at Attachment 4.

The outcome evaluation of the folate pilot was substantially based on a series of surveys conducted prior to and after the implementation of the folate pilot. These surveys elicited information on knowledge relating to folate and attitudes to the folate health claim. Information was also available from other sources including the food industry. The outcome evaluation found that, during the period of the pilot, there was a significant increase in knowledge about folate as well as about the folate-NTD link amongst women of the child-bearing age. Despite this, the food label rated poorly as a source of information about folate and NTDs. The executive summary of the outcome evaluation is at Attachment 4.

3.5 Related issues

Application A399

Subsequent to the above processes in relation to health claims, an application was made in late 1999 to review the wording of Standard A1(19)- the prohibition on health claims in the Australian Food Standards Code. A Preliminary Assessment was made for this application and public consultation sought in early 2000. In the light of the similar timeframes for both A399 and P153, the application has been withdrawn and the substance of A399 incorporated into P153. This matter is discussed in more detail in Section 7.1.

Proposal P169

In addition to the broader health claims issues being considered, a number of other issues must be considered under P153. These issues, which were originally included in Proposal 169 - Representational Issues - Claims About Food, were referred to P153 and include:

- Endorsements on the labels and advertising of food by organisations whose name includes a disease. This is currently prohibited by Australia and New Zealand consultation. In the Full Assessment Report for P169 it was considered that these endorsements should be referred to P153 for assessment.
- Claims about non-cariogenic foods/food constituents (i.e. those that do not promote tooth decay). The initial consideration of this issue in P169 was to not include specific provisions permitting this type of claim (this claim is currently permitted in the New Zealand Food Regulations but prohibited in Australia).
- Slimming or weight-reducing claims. The initial consideration of this issue in P169 was to retain the prohibition on claims that a food is a slimming food or has intrinsic weight-reducing properties.

These issues were all referred to P153 for assessment as they were considered potential health claims. The full consideration given to these issues from P169 is in Section 13.5.
3.6 An international perspective on health claims

The issue of health claims has been and continues to be addressed internationally by Codex and by individual countries. A number of countries have allowed the introduction of health claims using a variety of regulatory and management models and many now have well established systems for the management of health claims. These countries include: the United States; Japan; South Africa (who have adopted claims approved in the United States); and Sweden. The Netherlands has a system for scientific substantiation of health claims and allows them to be implemented under a voluntary Code of Practice and Canada is currently in the process of developing a system for the management of health claims.

Australia and New Zealand however, were the first countries in the world to trial a management framework for health claims in order to explore the potential impact of allowing health claims in the marketplace.

A more detailed discussion of current practice in managing health claims in the countries outlined above, is included in ‘International Regulation of Health Claims’ at Attachment 6.
4. HEALTH CLAIMS POLICY

4.1 Introduction

The issue of whether or not a review of health and related claims should result in a relaxation of the current prohibition on health claims and the introduction of a system whereby health claims are permitted in Australia and New Zealand has been a contentious one for a number of years with strong views in relation to both the potential benefits and risks. Since the emergence of health claims internationally, some empirical evidence is available to support various aspects of the use of health claims. However, many arguments provided in support of and against the use of health claims are based largely on theory and speculation. The discussion below in relation to the advantages and disadvantages of health claims is based on common theory, information submitted in response to P153 and where possible, published literature.

Health claims may be viewed as a regulatory tool to allow industry to communicate substantiated claims in relation to their products, and/or as a public health intervention. Either way, if a system to regulate health claims is to be introduced in Australia and New Zealand, it should be based on a sound policy framework and appropriate guiding principles. A health claims system must also be consistent with current health and nutrition policies and have the potential to support public health initiatives in both countries.

4.2 The public health environment in Australia and New Zealand

Any proposed health claims system in Australia and New Zealand, whether it be primarily a tool for regulating claims made by the food industry or a broader public health intervention, must be consistent with current public health nutrition policy. As stated previously in this chapter, the introduction of a health claims system may provide an additional tool to support public health initiatives in Australia and New Zealand.

4.2.1 Australia

In Australia, key nutrition guidelines and policies that provide a policy framework for health claims include:

- the Recommended Dietary Intakes (NHMRC, 1991)
- the Dietary Guidelines for Australians (NHMRC, 1991);
- the Dietary Guidelines for Children and Adolescents (NHMRC, 1995);
- the Dietary Guidelines for Older Australians (NHMRC, 1999);
- the National Food and Nutrition Policy (Commonwealth Department of Health and Community Services, 1992);
- the Australian Guide to Healthy Eating (Commonwealth Department of Health and Aged Care, 1998);
- the draft Eat Well Australia Strategy (SIGNAL, 2000); and
- the National Health Priority Areas (Commonwealth Department of Health and Aged Care, 1997).

These guidelines and policy tools are central to a number of public health interventions.
Proposed health claims should not conflict with the principles espoused in any of these tools and where possible should support their principles and related interventions. For example, The Dietary Guidelines for Australians; for Children and Adolescents; and for Older Australians provide broad guidelines that are central to public health nutrition in Australia and provide the basis for a range of potential generic health claims.

The draft Eat Well Australia Strategy has outlined nutrition promotion priorities that could be supported by health claims. These include:

- preventing overweight and obesity;
- increasing the consumption of vegetables, legumes and fruit;
- promoting optimal nutrition for women, infants and children; and
- improving nutrition for vulnerable groups, including rural and isolated populations, low income groups and Aboriginal and Torres Strait Islander people.

In terms of broad public health priorities, the National Health Priority Areas are:

- cardiovascular health;
- cancer control;
- injury prevention and control;
- mental health;
- asthma; and
- diabetes mellitus.

The areas of cardiovascular health, cancer control and diabetes mellitus are all public health priorities that could be supported by the effective use of health claims.

A recent major study on the burden of disease and injury in Australia conducted by the Australian Institute of Health and Welfare highlights the significant contribution of nutrition-related conditions to the health of Australians (AIHW, 1999). The study uses the Disability Adjusted Life Year (or DALY) to quantify the burden of different diseases, and injury, on the life of Australians. The DALY adds together the years of life lost through all deaths in 1996 and the years of healthy life lost through living with a disease, impairment and disability for all cases beginning in 1996.

Three of the 10 leading causes of disease burden (DALYs) in 1996 were related to diet:

- Ischaemic heart disease was the leading cause of disease burden, at 12.4% of the total DALYs;
- Diabetes mellitus was ranked 7th at 3%; and
- Colorectal cancer was ranked 8th at 2.7%.

The study also assessed the attributable burden for 10 major risk factors for disease or injury. Several diet-related factors were included:

- Hypertension (5.4%);
- Overweight and obesity (4.3%);
- Inadequate intakes of fruits and vegetables (2.7%); and
- High blood cholesterol (2.6%).

24
These factors rated moderately compared to a high for tobacco (9.5%) and a low for unsafe sex (0.9%).

4.2.2 New Zealand

In New Zealand, key nutrition guidelines and policies that provide a policy framework for health claims include:

- Guidelines for Infants and Toddlers (Public Health Commission, 1995);
- Guidelines for Pregnant Women (Public Health Commission, 1995);
- Guidelines for Healthy Breastfeeding Women (Public Health Commission, 1995);
- Guidelines for Healthy Adolescents (Public Health Commission, 1995); and
- Food and Nutrition Guidelines for Older People (Public Health Commission, 1993).

In New Zealand the priorities for public health nutrition have recently been re-focused following the results of the latest national nutrition survey (NNS, 1998). These priorities should be viewed in conjunction with the strategic direction for public health, outlined in Strengthening Public Health Action: strategic direction to improve, promote and protect public health (Ministry of Health, 1997).

For nutrition the key areas of focus recommended are:

- Reduction in obesity;
- Increase in physical activity;
- Reduction in non-communicable diseases (especially coronary heart disease, cancers and diabetes);
- Improvement in rates of breastfeeding;
- Improvement in child health - with a focus on some micronutrients - iron, calcium and iodine;
- Ensuring access to all of affordable and appropriate nutritious foods (improvement in food security).

These areas of recommended action and improvement are also encompassed and strengthened by one of the national objectives - "To reduce the incidence of food-related health disorders by improved nutrition".

The targets supporting this objective are based on the National Food and Nutrition Guidelines, and are consistent with the directions recommended in Australia. These are:

- Increase consumption of breads and cereals;
- Increase consumption of fruit and vegetables;
- Improve calcium intakes;
- Decrease intakes of total fat;
- Decrease intakes of saturated, plus trans, fatty acids;
- Decrease sodium intakes and
- Decrease sucrose intakes;
- Decrease obesity;
- Increase breastfeeding at both three and six months;
- Increase physical activity in adult population.
As well as being the directions for new national research in the food and nutrition area, these goals and targets provide direction for the purchase and delivery of public health nutrition programmes nationwide and are used by industry in the development and promotion of nutrition-related activities.

In the most recent report for the Ministry of Health, Our Health Our Future (MOH, 1999) improvement in some of the nutrition-related indicators has been identified as a key strategy in reducing premature morbidity and mortality.

It is estimated that 600 deaths (2% of all deaths) are attributable to inadequate fruit and vegetable consumption and 900 deaths (3% of all deaths) are attributable to obesity.

Nutrition and diet were highlighted as key risk factors for diabetes, coronary heart disease, high blood pressure, and stroke. The report states ‘data limitations do not allow "diet" to be included as actual cause of death. Yet if the contribution of diet to obesity, diabetes, blood lipid profile, and high blood pressure could be estimated, and added to the estimate for cancer and other deaths attributable to inadequate intakes of fruit and vegetables, diet may in fact rival smoking in terms of its impact on mortality’.

4.3 Health claims in Australia and New Zealand - the advantages and the disadvantages

4.3.1 The advantages of health claims

Impact on healthy choices

One of the primary arguments for allowing health claims in Australia and New Zealand includes the notion that health claims are an important means of communicating information about diet and disease and could effectively assist consumers in making appropriate diet choices, resulting in their improved health. It is claimed that health claim prohibitions as they currently stand are confusing, restrictive and inhibit the dissemination of nutrition messages, denying consumers the opportunity to make healthy choices. This notion is supported by Williams (1998) who suggests that the current prohibitions prevent food companies using health claims that might make messages more understandable and compelling for consumers. Williams (1998) refers to a study undertaken by CSIRO in 1993 which found that there was considerable public support for the concept of allowing health claims on food packaging and advertising with 80% agreeing that health claims approved by health authorities would be very or quite useful.

Further to this, a study undertaken by the National Institute of Nutrition in Canada found that 92% of respondents perceived health claims on foods would be fairly or very useful (National Institute of Nutrition, 1999).

Proponents for health claims suggest that by allowing health claims on food packaging, the information has the potential to ‘reach’ every household and that consumers’ processing of this information is relevant, timely, and convenient. Health claims also have the potential to target either the general community or specific target groups with dietary advice relevant to such groups. The information is also relatively sustainable in that once it is on a label, it will continue to be presented in store and in the home and can potentially be referred to on numerous occasions. Despite this, in terms of their public health impact, it is difficult to determine the effectiveness of the public health impact of health claims. The results of the
outcome evaluation of the folate pilot demonstrated a significant increase in consumer
knowledge of the folate-NTD link (Watson, 2000).

In contrast, results of a study undertaken by Levy et al (1997) suggest that health claims have
limited ability to communicate information about the products’ health benefits. It also found
that ‘consumers did not assume that health claims on product labels fulfilled a public health
information function.’ Instead, consumers appeared to view health claims on food labels as
they would advertisements.

A further purported benefit is that health claims can be an additional nutrition education tool
that can be used to support current health initiatives undertaken by both government and non-
government organisations. This was the case in the folate pilot where the folate health claim
was used in conjunction with a range of government and non-government organisation
nutrition education activities. A further example of how this could be the case in the future is if
a health claim on fruit and vegetables could be used by governments, non-government
organisations and health professional groups to support a broader national initiative to promote
the consumption of fruit and vegetables. Current nutrition policies and promotions that provide
a framework with which health claims could be linked in Australia and New Zealand are
discussed further in this chapter.

Industry and costs

Many proponents of health claims believe that the current restriction on health claims unfairly
disadvantages the food industry because unlike many other organisations, they are unable to
communicate the benefits of certain foods in relation to health outcomes. Proponents also
believe that the benefits of certain nutrients and foods in relation to specific diseases or
disorders have been adequately substantiated in the past, and therefore, these links should be
able to be communicated to the public on relevant food labels. In addition to this situation
being potentially inequitable to the food industry, Williams (1998) suggests it is inequitable to
sub-groups of consumers. He suggests that those consumers who are well educated and can
read scientific literature are able to access information to help make better food choices but
those who are less educated cannot.

By contributing to the improvement of consumers’ health, it could be argued that health claims
have the potential to save government resources far in excess of the amount necessary to
implement a health claims system. Williams (1998) refers to Lester (1994) who claims that in
Australia the cost of diet-related disease was estimated to be $2037 million per annum in 89-90.
Further to this, as discussed in section 4.2, a recent study was undertaken by the AIHW using
DALYs to quantify the burden of different diseases and injury on the life of Australians.

It was found that three of the 10 leading causes of disease burden were related to diet. Williams
(1998) suggests that the development of new functional foods may be a strategy to combat diet-
related disease.

Health claim prohibitions are thought to inhibit product development, research and marketing
of nutritious and functional foods - “manufacturers state candidly that if they do not have the
ability to promote the potential health benefits of their products to consumers, that research and
development into functional foods is unlikely to proceed” (Lawrence & Rayner, 1998). If
health claims were allowed, industry would have a more secure environment and increased
incentive to commit resources for innovative development and marketing of foods that support
national nutrition policies and principles. If this was the case, technological advances in
nutrition science and food technology that have been and continue to be made, could be recognised on food labels.

In support of this notion, Levy et. al (1999) refer to studies (Ippolito, 1990a, Mathios, 1991) which document changes in the healthfulness of cereals offered before and after the widespread use of health claims in advertising. They found that cereals introduced following the introduction of certain health claims had a higher average fibre content, lower fat content, and lower sodium content.

Other issues
Finally, while not strictly an ‘advantage’ of health claims per se, a further argument in support of permitting some health claims on food labels is to ensure consistency with the provisions for complementary medicines. The recent development of levels of evidence criteria to support the regulations permitting claims on complementary medicines in Australia has the potential to create an unlevel playing field between foods and supplements, and may mislead consumers as to the health benefits of supplements over foods. A review of the prohibition on health claims would enable better management of the interface between therapeutics and foods.

4.3.2 The disadvantages of health claims

Impact on diet
The primary argument against the introduction of health claims is in relation to the principle that the reduction in risk of disease is affected by the total diet and life-style pattern, not the use of an individual food. This view is supported by Lawrence and Rayner (1998), who state that ‘it is the total diet, not individual foods that determine health’ and the Public Health Association of Australia (PHAA) (2000) who argue that health claims undermine public health nutrition through medicalisation of the food supply. Many people hold the view that the nutrition information necessary for consumers to make healthy choices is currently already permitted on food labels in the form of nutrition content and nutrition function claims and therefore health claims are unnecessary and may in fact lead to consumer confusion. Further to this, PHAA (2000) suggest that to allow food products to contain information not proven to be beneficial in making a positive contribution to consumer food selection, runs the risk of diluting the positive effects of useful food labelling.

PHAA suggest that health claims can oversimplify what are often very complex issues (2000). The chronic diseases in which diet has been implicated to play a causative and/or preventative role and for which health claims could be anticipated, are multi-factorial in nature both in terms of aetiology and progression and the benefits of single foods or single nutrients is highly contentious (PHAA, 2000). The precise role for many such diseases remains to be determined therefore, to suggest that intake of a particular food can address the issue is an over simplistic approach.

This raises concerns that health claims may lead consumers to focus on certain products rather than a variety of foods resulting in their diet being skewed inappropriately. Excessive consumption of one particular product, particularly fortified products may occur, potentially resulting in a nutrient imbalance. In addition, the role of diet in disease aetiology for each individual cannot be predicted because of marked individual variability resulting mainly from hereditary and lifestyle factors. As stated by the PHAA (1998), ‘Truswell recently listed many uncertainties arising from recent nutrition research, all of which make highly problematic the use of health claims as vehicles for clear consumer nutrition education’. In relation to the
validity of potential health claims, even though claims may go through a process of rigorous scientific substantiation, new developments are always taking place in nutrition science and food technology and claims may not always remain valid and may in fact become misleading.

This situation although manageable, may be resource intensive in order to review the substantiation of existing claims on a regular basis.

**Impact on industry**

The introduction of health claims may unfairly disadvantage certain sectors of the food industry. Firstly, it may disadvantage those food industry groups that are dealing in unpackaged food, primarily due to the fact that without a package, it is more difficult to display a health claim in association with the food. Secondly, it may disadvantage smaller companies whose resource base for developing and marketing health claims are limited compared to larger multi-national companies. Lawrence (1998) concurs with this notion as he states that ‘apart from the difficulty of displaying a health claim on a product that does not come in a wrapper or a packet, the research and development that will generate the scientific data to justify a potential health claim will require substantial investment. It is highly processed, value-added products that would more likely be the beneficiaries of this investment’. It should be noted that this was not necessarily the experience in the folate pilot, where both fresh produce (which is largely unpackaged) and processed foods were promoted. In addition, a wide range of food producers took part in the pilot, including small and large businesses.

The financial implications of introducing health claims is another area of concern, with discussion being centred in two key areas. Firstly, there is concern that by introducing health claims on product labels, the cost of individual products will increase, having a direct impact on the consumer. Secondly, the cost of a health claims system to governments has been raised. Following the process evaluation of the folate pilot, ARTD (1999) stated that ‘it is clear from the pilot that there are significant costs associated with a health claims system and that these costs will be primarily borne by ANZFA’. In addition to this and as a result of such costs, there is concern that the implementation of a health claims system will divert resources and expertise from other more important public health issues and other education strategies that may have greater potential for improving public health.

**Public health impact**

Many opponents to the introduction of health claims consider that there is no evidence that health claims affect public health outcomes and in fact if introduced in isolation, may be counterproductive to health. Contrary to this, Ippolito and Mathio (1990), after examining trends in the breakfast cereal market before and after the approval of health claims in the United States, suggest that there was an increase in the purchase and consumption of high fibre breakfast cereals as health claims were incorporated into advertising activities.

These results however, have been questioned by the authors who suggest that the study must be interpreted with caution because: the study did not control for the volume of advertising in the pre and post health claims period; and the study only collected food consumption data on women aged 19-50 years, a group that are more aware of health matters. In support of their concerns PHAA (2000) refer to a study by Fullmer et al (1991) that found that consumer understanding of actual messages conveyed by health claims was low and in terms of impact on food choices, health claims only encouraged product-specific knowledge. In contrast, the outcome evaluation of the folate pilot indicated that consumer awareness and knowledge in
relation to folate and its link with NTDs, increased significantly during the pilot (Watson, 2000).

It has been argued that the international health claims systems in place are ineffective in positively effecting public health. As stated in a report of the International Association of Consumer Food Organisations (IACFO) (1999), ‘all (systems) seem to be failing to protect consumers from dubious health claims and poorly tested ingredients’. In addition to this, results of a study by Levy et al (1997) in relation to the introduction of health claims in the United States, do not support the use of health claims as being an effective public health intervention to change people’s food choices to achieve healthier diets. Despite this, the primary difference between the health claims experience internationally and that in Australia and New Zealand, is that in Australia and New Zealand, a health claim was trialled in the context of a management framework which was considered to ‘provide a sound basis for the appropriate, effective and efficient management of the folate health claims (ARTD, 1999). In the case of the folate pilot, it was demonstrated that governments, industry and non-government organisations could work in partnership to implement the management framework as a range of organisations contributed to various components of the pilot, as described in the Executive Summary of the report of the Process Evaluation (ARTD, 1999).

4.4 Implications for a health claims system in Australia and New Zealand

Given the advantages and disadvantages of health claims as discussed, together with the experience gained from the folate pilot and from that of other countries, it is essential that should the current prohibition be lifted, a system for the management of health claims be based on sound policy principles.

The following set of principles are proposed as the foundation for a health claims system in Australia and New Zealand. Health claims must:

- reflect consistency with the objectives of the ANZFA Act; COAG Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies and the 1995 New Zealand Regulatory Principles and other legislation;
- be truthful; not misleading and unambiguous;
- be consistent with the national nutrition guidelines, nutrition policies and national health policies of Australia and New Zealand;
- be based on rigorous scientific assessment of the health benefits of the nutrient(s) or food(s) within the context of the food about which the claim is made;
- be appropriate and realistic: the amount of food to be consumed to obtain the claimed benefit should be appropriate within the context of a normal diet;
- be stated within the context of the total diet;
- have clear qualifying/disqualifying criteria for eligibility of use;
- include key components of information as determined for each individual claim;
• be accompanied by appropriate consumer education;
• be monitored and evaluated at regular intervals;
• be enforceable; if the claimed effect is attributed to a constituent of the food, methods must be available to assess the presence of the constituent in the amount claimed;
• have a transparent system for dealing with complaints; and
• be developed and managed on a whole of government and whole of industry approach to ensure consistency of policy and application across all portfolios and levels of government and across all food sectors.
5. RELEVANT PROVISIONS

*Australian Food Standards Code*

Standard A1(19) currently prohibits health and related claims.

"(19) (a) Save where otherwise expressly prescribed by this Code, any label on or attached to a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import.

(b) Any label on or attached to a package containing or an advertisement for a food shall not include the word 'health' or any word or words of similar import as a part of or in conjunction with the name of the food.

(c) Save where otherwise expressly prescribed by this Code, any label on or attached to a package containing or any advertisement for food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person.

(d) Save where otherwise expressly prescribed by this Code, the label on or attached to a package containing or any advertisement for food shall not contain the name of or a reference to any disease or physiological condition.

(e) Subject to subclause (f), (g) and (h), a food listed in column 1 of the Table to this subclause may have a health claim listed in column 3 of the Table made in respect of that food, provided that the food meets the relevant eligibility criteria in column 2 of the table.²"

*New Zealand Medicines Act, 1981*

No food or dietary supplement shall be advertised or labelled as having a therapeutic purpose. A therapeutic purpose is defined as:

(a) Treating or preventing a disease; or
(b) Diagnosing disease or ascertaining the existence, degree or extent of physiological condition; or
(c) Affecting contraception; or
(d) Inducing anaesthesia; or
(e) Altering the shape, structure, size or weight of the human body; or
(f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any way; or
(g) Cleaning, soaking or lubricating contact lenses.

---

² Clause (e) is a temporary provision to allow the use of the folate/NTD health claim. This clause will cease in August 2002.
R. 4. GENERAL REQUIREMENTS FOR LABELLING OF FOODS--

(8) No label on a package of a food shall bear, as part of the name of the food or in association with the name of the food, the word "health" or any variation of that word.

R. 237. SPECIAL PURPOSE FOODS--

(1) Special purpose foods shall be foods that are specially processed or formulated to satisfy particular dietary requirements that exist because of--

(a) A particular physical or physiological condition; or
(b) A specific disease or disorder; or
(c) Both such a condition and a disease or disorder,--

and are presented as such.

(13) No label on a package of a food, except a special purpose food, shall bear the words "special purpose food", or words of similar meaning (such as, food for a specific dietary use).

(14) Every label used in connection with a special purpose food shall state the special purpose of the food.

(15) No food shall be described, expressly or by implication, as a special purpose food unless the food complies with the requirements of these regulations.

(16) No label on a package of any special purpose food, except an amino acid modified food, shall contain the name of any disease, disorder, or physiological condition in association with the name of the food.

(17) No label on a package of any special purpose food shall include, in the principal display panel, the word "health", or words of similar meaning, or any word of which "health" forms a part, except as part of the trading name in the statement required by regulation 4 (1) (c) of these regulations.

Codex Alimentarius (Alinorm 99/22A)

Codex generally prohibits claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are either in accordance with the provisions of Codex standards or guidelines for foods under jurisdiction of the Committee on Foods for Special Dietary Uses and follow the principles set forth in these guidelines or they are permitted under the laws of the country in which the food is distributed.

It is noted that the Codex Committee on Food Labelling is currently reviewing the matter of health claims and considering allowing health claims within certain parameters. However, the considerations are only at Step 3 of the process and it is therefore too early to predict likely outcomes (See Attachment 6).
6. OPTIONS INCLUDING REGULATION IMPACT STATEMENT (RIS)

The rest of this report is structured in the following way:

Section 6
- Four options for the regulation of health claims are presented in Section 6.1.

Section 7
- A discussion of the proposed revision to the health claims standard.

Section 8
- Two potential management frameworks for health claims are described.

Section 9
- Detailed information on the regulation and enforcement element of the management frameworks.

Section 10
- Detailed information on the scientific substantiation element of the management frameworks.

Section 11
- Detailed information on the education and communication element of the management frameworks.

Section 12
- Detailed information on the monitoring and evaluation element of the management frameworks.
Figure 1- outline of the presentation of Sections 6-12

Section 6 Options for the review of health claims regulations

A. No amendment to health claims regulations
B. Amended health claims regulations but no exemptions
C. Amended health claims regulations with exemptions
D. No regulation of claims in the joint Code

Section 7 Proposed revision of health claims standard for joint Code

Section 8 Options for management frameworks for health claims

Co-regulation with general approach to education and monitoring, placing the focus in the context of the changes to the Code as a whole.

Co-regulation with a more integrated approach to education and monitoring with the focus on incorporation into current public health initiatives

Sections 9-12 Detail of elements of the management frameworks for health claims

Regulation and Enforcement (Section 9)
Substantiation (Section 10)
Education and Communication (Section 11)
Monitoring and evaluation (Section 12)
6.1 Options and regulation impact statement

ANZFA is required, in the course of development of regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The Regulation Impact Statement (RIS) identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

6.1.1 Issue / objective

The issue and objective are outlined in Section 2.

6.1.2 Options

There are four proposed options for regulating health and related claims made in relation to food. In summary these are:

A  The current prohibition on health and related claims would be retained (i.e. no amendment to the current regulations);
B  Amendments to the current provisions with no exemptions (i.e. no health claims but a tightening/clarification of the provisions);
C  Amendments to the current provisions including exemptions (i.e. health claims permitted under certain conditions on a claim by claim basis); and
D  Deletion of the current provisions (i.e. any health and related claims would be subject only to food and fair trading laws and/or self-regulation by industry).

**Option A: The current prohibition on health and related claims would be retained (i.e. no amendment to the current regulations).**

*Description*

The current prohibition on health and related claims would be retained and the current temporary permission for the folate claim withdrawn following the expiry of the permission in August 2002. Thereafter no health claims would be permitted.

*Government*

*Advantages*

- Health claims would not be permitted therefore no burden on ANZFA in relation to processing of applications for health claims.
- Reduced costs for regulators as no resources required for ongoing maintenance of a health claims system. As stated in the final report of the process evaluation of the folate pilot (Attachment 4, Appendix 1) there are significant costs associated with a health claims system, such as those for education, monitoring and substantiation, a great proportion of which were borne by ANZFA.
Disadvantages

- Will result in continued confusion amongst regulatory and enforcement agencies and industry as to what is permitted or prohibited by the regulations. The confusion that exists has been illustrated by complaints that have been made regarding products on the market displaying permitted nutrition messages that appear to all intents and purposes to be health claims. This situation is discussed in the final report of the process evaluation of the folate pilot (Attachment 4, Appendix 1). Similarly, a number of products on the market have been found to display claims which may or may not contravene Standard A1(19), according to interpretation. This confusion poses a cost burden on enforcement agencies in terms of the resources spent liaising with industry to avoid breaches of the regulations or take action to correct breaches.
- The current inconsistency between the regulation of claims on foods and complementary medicines will continue, insofar as there are currently some health-related claims that are more easily made on complementary medicines and therapeutic goods than on foods.
- Issues of uncertainty may arise due to subtle differences between the current legislation in Australia and New Zealand. For example the definition of a therapeutic claim (see Section 5) differs between the two countries, with the New Zealand definition being more detailed. This could result in different interpretations and therefore use and enforcement of claims in the two countries.
- Continued limited opportunity to support public health nutrition priorities with information on food labels.

Consumers/Public health

Advantages
- No change to current claims or current access to information on labels.

Disadvantages
- Risks to public health and safety may result from potentially misleading statements made in labels and/or advertisements for food products, due to confusion as to the scope and intent of the current regulations.
- Less information available regarding the role of individual foods within the diet.
- Inconsistency with the regulations for complementary medicines and therefore inconsistency between foods and complementary medicines with respect to allowable claims.

Industry

Advantages
- No labelling or advertising changes required for those products currently outside the intent of the regulations.
- Ability to take advantage of the flexibility of interpretation afforded by the ambiguity of the current regulations.

Disadvantages
- Unfair advantages to manufacturers making claims outside the intended prohibition where action is not taken by enforcement agencies. This point has been raised by a member of the processed food industry in a submission to Application A399.
They claim that ‘companies are fast concluding that health claims are permissible’ and that a review of A1(19) should be undertaken to ensure that ‘law-abiding food manufacturers and marketing companies are not further competitively disadvantaged in the Australian market place.’ (Attachment 3)

- Inconsistency with the regulations for complementary medicines and therefore inconsistency between foods and complementary medicines with respect to allowable claims.
- May result in reduced product innovation due to inability to make claims. This is supported in published literature that is discussed in ‘Advantages of health claims’ in Section 4.2.1.
- Continued confusion for industry due to ambiguity in the current regulations, placing them at risk of prosecution. The confusion pose a cost burden in terms of industry having to recall products and change labels/advertising if the regulations are inadvertently breached.

**Option B: Amendments to the current provisions with no exemptions (i.e. no health claims permitted but a tightening/clarification of the provisions)**

**Description**

The current provisions would be amended in order to clarify the intent of the prohibition and address any areas of ambiguity, but no claims would be permitted.

**Government**

**Advantages**

- Health claims would not be permitted therefore no burden on ANZFA in relation to processing of applications for health claims.
- Reduced costs for regulators as no resources required for ongoing maintenance of a health claims system. As stated in the final report of the Process evaluation of the folate pilot (Attachment 4, Appendix 1) there are significant costs associated with a health claims system, such as those for education, monitoring and substantiation, a significant proportion of which were borne by ANZFA.
- Clearer regulation will serve to ensure protection of public health and safety by clarifying what is permitted or prohibited.
- Will clarify the intent of the prohibitions for industry and enforcement agencies, (as discussed in the submissions to Application A399 at Attachment 3) and therefore should lead to reduced costs to enforcement agencies.
- Harmonisation of the regulations between Australia and New Zealand and therefore clarity for governments as to what is permitted or prohibited in both countries.

**Disadvantages**

- Inconsistency with the regulations for complementary medicines and therefore inconsistency between foods and complementary medicines with respect to allowable claims. This may result in lobbying from the food industry to create a “level playing field” for foods and complementary medicines.
- Continued limited opportunity to support public health nutrition priorities with information on food labels.
Consumers/Public health

**Advantages**
- The possibility of potentially misleading claims being made would be reduced thereby helping to protect public health and safety.
- Consumers would still be able to obtain some information through nutrition claims and Nutrition Information Panels.
- Some consumers may see it as an advantage that the area of functional food growth may be restrained due to inability to make claims.

**Disadvantages**
- Inconsistency with the regulations for complementary medicines and therefore inconsistency between foods and complementary medicines with respect to allowable claims. This may create confusion for consumers and lead to increased reliance on complementary medicines rather than foods.
- Confusion may result from the removal of some current claims.
- May result in reduced range of new products available due to inability to make claims.

Industry

**Advantages**
- Will pose no additional burden on industry as it is designed only to clarify the intent of the current regulations.
- Will make it easier for industry to comply with the food legislation due to improved clarification.
- There will be harmonisation between the regulations in Australia and New Zealand and therefore will make it easier to develop products for the Australian and New Zealand markets.

**Disadvantages**
- Will remove the opportunity for making certain statements on labels and in advertising that were afforded by the ambiguity of the current regulations.
- Inconsistency with the regulations for complementary medicines and therefore inconsistency between foods and complementary medicines with respect to allowable claims.
- May limit innovation with product development due to inability to make particular claims.

**Option C: Amendments to the current provisions including exemptions i.e. health claims permitted under certain conditions**

**Description**

Under this system, the current prohibition on health and related claims would be revised and exemptions to this general prohibition would be added to permit certain claims that have been assessed and approved by ANZFSC. The regulations in the joint Code would be supported by an industry Code of Practice outlining a list of permitted claims; eligibility criteria; examples of model claims; guidelines for the development of education activities and monitoring activities; and guidelines on the wording of the claim.
As part of Option C, two frameworks have been proposed for managing exemptions to the general prohibition on health claims. Both frameworks are based upon a co-regulatory approach, as used in the folate pilot. The frameworks have the same approaches to regulation, enforcement and substantiation but differ in their recommended approaches to education and monitoring. Framework 1 proposes a general approach to education and monitoring, placing the focus on education and monitoring activities in the context of the changes to the joint Code as a whole. Framework 2 builds upon the elements in Framework 1, and proposes a more integrated approach to education and monitoring with the focus on incorporation into current public health initiatives. Detailed information on each of the framework elements is outlined in Sections 9-12. Framework 1 is being recommended on the basis that it meets all the essential elements of a framework for managing health claims while being sustainable.

**Government**

*Advantages:*
- By regulating through the joint Code, protection of public health and safety would be assured.
- Each permitted health claim would be subject to substantiation by experts and extensive public consultation. This may increase public confidence in the health claims system.
- Removes sole responsibility from government enforcement agencies as the co-regulatory model will involve industry in addressing complaints re alleged breaches.
- Has the compounded benefit of the involvement of industry in addition to government and other agencies in the development and management of the system by virtue of a co-regulatory system.

*Disadvantages:*
- Substantiation of health claims would be very time consuming and costly (although some of these costs may be able to be recovered from the applicant).

**Consumers/Public Health**

*Advantages:*
- By regulating through the joint Code, there should be more effective protection of public health and safety.
- Provides the opportunity to support regulation with an independent management framework including elements such as scientific substantiation, education and monitoring. If health claims were to be introduced without an accompanying education campaign supported by the public sector, consumers may view them with suspicion, including those that are well-founded. This issue is discussed in ‘Advantages of health claims’ in Section 3.6.2.1 where a study by Levy et al. (1997) found that in certain cases, consumers appeared to view health claims on food labels as they would advertising.
- This option requires that manufacturers present claims in the context of a healthy diet. In the absence of this, the statements made on labels may have the potential to lead to distorted food intakes and mislead consumers about the role the products can play in reducing the risk of disease. This aspect is discussed further in ‘Disadvantages of health claims’ in Section 4.2.2.
- Each permitted claim would be subject to substantiation by experts and extensive public consultation.
**Disadvantages:**
- If the system is not well-designed in terms of substantiation, monitoring, education and enforcement, it may have the potential to confuse consumers or mislead them as to the role of individual foods in the aetiology of diseases.

**Industry Advantages:**
- Each permitted health claim would be subject to substantiation by experts and extensive public consultation. This may increase public confidence in the health claims system.
- Provides an opportunity for industry to communicate independently substantiated messages about the health benefits of their products, as discussed in the ‘Advantages of health claims’ in Section 4.2.1.
- Provides industry with clear guidance on how to use the claims and their responsibilities in this regard.
- Provides industry with an opportunity to participate in the regulation and enforcement of claims through the establishment and management of a code of practice.
- Protects responsible companies from irresponsible competitors. As noted above, a member of the processed food industry in a submission to Application A399 discussed the importance of ensuring that ‘law-abiding food manufacturers and marketing companies are not further competitively disadvantaged in the Australian market place’.

**Disadvantages:**
- Will remove the opportunity for making certain statements on labels and in advertising that were afforded by the ambiguity of the current regulations.
- Will require the contribution of resources from industry to help support the system (the implementation of the Code of Practice, education and monitoring and substantiation).

**Option D: Deletion of the current provisions (i.e. any health and related claims would be subject only to food and fair trading laws and/or self-regulation by industry).**

**Description**

Under this system, the general prohibition on health claims would be removed from the respective Australia and New Zealand legislation. Under the prohibitions on false, misleading or deceptive representations in food and fair trading laws, any health claims on food products and the associated advertising would be required not to be ‘deceptive or misleading’. Action would only be considered if a complaint was made about the labelling or advertising of products or if enforcement agencies consider a breach has occurred.

Action in relation to alleged misleading or deceptive conduct could be initiated by enforcement agencies such as fair trading departments or health departments or taken in response to complaints that are received. In deciding whether to take action enforcement agencies will consider a series of factors including whether there appears to be blatant disregard for the law, the matter particularly affects disadvantaged consumers and there is significant public detriment. Food manufacturers would be required to undertake their own substantiation of claims and this substantiation would only require scrutiny by experts if a complaint were made.
Industry may need to instigate its own compliance and enforcement procedures. The onus would fall on industry to develop guidelines and protocols, possibly through the development of a self-managed code of practice, as to which claims are appropriate and how they should be substantiated etc.

**Government**

*Advantages:*
- Less time consuming and costly for ANZFA as there are significant costs associated with a health claims system that may be primarily borne by ANZFA (Attachment 4, Appendix 1).

*Disadvantages:*
- Any challenge of claims in a court of law will primarily reflect legal rather than scientific considerations. This may diminish public confidence in food standards and the public health sector.
- Australian and New Zealand Fair Trading agencies may not have the resources to manage the complaints that may arise from this system.
- Generally, action is only taken if a complaint is made. By this time, the product may have been on the market for some time and the information been taken up by many consumers.
- In some circumstances there are difficulties for private litigants and enforcement agencies in bringing legal action in relation to certain types of misrepresentations because the onus is on the party bringing the action to provide evidence that the claims or representations are misleading or deceptive.

**Consumers/ Public Health**

*Advantages*
- Allows consumers to be informed of the beneficial effects of some products. The current regulations could be viewed as unnecessarily restrictive and withholding useful information from consumers.

*Disadvantages:*
- Will result in continued use of claims on labels and in advertising that place consumers at risk of being mislead about the role individual food products can play in reducing their risk of developing disease.
- Unlike the ANZFA Act, Fair Trading Laws do not have the protection of public health and safety as one of their core priorities.
- Any challenge of claims in a court of law will primarily reflect legal rather than scientific considerations. This means a court may rule in favour of a claim that is not scientifically sound.
- There would be no requirement for a supporting framework therefore, there may be no supporting scientific substantiation, education and/or monitoring. Absence of these elements may create situations which result in loss of credibility with consumers.
- There would be no requirement for manufacturers to present claims in the context of a healthy diet. The statements made on labels may therefore have the potential to lead to distorted food intakes, mislead consumers about the role the products can play in reducing the risk of disease and lead to worse consumer health outcomes.
• There would be the potential for unsubstantiated claims that have not been adequately assessed. This is best illustrated by the body of evidence for the association between beta-carotene and cancer risk. As discussed in ‘International Regulation of Health Claims’ at Attachment 6, at the time that the FDA reviewed this health claim, there was strong evidence that high intakes of fruits and vegetables rich in carotenoids were associated with a reduced risk of developing cancer, but it was unclear whether the component of fruits and vegetables responsible for reducing the effect was beta-carotene or some other component. For this reason the claim was not permitted. The decision was further supported when a randomised, controlled trial in Finland found a significant increase in the rate of cancer in the beta-carotene supplemented group. This example highlights how a robust, independent system of scientific substantiation is critical for industry, consumers and the public health sector if health claims are to be permitted.

**Industry**

*Advantages:*

• Freedom for companies to communicate the health benefits of their products.

*Disadvantages:*

• Potential lack of clarity for industry in relation to permitted claims.
• Potential marketing disadvantages between companies if the permission for claims remains unclear.
• Higher costs to industry overall as claims may need to be substantiated repeatedly by each individual company that wishes to use the claim.
• Likely loss of international market confidence in the reliability of label information on Australian and New Zealand food labels.

6.1.3 Consultation

In developing P153 there has been one round of public comment, which drew 59 responses. Subsequently, Application A399, Review of Standard A1(19) – Claims Made About Foods, was raised to which 45 submissions were received. Attachment 3 contains a list of the submitters to P153 and A399 and a summary of comments made regarding the issues. There has also been consultation with a number of expert panels consisting of representatives from industry, government and consumer organizations. These are referred to within the context of Sections 9, 10, 11 and 12 and their reports are at Attachment 5. No comments were received in response to P170 as the usual consultation processes were truncated as a result of parliamentary direction.

6.1.3.1 Comments received in response to Proposal P153

There were a number of submitters in favour of retaining the current prohibition on health claims with exemptions being permitted and listed in the Code, including further suggestions by some that this regulation be incorporated into an overarching nutrition information standard, or comprise a separate section of the Code. Furthermore, there were a number of recommendations that a supporting Code of Practice be developed.

A number of industry submitters expressed a preference for a self-regulatory mechanism or suggested that food and fair trading laws in conjunction with industry-developed guidelines may adequately address the issue.
There were concerns raised by industry that, by not allowing health claims on labels, consumers were reliant on information from other sources, e.g. media and popular press, which may not be reliable.

Although it was also suggested by some submitters that immediate adoption of claims permitted in the USA would be an appropriate approach, views on the adoption of the USA health claims system as under the Nutrition Labeling Education Act (NLEA) were divided.

There were comments from public health and consumer bodies that health claims should be considered in context with dietary reference tools e.g. guidelines, national food selection guides, recommended dietary intakes, food endorsement programs and food industry nutrition education initiatives. Two nationally representative consumer groups were concerned that compliance with current laws [in relation to health claims] was poor and that any consideration of health claims should be made in the context of all other relevant food label information e.g. nutrition claims, nutrition information panels and ingredient lists.

The Association of New Zealand Advertisers Inc. raised the issue of incorporation of health claims regulation into provisions for advertising. Further to this, in response to A399, The Advertising Standards Authority, New Zealand (ASA), maintained that Standard A1(19) disadvantages consumers as it is in their interests to be fully informed about foods which contribute to a healthy diet. As an alternative, the ASA proposed that a Code of Advertising be introduced and to remove all reference to advertising in Standard A1(19).

6.1.3.2 Comments received in response to Application A399

A number of organisations such as the Public Health Association of Australia (PHAA) remain opposed to the introduction of health claims. However, in support of health claims, it was maintained by others that there is a public health benefit to making health-related claims and that there is an incentive for companies to create products that will assist consumers from a health and medical perspective. More detailed information on submitters’ comments may be found in Appendix 2 of Attachment 3.

6.1.4 Conclusion and preferred option

ANZFA’s preferred option is Option C. The regulations relating to the current prohibition on health claims are in need of review. Option A is not feasible as the current regulations are inconsistent, duplicatory and open to interpretation, creating difficulties for government, industry and consumers.

Option B is not desirable as the current regulations are also not in keeping with modern regulatory practice. One of the key principles underpinning the development of the joint code has been the reduction of prescription to enhance innovation by industry. However, this needs to be balanced against the need to protect public health and safety and to ensure that consumers have adequate information with which to make informed food choices. For this reason, Option D should also not be considered, as it will not provide a system that protect consumers against unsubstantiated claims and ensure public confidence in the system.
In the interests of providing for informed choice by consumers, ANZFA considers there is scope for claims linking a particular food to health/disease outcomes to be provided on food labels and, that such claims bear the potential to support national public health and nutrition initiatives. However, permissions for health claims should be subject to rigorous substantiation and managed within the context of a comprehensive framework.

It should be noted that the implementation of Option C would be associated with significant costs. These costs would be in relation to:

- substantiating the claimed relationship as part of the process of processing an application or proposal;
- ensuring the system is enforced;
- ensuring that there is adequate education and monitoring to support any claims that may be permitted.

Under ANZFA’s current act there are 2 issues that have some bearing on the costs associated with this system:

- A charge will be fixed, covering the full cost of processing an application where an application confers a captureable commercial benefit to the applicant. An application would be assessed as having an exclusive captureable benefit if: the applicant can be identified as a person or body that may derive a financial gain from the adoption of the standard that would be prepared in relation to that application; and any other unrelated persons or bodies, including unrelated commercial entities, would require the agreement of the applicant in order to benefit financially from the approval of the application.
- ANZFA is required to develop and publish, by 30 June each year, a 3-year work program for managing applications and proposals. Applications and proposals will be prioritised in the work plan in accordance with the section 10 objectives of the Act. All other applications will be dealt with as they are received. Applicants will also have the option of paying a fee to have their applications processed more expeditiously. Additional contract services will be engaged by the Authority to enable this to occur without affecting the processing of other applications on the work plan.

Option C shares the responsibility for a health claim system and allows some flexibility in relation to the practical implementation of a management framework.

6.1.5 Further issues

Within the context of Option C there are other issues for consideration, specifically: whether the system should be co-regulatory with an associated code of practice; and different approaches in relation to the extent of education and monitoring activities applied. Such considerations are discussed further in Sections 8, 9, 11 and 12.

For a diagrammatic representation of these expanded approaches to Option C, refer back to Figure 1 at the beginning of this section.
7. ASSESSMENT - PROPOSED REDRAFTING OF THE CURRENT PROVISIONS RELATING TO HEALTH CLAIMS

The issue of redrafting the current prohibition on health claims was raised in the Preliminary Assessment report of P153 in 1997. A consultation on the strengths and weaknesses of the current regulations, and some proposed redrafting of the regulations, was conducted as part of a consultation on an application from NSW Health in late 1999 to review the health claims regulations ahead of the review taking place in P153. The Application (A399) was subsequently withdrawn on the basis that the issues will be addressed in P153. The submissions to the Preliminary Assessment of P153 and A399 have therefore assisted in defining the scope and content of the proposed new Standard.

7.1 Revision of current health claims regulations

The redrafting of the current regulations has been based on the option recommended by ANZFA in section 6.1 above, i.e. Option C – revision of the current regulations to clarify the intent and scope of the prohibition on claims, with exemptions to the prohibition on a claim-by-claim basis.

The proposed new Standard 1.2.7 of the joint Code (Health, Nutrition and Related Claims About Food) is at Attachment 1. The proposed new Standard has the following elements:

7.1.1 Scope

The proposed Standard defines three categories of claims, as illustrated in Figure 2 below.
• **Nutrition claims**

**Current situation** - Regulation 2(1) of the New Zealand Food Regulations (1984) defines a nutrition claim as: ‘Any representation that states, suggests or implies that food has particular nutritional properties….and includes negative claims.’

Standard A1 (13) of the Australian Food Standards Code defines a nutrition claim as: ‘A representation that states, suggests or implies that a food has a nutritional property whether general or specific and whether expressed affirmatively or negatively.’

Manufacturers, enforcement officers and nutritionists commonly refer to “nutrition messages” as messages on food packages and advertising that link the food or nutrients in the food to a general health outcome but not to a disease or therapeutic action. Examples include “Helps build healthy bones”, “restores vitality” or “helps vitalise body and mind”. There is no mention of a disease or enhanced function. The intent was for such messages to describe the role of nutrients in the normal functioning of the body. However in recent times there has been an emergence of newer messages (enhanced function claims) that describe the role of nutrients in enhancing the functioning of the body.

**Proposed in Standard 1.2.7**

- **nutrition content claim** means a claim in relation to food which describes or indicates the presence or absence of a nutrient, energy content or biologically active substance in that food.

- **nutrition function claim** means a claim in relation to food which describes the physiological role of a nutrient, energy content or biologically active substance in the food, in the growth, development, maintenance and other like functions of the human body.

**Rationale** – The current definitions of nutrition claims in the Australian and New Zealand regulations relate to ‘nutritional property’. ‘Property’ in essence relates to the nutrition content of a food, and the function of the nutritional constituents in the food. It is considered that splitting the definition of nutrition claims into nutrition content and nutrition function claims, when viewed in the context of the definition of a health claim, more clearly describes the continuum of nutrition and health-related messages on food labels as illustrated in Figure 2.

• **Health claims**

**Current situation** - often referred to as therapeutic claims, these claims are usually associated with a link between a nutrient or nutrients and a disease or therapeutic outcome.

“Health claim” is not defined in either New Zealand or Australian legislation. The current Australian and New Zealand regulations relating to health claims are outlined in Section 5 – Relevant Provisions.
Proposed in Standard 1.2.7

It is considered important to include a definition of a health claim in the new Standard. The following definitions are proposed:

**health claim** means a claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a -

(a) enhanced function claim;
(b) reduction of disease risk claim; and
(c) claim that a food is a slimming food or has intrinsic weight-reducing properties;

but excludes a –

(d) nutrition function claim; and
(e) nutrition content claim; and
(f) claim of therapeutic or prophylactic action.

**Rationale** – the definitions in the drafting reflect some of the considerations being undertaken by Codex on health claims, to the extent that both ‘risk reduction’ and ‘enhanced function’ claims are encompassed in the definition of a health claim3. A ‘risk reduction’ claim relates the consumption of a food or constituent of a food to a reduced risk of developing a disease. An ‘enhanced function’ claim relates the consumption of a food or constituent of a food to the functioning of the body beyond that expected in terms of normal growth, development, maintenance etc. Enhanced function claims will commonly contain the words ‘enhances’, ‘increases’, ‘reduces’ or words of similar intent. Slimming and weight-reduction claims have also been included in the definition of a health claim (the considerations relating to these types of claims were transferred to P153 from another proposal, P169 – Representations about food, as described in Section 2).

7.1.2 Prohibitions and permissions

- **Nutrition content and nutrition function claims**

These claims are permitted. For both categories of claims a nutrition information panel, as specified in Standard 1.2.8 must accompany the claim. For nutrition function claims only, a statement of the importance of dietary variety must accompany the claim.

- **Health claims**

The new Standard proposes that health claims (including enhanced function claims, risk-reduction claims and slimming claims) be prohibited unless specifically permitted (i.e. unless listed in the Table to Paragraph 6(b) – refer Attachment 1). Claims will only be listed in the table after going through the ANZFA approval process, including the substantiation of the

---

3 The current draft Codex standard, which is at step 3, also includes ‘nutrient function claims’ in the definition of health claims. The intent of Codex in doing this is unclear. For the purposes of the proposed Australian and New Zealand standard it is not considered appropriate to include these types of claims in the definition of health claims, as these types of claims are regulated differently in the standard.
claim, as described in Section 10. The current temporary permission for the folate/NTD claim would be made permanent in the new Standard.

Foods will be prohibited from carrying an approved claim if they:

- Are a food standardised in Parts 2.7 (Alcoholic beverages) or 2.9 (Special Purpose Foods) in the joint Code. Alcohol is a drug that can have a significant impact on the health of the population if consumed at more than moderate levels and the inclusion of a health claim on this category of products is undesirable as it may promote increased consumption. Foods in Part 2.9 of the Code are designed for specific nutritional or functional purposes and are likely to be consumed by particular population sub-groups for particular needs and are therefore not considered suitable to carry claims.

- If they do not meet the generic eligibility criteria for carrying a claim as specified in subclause 6(a). These criteria are that the food contains, per serve as specified in the nutrition information panel –
  
  (i) no more than 14 g of fat, of which no more than 5 g is saturated fat;
  (ii) no more than 500 mg of sodium; and
  (iii) no less than 10% of the Recommended Dietary Intake of a nutrient, prior to fortification, other than sodium and potassium.

The rationale for these criteria are described in Section 10.

There are also specific prohibitions on the use of claims for therapeutic or prophylactic action. This is a continuation of the current prohibitions in subclauses (a) and (c) of clause A1(19) and those in the New Zealand Medicines Act of 1981.

In addition, claims that could be interpreted as advice of a medical nature are prohibited. This is a continuation of the current prohibition in clause A1(19) of the Australian regulations. This includes the following types of information on labels or in advertising:

- Statements such as: ‘Doctors recommend …’; ‘Dr/Professor XXX recommends …’; ‘The New Zealand Heart Institute recommends …’.
- Illustrations or images that are related to medical situations, such as stethoscopes, electrocardiograms etc.

**Use of the word “health”**

The use of the word ‘health’ is also prohibited in: the name of food; any generic or specific description of food; or the trade name or trade mark of any food. This is a modification of the prohibition in subclause (b) of clause A1(19) and subclause (8) of clause R.4 of the New Zealand Food Regulations. The prohibition is retained as the word ‘health’ or its derivatives in the name or description of a food could be interpreted as being an implied health claim. The modified prohibition was raised in A399 and was generally not supported as it extends the current prohibition to include descriptions of foods and trade names and trademarks. This has the potential to remove several long-established products from the Australian and New Zealand markets where the word ‘health’ appears in the trade name and trademarks of foods.
As a means of reaching a compromise position, the provisions in the US food regulations were considered. The use of the word ‘health’ is permitted in the US provided the products meet certain pre-defined criteria. It is therefore proposed in Standard 1.2.7 that products will be exempt from the prohibition if they meet the following criteria:

the food contains, per serve as specified in the nutrition information panel –

(a) no more than 3 g of fat;
(b) no more than 1.5 g of saturated fat;
(c) no more than 500 mg of sodium; and
(d) no less than 10% of the Recommended Dietary Intake of a nutrient, prior to fortification, other than sodium and potassium.

Other requirements

Any foods carrying an approved health claim must also contain a nutrition information panel (as described in Standard 1.2.8) and a statement must accompany the claim on the importance of dietary variety.

7.1.3 Links to Standard 1.2.8 – Nutrition Information Requirements

There are integral links between the proposed Standard 1.2.7 and Standard 1.2.8 of the Joint Code.

Standard 1.2.8 sets out nutrition information requirements in relation to food, including when nutrition information is required to be provided and the manner in which it must be provided. Division 4 of the standard also contains requirements relating to certain nutrition claims (fatty acids, lactose, gluten etc).

The proposed Standard 1.2.7 would have the effect of removing the definition of ‘nutrition claim’ from Standard 1.2.8 (as described in section 6.2.1.1 above). There is also the potential to move Division 4 from Standard 1.2.8 to Standard 1.2.7 to situate the regulations relating to all nutrition and health-related claims within the one standard.

7.2 Issues raised in submissions

7.2.1 Submissions to the Preliminary Assessment of P153

Thirty-eight of the 59 submissions to P153 generally supported a review of the current regulations relating to health claims. Reasons for supporting the review were varied and included concerns that the current regulations are confusing, restrictive, and inconsistent between Australia and New Zealand, and between foods and therapeutic goods. Very little specific comment was received on the actual content of the current regulations. The full summary of submissions to P153 is at Appendix 1 to Attachment 3.
7.2.2 Submissions to A399

A399 proposed amendments to the drafting of the current regulations to clarify the intent and scope of the current prohibition. While the majority of respondents did not support the application, many submitters made this comment in the belief that the issues raised in the application should be addressed in P153.

The full summary of submissions to A399 is at Appendix 2 to Attachment 3.

A comparison of the current clause, the clause proposed in A399, and the new proposed Standard is at Attachment 7.
8. ASSESSMENT - MANAGEMENT FRAMEWORKS FOR HEALTH CLAIMS

8.1 Introduction

In Section 6, it was recommended that the current health claims provisions be amended and that exemptions to the prohibition be permitted on a claim by claim basis (i.e. Option C). Consideration now needs to be given to how any health claims introduced under Option C would be managed.

Potential frameworks have been considered with due reference to:
- the experiences of the folate pilot (see Attachment 4)
- comments received in submissions to the Preliminary Assessment for P153 (see Appendix 1 of Attachment 3);
- where applicable, to A399;
- expert advisory groups convened by ANZFA (Refer Attachment 5 for reports of these groups.

As a result of the above processes, two potential frameworks have been identified. These co-regulatory frameworks both require the same scientific substantiation and enforcement, but have different options for monitoring and evaluation, and education and communication. One framework proposes a general approach to education and monitoring, whereas the other proposes a more integrated approach.

8.2 Objectives of a management framework

The principles of a framework for any health claims system are given in Section 4.4.

8.3 Comments received in response to the Preliminary Assessment for P153, in relation to management frameworks

A number of comments received in response to the Preliminary Assessment for P153 suggested that only a framework which serves to improve public health would be supported, and that any such regulatory framework should encompass all labelling, advertising, electronic print and sales promotion relating to health claims. It was also suggested that where a health claim is on a label, reference to further substantiating information should be provided. More detailed information on these comments may be found at Appendix 1 of Attachment 3.

8.4 Issues raised in process evaluation of the folate pilot

The process evaluation (ARTD, 1999) identified seven key strengths of the management framework as used in the folate pilot - namely:
1. the five elements of the management framework adequately covered the main areas and issues which needed to be addressed in managing the folate health claim;
2. it ensured that relevant partners were engaged in elements of the framework that related to their needs and issues;
3. expert committees provided a credible, independent basis for substantiating the health claim and establishing the eligibility criteria for approved foods;
4. the co-regulatory system achieved a balance between industry self-regulation and legally-binding enforcement of the Food Standards Code by government agencies;
5. the individual product approval system was administratively simple and efficient;
6. the Code of Practice Management Committee provided a mechanism for industry involvement in ensuring compliance with the Interim Code of Practice for the Communication of the Health Benefits of Food Products and maximised the efficient use of existing infrastructure; and
7. the monitoring strategy involved the collection of an appropriate range of process and short-term outcomes data, taking advantage of existing nutrition and health surveys and industry data.

Seven limitations were also identified including:
1. Inadequate integration and co-ordination of policy and industry context with New Zealand and Australia resulting in lack of participation of New Zealand industry;
2. The need for guidelines on the requirements and scientific substantiation for future health claims;
3. Lack of public consultation on the diverse views on rationale and merits of folate health claims;
4. The need to understand the role and functions of the Code of Practice Management Committee to avoid confusion between self regulation and co-regulation;
5. The need to clarify the interface between the surveillance responsibilities of the Code of Practice Management Committee and the enforcement agencies in Australia and New Zealand;
6. Sustainability of a public education campaign; and
7. Uncertainties about the comparability and usefulness of the data when establishing the outcomes of the pilot.

8.4.1 Assessment of issues

There has been considerable debate as to: a) the purpose of health claims per se; and b) the purpose of regulating claims i.e. whether the purpose of a health claim management framework system should be to actively serve to improve public health, or whether it is purely a regulatory tool which safeguards public health. These aspects have been considered throughout the discussions on management frameworks and are addressed accordingly within each of the framework elements described in Sections 9, 10,11 and 12. They are also reflected in the objectives for frameworks as outlined above. Similarly, it has been recognised that substantiation is a critical factor in the overall success of any future permissions for health claims and this is addressed in detail in Section 10.

8.5 Elements of a management framework

The folate pilot was based on a management framework comprising five elements i.e.: regulation; scientific substantiation; education and communication; monitoring and evaluation; and surveillance and enforcement. Due to the success of this framework (ARTD, 1999) it is proposed to continue with this approach in relation to health claims more broadly. However, it is also considered that as the regulation and enforcement procedures are so integrally linked, it is more expedient to consider these within the one element.

Each of these elements is considered in turn below. These considerations have taken into account submitters’ comments, and the results of the evaluation of the folate pilot.
**Framework 1:** Co-regulation using a system similar to that tested in the folate pilot, with the focus of education and monitoring on protection of public health and safety *(preferred approach).*

<table>
<thead>
<tr>
<th>Regulatory mechanism; Compliance and enforcement</th>
<th>Substantiation and qualification</th>
<th>Education and communication + Monitoring and evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(see Section 9)</td>
<td>(See Section 10)</td>
<td>(See Sections 11 and 12)</td>
</tr>
<tr>
<td>A co-regulatory approach would be adopted whereby the prohibition on claims remains, with exemptions, and a code of practice developed in conjunction with industry to support the regulations.</td>
<td>Applications for claims submitted for approval would need to be accompanied by supporting evidence, for review and assessment by ANZFA.</td>
<td>Education and monitoring activities would be largely funded by industry and supported by the public sector and possibly non-government organisations. The focus of the public sector in both the education and monitoring elements of the framework would be to:</td>
</tr>
<tr>
<td>Enforcement through the code of practice management committee and state/territory and New Zealand governments.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Framework 2:** As for Framework 1 but with a more comprehensive approach to education and monitoring.

<table>
<thead>
<tr>
<th>Regulatory mechanism; Compliance and enforcement</th>
<th>Substantiation and qualification</th>
<th>Education and communication</th>
<th>Monitoring and evaluation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(See Section 9)</td>
<td>(See Section 10)</td>
<td>(See Section 11)</td>
<td>(See Section 12)</td>
</tr>
<tr>
<td>A co-regulatory approach would be adopted whereby the prohibition on claims remains, with exemptions, and a code of practice developed in conjunction with industry to support the regulations.</td>
<td>Applications for claims submitted for approval would need to be accompanied by supporting evidence, for review and assessment by ANZFA.</td>
<td>Education and communication as for Framework 1, but with the focus on a more integrated approach, linking education on health claims into current public health initiatives and an increased focus on education on individual claims.</td>
<td>Monitoring and evaluation as for Framework 1, but it would also extend into exploring the impact of health claims on health outcomes. As for education, there would be a focus on linking monitoring and evaluation strategies to current national monitoring initiatives.</td>
</tr>
<tr>
<td>Enforcement through the code of practice management committee and state/territory and New Zealand governments.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. ASSESSMENT - FRAMEWORK ELEMENT 1- REGULATION, SURVEILLANCE AND ENFORCEMENT

9.1 Introduction

Background information on regulation and the culmination of the deliberations of the expert advisory group on regulation and enforcement can be found in Attachment 5.

The co-regulatory approach has been discussed above in Section 7.1, and two potential frameworks outlined. Any such framework will also require effective surveillance of compliance in order to ensure the regulatory measures are being adhered to, and adequate enforcement to address any determined breaches of the regulation.

9.2 Objectives

One of objectives proposed of health claims outlined in Section 4 was that health claims must be enforceable. The following principles are proposed in relation to ensuring this objective is met:

1. Claims need to be strictly regulated and defined.
2. Enforcement must be adequate to support the regulation and to act as an effective deterrent to breaches of the regulation;
3. Imported and domestic products should be treated equitably;
4. Enforcement activities should be addressed primarily through a suitably representative management committee, with referral to a shared responsibility between New Zealand and Australian industry and governments;
5. States and Territories and New Zealand must adopt a harmonised approach with respect to enforcement of health claims; and
6. Surveillance must be sufficiently frequent and diligent to maintain compliance.

9.3 Regulation

9.3.1 Issues raised in the process evaluation of the folate pilot

The process evaluation report recommended that co-regulatory processes should include:

- amendments to the joint Code for each permitted health claim;
- an administratively simple pre-market approval process based on individual product applications from food companies and associations to ANZFA; and,
- a Code of Practice for the Communication of the Health Benefits of Food Products which provides best practice guidelines for companies and organisations wanting to use approved health claims.

9.3.1.1 Assessment of the issues

Product by product approval

In the folate pilot a system of product-by-product approval was used. This system required the manufacturer to submit specific information relating to the actual food that was to carry the folate claim, and subsequent assessment of this information by ANZFA and listing the
product in the Australian *Food Standards Code* and the New Zealand Medicines Act prior to permitting the release of the food/product with the associated claim. This process ensured tight control over products carrying the folate claim and, for the purposes of the pilot was both prudent and easily implemented. However, when considering health claims more broadly such a system would be very resource intensive and potentially seriously disrupt the timely release of submitted foods onto the market.

This provision is not being promoted in either of the above options because it would be so resource intensive as to be potentially unmanageable under current resourcing arrangements, and would require frequent amendments to the new Code. Long delays in adding approved products to the exemption list within the regulations would also be anticipated due to the required approval by the Australia New Zealand Food Standards Council (ANZFSC) before amendments to the Code can be made.

**Code of practice**

If a co-regulatory system were to be adopted, this would require the development of a code of practice, potentially similar to that trialled in the folate pilot i.e. the *Interim Code of Practice for the Communication of the Health Benefits of Food Products*. Such a code of practice could cover:

- a list of permitted health claims;
- the eligibility criteria that a food must meet in order to carry the claim;
- examples of model claims;
- guidelines for the development of education activities/communication resources for the health claim;
- guidelines for monitoring activities;
- guidelines as to the essential elements that must be included on the label;
- guidelines for the wording of the claim; and
- penalties for breaches of the provisions in the joint Code.

The code of practice would outline:

- guidelines for the wording of health claims so that the claims reflect the nature of the evidence and the claim made;
- restrictions on the use of health claims;
- additional information which must be provided by companies for consumers when communicating the health benefits of foods;
- additional information which companies using health claims are encouraged to provide for consumers; and
- data which companies must provide to ANZFA for the purposes of monitoring the effect of health claims.

A committee would be formed to manage the code of practice based on that used in the folate pilot. For example:

- Chairperson - independent;
- Secretary - the Executive Director of the Australian Food and Grocery Council, or the Grocery Manufacturers Association, or their nominee;
• Members - four nominees from member companies supporting industry organisations (with representation from Australia and New Zealand)
  - one nominee from the Australian Supermarket Institute
  - one nominee from ANZFA
  - one nominee from the States and Territories
  - one nominee from the New Zealand Ministry of Health
  - one nominee each from Australian and Competition and Consumer Commission and the New Zealand Commerce Commission
  - four nominees representing community interests, two each from New Zealand and Australia.

9.4 Surveillance and enforcement

9.4.1 Issues raised in the process evaluation of the folate pilot

The process evaluation report raised a number of issues related to surveillance and enforcement processes that are important to consider if health claims and/or nutrition messages are permitted more generally. These included the need to:

• Establish a Code of Practice Management Committee to ensure compliance with the *Code of Practice for the Communication of the Health Benefits of Food Products*.
• Develop and promote guidelines on how the Code of Practice Management Committee would mediate and attempt resolution of complaints and alleged breaches of the Code.
• Clarify the interface between the Code of Practice and the responsibilities of New Zealand and Australian state/territory government agencies to enforce the *Food Standards Code*.
• Examine the resource implications of New Zealand and Australian state/territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee for breaches that are unable to be resolved at the Code of Management Committee level.

9.4.1.1 Assessment of issues

As raised in the process evaluation, a Code of Practice Management Committee has been proposed and guidelines developed as to how the system will work. Clarification has been sought of the interface between the Code of Practice and the responsibilities of New Zealand and Australian state/territory agencies to enforce the joint Code and this is detailed in the section below.

*The proposed system for dealing with complaints*

In the first instance, complaints made should be referred to the code of practice management committee for resolution. If the code of practice management committee is unable to resolve the complaint, the complaint should be referred onto the jurisdiction in which the product is manufactured for further action by the appropriate State, Territory or New Zealand health officers.
It was suggested that there was a need to examine the resource implications of the proposed system. These resource implications are discussed further under other issues raised in submissions in Section 13.1.

9.5 Further issues

9.5.1 New Zealand legislation

The harmonisation of food regulations between Australia and New Zealand requires consideration of all relevant legislation within both countries. The current Australian and New Zealand regulations are outlined in the Relevant Provisions (Section 5).

The Ministry of Health has recently undertaken to conduct a project to investigate the options for dealing with health claims in relation to food products within the current New Zealand medicines legislation. One option being considered proposes modifications to the medicines legislation to allow health claims that have been permitted within the joint Code to be legally made and remove the need for these to be considered on a case by case basis. Under this option the permissions for health claims on food products will be considered under food legislation rather than medicines legislation. In addition, ANZFA considers it would be desirable if the provision in the Medicines Act for “related products” insofar as they relate to food, could be transported to a more appropriate legislation such as the New Zealand Food Act.

9.5.2 Listing of approved claims

A major difference to consider between the folate pilot and any other future health claims system is that surveillance was made considerably easier in the folate pilot due to the pre-approval system, which ensured a list was kept of all approved claims. Also, as part of the pilot process, industry members using the health claim provided ANZFA with details of products bearing the claim and any associated advertising or educational materials.

Similarly, in New Zealand there is a service contracted by the Ministry of Health from Auckland Healthcare called the New Zealand Therapeutic Database (NZTDB). Key outputs of the service include:

- the annual publication of eight “free from” publications;
- annual collection and collation of data on ingredients and additives and some nutrients used by New Zealand food manufacturers and some Australian manufacturers;
- annual collection of data from manufacturers of fortified products.

The data are provided free of charge to registered dietitians in New Zealand and available at minimal cost to the general public. Information can also be obtained from the NZTDB website.

It cannot be assumed that the availability of such information would be an integral part of a broader health claims system. However, if such a system were able to be implemented within a management framework for any future health claims, this would greatly facilitate surveillance and enforcement processes. Any such possibilities are primarily dependent on resources, which are discussed further in this report in Section 13.1.
10. ASSESSMENT - FRAMEWORK ELEMENT 2 - SCIENTIFIC SUBSTANTIATION

10.1 Introduction

Scientific substantiation is the process by which a decision is made on the basis of all available scientific evidence as to whether the weight of evidence supports the claimed relationship between a food or food substance and a disease/health outcome.

This process is important as it helps ensure that claims are true, valid and not misleading. The substantiation process also involves setting qualifying/disqualifying criteria that a food must meet before they are permitted to carry the claim to help ensure the food is making a positive contribution to the overall diet, regardless of any claims it may carry. Additional criteria ensure that the food contains the desired nutrient/active ingredient in the amount necessary to see the effect claimed in the health claim.

In the development of a standard for health claims on food labels the need to clarify and clearly define the category of nutrition function claims (or some other term for the category) becomes essential. It is also important that there is consistency in approach. If the consumer can be assured of the scientific robustness of a claim about calcium and osteoporosis should they not also be assured of the scientific robustness of a claim about calcium and healthy bones?

The experience of the USA, where companies have made nutrition function claims in lieu of health claims where no substantiation process is required needs to be remembered in the consideration of the regulation of nutrition function claims. However, nutrition function claims can currently be made on food labels in Australia and New Zealand with no restricting legislation. Although there are some dubious nutrition function claims currently on food packages, in general, there has been a level of responsibility taken by the majority of food industry to keep nutrition function claims truthful and distinct from health claims.

Part A – Standards of evidence required for health claims and nutrition function claims

10.2 Objectives

One of the objectives proposed for health claims outlined in the Section 4 was that health claims must be based on rigorous scientific assessment of the health benefits of a food or food constituent. The following principles are proposed in relation to ensuring this objective is met:

1. To ensure the claims are valid, claims must be based on a thorough, independent review of the totality of the evidence.
2. Claims should not be permitted unless, after such a review, there is a significant level of agreement by experts that there is a convincing relationship between the food/food constituent and disease or health outcome.
3. Claims may need to be reviewed periodically to ensure they continue to meet the level of evidence required as new evidence comes to light.
4. Nutrition function claims require the same level of substantiation as health claims. Manufacturers making nutrition function claims should undertake such substantiation and hold the evidence to support their claims.

10.3 Summary of submissions to P153

A number of submissions to P153 commented on the process of scientific substantiation of health claims. The issues that arose from submissions were:

- There was general support for the substantiation of each health claim on a case-by-case basis before a claim was permitted.
- A number of submitters felt an expert panel should carry out the scientific substantiation process. It was felt that relevant representation, transparency and efficiency were essential for consumer confidence in a health claims system.
- There was general discussion about issues pertaining to scientific substantiation. One submitter commented that the evidence should come from controlled human intervention trials, epidemiological data, animal models and other biological evidence. Another submitter recommended that scientific substantiation must evaluate nutritional criteria, dose specificity and directions for use. Another submitter recommended the development of guidelines for substantiation.

10.4 Summary of issues raised in the process evaluation of the folate pilot.

Issues raised that related specifically to the permission of health claims generally were:

- There was broad support of the use of expert panels to adjudicate scientific evidence. However members of panels would be judged by their professional reputation and independence.
- It was recommended that guidelines be developed which specify the requirements and standards for substantiation.
- It was pointed out that the level of substantiation required for each claim is likely to vary between claims depending on the availability of credible evidence and the perceptions of the issues associated with the claim.
- Epidemiologists raised concerns about the difficulty in establishing a causal pathway between food intake and risk of disease.
- Industry sought scientific processes that were administratively simple and timely.
- Industry supported that where substantiation had already been established by a credible organisation, for example the claims allowed in the US, the process should focus on checking appropriateness for Australia and New Zealand.
- Any process needs to support public confidence in a health claims system.

10.4.1 Assessment of issues

The process for substantiating a health claim is outlined below. As suggested in the summary of submissions, it is proposed that substantiation will be carried out by an expert panel on a case-by-case basis before an exemption is added to the Joint Code. Guidelines for substantiation have been developed and include guidelines on the type of evidence necessary to substantiate a claim. As detailed below, it is proposed that the process of substantiation will include evaluating nutritional criteria, dose specificity and directions for use.
Although industry groups supported that where substantiation had already been established by a credible organisation, the process should focus on checking appropriateness for Australia and New Zealand, the Expert Committee for the Scientific Substantiation of Health Claims did not support this. The reasons they gave are outlined in Appendix 2 of Attachment 5.

It was felt that by using an expert panel to assess carry out the substantiation of health claims and providing guidelines as to the levels of evidence required to support health claims, this would help to increase public confidence in the system. However, by using such a system, processes are not administratively simple and timely.

10.5 The proposed substantiation framework for health claims

```
Application/proposal raised

Issues that need to be addressed are identified

Claim is consistent with over-riding principles

Preliminary assessment – public comment

Substantiation by Expert Advisory Group

Consumer testing to establish the communications effectiveness (See Section 7.4)

Full Assessment Report – public comment

Inquiry

Recommendation to ANZFSC
```
10.6 The proposed substantiation framework for nutrition function claims

Nutrition function claims will be required to meet the same substantiation requirements as health claims. However, instead of submitting the evidence to ANZFA in an application, the sponsor would be required to “hold” the evidence. This means the food industries are required to carry out their own substantiation to ensure that the totality of the scientific evidence is “convincing” and therefore supports the nutrition function claim, however this information will only be required to be produced on request. If requested, the food industry will have to produce copies of the references on which they based their substantiation before the end of a two week period.

10.7 Procedures for substantiating a health claim or nutrition function claim

The purpose in setting criteria for the scientific substantiation of a health claim is to ensure that health claims describe relationships between diet and health that are proven to exist. The assessment of the validity of the relationship between a claimed disease and a food or food constituent is based on the consistency, strength, relevance and quality of evidence. It is recognised that a variety of experimental approaches may contribute to the substantiation of a proposed health claim. Because of the limitations of the various research methods that can be used to study substance/disease relationships, it is not possible to specify the type or number of studies needed to support a health claim. When substantial evidence from different types of studies give consistent results, together with supportive evidence from experimental and other biological research, this may be judged to be convincing evidence of a causal relationship (World Cancer Research Fund, 1997). Safety issues need to be considered before arriving at a scientific assessment of the claim. A final decision on whether the claim is substantiated must take into account policy guidelines relating to nutritional qualifying/disqualifying criteria.

Step 1: Identifying studies

The scientific evidence that underlies substantiation of a health claim may be drawn from the following types of data:
1. data on biological mechanisms: data derived from chemical, cellular, human experimental or animal models investigating plausible mechanisms of action of foods or food substances.
2. clinical and intervention data:
   • observational studies of populations or groups assessing associations between food substances and disease (case-control, cohort, correlational, cross-sectional); and
   • intervention trials involving human subjects.
The different types of studies provide evidence of strength. The Australian National Health and Medical Research Council (NHMRC) has developed a framework for levels of evidence for developing clinical practice guidelines (NHMRC, 1998). This framework has been modified for use in these guidelines for the substantiation of health claims for the following reasons:

1. For assessing public health nutrition data randomised controlled trials (RCT) are available for diet and a risk factor for a disease (e.g. plasma cholesterol, blood pressure) but are rare for a pure nutrient and disease and for diet and disease. When diet is the intervention, confounding factors are possible in ways not encountered in drug trials. It is therefore questionable for nutrition whether a single randomised trial of food and disease (said to be level II) is better evidence than a set of good, large well-designed cohort studies (said to be level III-2).

2. It is generally accepted among public health nutritionists that cohort studies are more reliable than case-control studies (World Cancer Research Fund, 1997; Willett, 1990; Mann, 1997). This principle is exemplified by the greater reliance placed on cohort (prospective) studies than on case-control studies in considering the relationships between diet and coronary heart disease and diet and cancer.

The system for grading evidence with respect to using it to substantiate health claims relating to food is therefore:

Grade A: evidence obtained from a systematic review of all relevant randomised controlled trials.

Grade B: evidence obtained from properly designed randomised controlled trials or evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

Grade C: evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies).

Grade D: case-control studies, or interrupted time series with a control group.

Grade E: evidence obtained from comparative studies with historical control, two or more single arms, or interrupted time series without a parallel control group.

Grade F: evidence obtained from case series, either post-test, or pre-test and post-test.

Grade G: other relevant information including reports of expert committees.

Step 2: Evaluating the quality of the evidence from studies

Providing an explicit and standardised appraisal of all relevant studies that have been identified is important. Overall, the features that are most important to address are those that involve selection and measurement bias, confounding variables and follow-up of participants (National Health and Medical Research Council, 2000).
In evaluating the studies to assess the potential validity of a food substance and disease relationship the following must be taken into account:

- **Strength and quality**
  Consideration must be given as to whether the study was relevant and the study design was appropriate for exploring the proposed relationship and if the results are of sufficient significance to minimise the occurrence of these same events by chance. Studies must meet conventional standards of quality. This includes sample size, outcome, dietary collection methods, matching of groups, relevant confounders, reporting odds ratios. The results from multiple studies with inadequate sample size to detect a difference with confidence may be combined, under certain circumstances, through structured analyses, such as meta-analyses, that provide confident estimates of an effect not observed from individual studies (Keystone, 1996).

- **Biological plausibility**
  The evidence of a causal relationship is enhanced if there is a known or postulated biological mechanism by which the exposure might reasonably alter risk of developing the disease (Hennekens, 1987).

- **Dose-response relationship**
  Consideration must be given to whether the data demonstrate a plausible dose-response relationship that would support the hypothetical activity of the food substance (Keystone, 1996). The possibility of a threshold effect should also be considered.

- **Bioavailability in food**
  The nutrient/active ingredient must be in a form that can be readily absorbed into the body as part of a normal diet, and which influences blood and tissue concentrations of the nutrient/active ingredient sufficiently to exert a clinical effect. Therefore, when assessing studies, the form of the nutrient/active ingredient needs to be considered in terms of its effects when present in food as opposed to a supplement.

- **Safety Issues**
  The safety of authorising a health claim regarding a food or food substance needs to be addressed. In particular:
  1. Is there any evidence of acute or chronic toxicity or other safety concerns relative to the consumption of this food or food substance?; and
  2. Are there any negative health consequences of consuming this food or food substance or of the resulting diet? (Keystone, 1996)

- **Target group**
  It is necessary to consider which groups in the population will be affected by the health claim. If the beneficial effect of the food or food constituent only occurs in a specific sub-group of the population, it needs to be considered whether a health claim on food products would be useful to this subgroup, including gender, ethnicity, physiological status, age, or whether there are other more effective ways in which the information can be conveyed to the subgroup.
Ability to obtain the required dose from foods
Having ascertained that a specified amount of a food/active ingredient is needed in order to obtain the observed benefit, it must be considered whether this is an amount that can be reasonably obtained from food consumed in the context of a healthy diet.

**Step 3: Evaluating the totality of the evidence**

After relevant, good quality studies are identified and their strengths and weaknesses assessed, the totality of this evidence needs to be assessed. In addition, consideration should be given to the issue of publication bias and whether this will influence the totality of the evidence.

A scheme for categorising the totality of evidence for health claim substantiation is as follows (adapted from World Cancer Research Fund, 1997):

- **“Convincing”:** studies show consistent associations, with little or no evidence to the contrary. There should be a substantial number of acceptable studies, preferably including prospective designs and randomised controlled trials, conducted in different population groups, controlled for possible confounding factors. Any dose-response relationships should be supportive of a causal relationship. Associations should be biologically plausible. Laboratory evidence is usually supportive or strongly supportive.

- **“Probable”:** studies show associations that are either not so consistent, with a number and/or proportions of studies not supporting the association, or else the number or type of studies is not extensive enough to make a more definite judgement. Mechanistic and laboratory evidence are usually supportive or strongly supportive.

- **“Possible”:** studies are generally supportive, but are limited in quantity, quality or consistency. There may or may not be supportive mechanistic or laboratory evidence. Alternatively, there are few or no epidemiological data, but strongly supportive evidence from other disciplines.

- **“Insufficient”:** there are only a few studies, which are generally consistent, but really do no more than hint at a possible relationship. Often, more well-designed research is needed.

It is unlikely that a health claim would be approved on the basis of less than “convincing” scientific evidence.

**Step 4: Eligibility criteria**

Finally, having taken into account all the above factors and decided that the totality of the evidence supports authorising a health claim, certain eligibility criteria need to be developed that a product has to meet before it can be authorised to carry a health claim. These criteria need to be based on:

- the scientific evidence determining the amount of the nutrient necessary to potentially deliver the claimed reduction in disease risk;
- the variety of food sources that would also deliver the nutrient of interest; and
- the public health context.
10.8 Independent assessment of the evidence for a health claim

It is proposed that an expert committee be formed to carry out the process of substantiation. There needs to be a strong focus on nutrition expertise in this group. The core membership of the committee is proposed to be individuals with expertise in the areas of:

- nutrition science
- nutrition epidemiology
- public health nutrition
- clinical nutrition
- toxicology
- food composition
- food science
- In addition, individuals with expertise specific to the subject of each individual claim would be co-opted to provide advice to the core committee as the scientific basis for each claim is established.

The committee would review all the available literature and decide whether the evidence is sufficient to allow the health claim using the procedure outlined in Section 10.7.

The terms of reference of this group would be as follows:

1. To evaluate the available evidence on the health claim and each element thereof as it pertains to intake of the food or food constituent in the context of the total diet using the procedures established for substantiating a claim.
2. To identify restrictions on the use of the claim, including inappropriate target groups, safety issues, additional qualifying/disqualifying criteria.
3. To provide advice to ANZFA on whether the scientific evidence supports allowing a health claim.
4. To provide advice to ANZFA on the amount of the food or food constituent required to achieve the claimed benefit and any additional qualifying/disqualifying criteria that should apply to the claim.

10.9 The process for endorsements

Endorsements can be considered to be implied health claims. As such, the Standard proposes that endorsements from an organisation on foods conveying a claim that would otherwise be prohibited will not be allowed unless the organisation making the endorsement has had the criteria for the endorsement program approved and listed in the Table to clause 8 in the Standard. In addition, the label of any foods carrying an approved endorsement must also include a nutrition information panel and a statement on the importance of dietary variety.

Part B – The eligibility criteria that the product must meet before it is permitted to carry a health claim or nutrition function claim.

10.10 Objectives

One of the objectives proposed for health claims outlined in the Section 4 was that health claims must have clear qualifying/disqualifying criteria. The following principles are proposed in relation to ensuring this objective is met:
1 Foods carrying claims must make an appropriate contribution\(^4\) to the dietary intake of the nutrient that is the subject of the claim.
2 Foods carrying claims should also support the dietary guidelines in both Australia and New Zealand, with the link acknowledged through accompanying education program(s).
3 The food bearing the health claim should:
   - be appropriate for the target group;
   - not, by composition nor promotion, comprise a risk to the health of the target group, for example, alcoholic beverages; and
   - not deter consumption of a wide variety of foods, consistent with the philosophy behind the dietary guidelines e.g. complete special dietary foods.

Where appropriate:

4 There should be compatibility with Standard A9, of the Australian Food Standards Code (Standard 1.3.2 of the Joint Code, to be approved by Ministers later in 2000) with regard to established minimum reference amounts for “source” (10% RDI/serve) and “good source” (25% RDI/serve) of vitamin/minerals.
5 There should be encouragement of changes in the food supply, such as increased use by manufacturers of nutrient fortification permissions.
6 Account should be taken of the criteria laid down in the Code of Practice on Nutrient Claims.
7 Account should also be taken of the relevant Codex regulations.

10.11 Summary of submissions to P153

Seven submissions to P153 commented on eligibility criteria for products to carry a claim. Five submissions supported a framework with qualifying and disqualifying nutrients. One submitter felt that health claims should not be subject to pre-determined eligibility criteria, rather that criteria should be set on a food by food or group by group basis. Another submitter was opposed to the setting of “disqualifying levels” of some negative nutrients.

10.12 Recommendations from the process evaluation of the folate pilot

There was broad support for the principles used by working groups in establishing eligibility criteria for products to carry a folate health claim. Industry had concerns with the nutritional validity of more than 10 g of added sugar being a disqualifying criterion.

10.12.1 Assessment of issues

The proposed recommendations for eligibility criteria for foods to carry health claims are outlined below. As supported by the majority of submissions, a framework with qualifying and disqualifying nutrients has been used.

---

\(^4\) This means that: in the case of positive nutrients, a significant contribution of the nutrient in question should be made by the food e.g. folate, or; in the case of negative nutrients, the food itself should not provide undue amounts of the nutrient in question e.g. fat.
Industry had concerns with the nutritional validity of the added sugars criteria – this criteria is not being applied to health claims more generally. It has been replaced by the criteria that the food must contain, prior to fortification, at least 10% RDI of a nutrient for which there is an RDI other than sodium or potassium. The rational for this is outlined below.

10.13 General eligibility criteria to be applied to all health claims and nutrition function claims

All of the three criteria shown in the table below should be satisfied for a food to be eligible to carry a health claim or nutrition function claim.

As in the folate pilot, manufacturers are able to set the serve size for their products.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Criterion</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>total fat</td>
<td>&lt; 14g/serve</td>
<td>20% of recommended fat intake (based on 30% 8400 KJ energy intake)</td>
</tr>
<tr>
<td>saturated fat</td>
<td>&lt; 5g/serve</td>
<td>one third of total fat, based on Australian and New Zealand recommendations.</td>
</tr>
<tr>
<td>sodium</td>
<td>&lt; 500mg/serve</td>
<td>20% upper limit of RDI range for adult</td>
</tr>
</tbody>
</table>

The basis for deciding on these nutrients was that:

- Total fat and saturated fat are nutrients of public health significance.
- Because of the public health concern about high intakes of sodium and the fact Australia and New Zealand have a RDI for sodium and dietary guidelines on salt, it was considered appropriate to set an upper limit for sodium.

Unlike the folate pilot, where primary foods (fruits, vegetables, grains, legumes, meat, milk, yoghurt, eggs, nuts, seeds and fish) did not have to meet the disqualifying criteria provided they contained at least 40ug folate/serve, all foods would be required to meet the eligibility criteria. In terms of primary foods, this will mean that meats with a fat content of greater than or equal to 14g/serve will not be eligible for qualification to bear a health claim because they do not comply with the generic criteria. Nuts will be able to meet the total fat criteria if they use a 20 gram serve size (a commonly used serve size for nuts). All other primary foods would meet the criteria outlined above.

Nutrient density

In order for a food to be eligible to carry a claim, the food must also contain at least 10% of the RDI prior to fortification for a nutrient for which there is an RDI in Australia or New Zealand, other than sodium or potassium. This is to ensure that foods carrying a health claim are of moderate nutrient density. In the folate pilot, foods had to contain less than 10g of added sugars per serve. This worked well for positive nutrients (where the claim is for a food being high in a nutrient) but will not work for low fat or low sodium claims, or foods with a small serve size. For example, a serve size for jelly beans could be 10 grams, of which 9 grams is sugars. This would enable jelly beans to meet the added sugars criteria, as well as the other qualifying/disqualifying criteria and enable jelly beans to carry claims such as those for low fat or low sodium. However, if a 20 gram serve size was used, they would not meet
the added sugars criteria. If the 10% RDI criteria was applied, they would not be able to make a low fat claim regardless of the serve size. Therefore, the % RDI criteria more clearly reflects the intent, that is: to not allow health claims on foods of low nutrient density.

In addition, a health claim may not be in relation to a food if the food is listed in Standard 2.7 (Alcoholic Beverages) or 2.9 (Special Purpose Foods – Infant Formula Products, Food for Infants, Foods Formulated for Special Diets, Macronutrient Modified Foods, Formulated Meal Replacements and Formulated Supplementary Foods, Formulated Supplemented Sports Foods and Medical Foods) of the joint Code. This is in line with the principles listed in Section 10.10:

The food bearing the health claim should:
- be appropriate for the target group;
- not, by composition nor promotion, comprise a risk to the health of the target group, for example, alcoholic beverages; and
- not deter consumption of a wide variety of foods, consistent with the philosophy behind the dietary guidelines e.g. complete special dietary foods.

10.14 Establishment of claim-specific eligibility criteria

Claim-specific minimum entry criteria will be established by the Scientific Substantiation Expert Committee as described in Part A, Section 10.7, based on:
- scientific evidence that determines the amount of nutrient necessary to potentially deliver the claimed benefit; and
- the variety of food sources that would also deliver the nutrient of interest.
11. Assessment - framework element 3 - education and communication

11.1 Introduction

Education is important to ensure consumers are aware of label changes and what this information means, and thereby reduce the chances of consumers being misled or deceived. There are a number of proposed changes to labels as part of the development of the joint Code, in particular proposed requirements for mandatory ingredient listing, date marking, warning statements, nutrition labelling and percentage labelling. It will be necessary to educate consumers on these changes, as well as on health claims, if they are permitted in the future. Education is an important part of any health claims system irrespective of whether health claims are viewed as a regulatory tool by which food companies can make balanced, substantiated claims or a public health intervention. In addition, health claims can complement current public health initiatives by reinforcing messages on healthy eating promoted in dietary guidelines, food guides and other such tools.

Part A - Education initiatives to support health claims

11.2 The preferred approach for implementation of an education strategy for health claims

The Authority is proposing that the preferred approach for education strategies to accompany health claims is Approach 1. This is consistent with views from key informants of the public health sector to the process evaluation as noted below.

11.3 Objectives

One of the objectives proposed for health claims outlined in Section 4 was that health claims must be accompanied by appropriate consumer education. The following principles are proposed in relation to ensuring this objective is met:

1. At a minimum, education is required to ensure consumers know and understand the information on food labels, including health claims, and can use this information to select a healthy diet.
2. Where possible, education on health claims should be integrated into existing education initiatives to ensure sustainability.
3. There should be consistency in terminology within educational materials about health claims when referring to the food or food constituent, the disease and the target group.
4. Food companies have a responsibility to educate consumers about any health claims they make about their products.
11.4 Submissions to P153

Nineteen submissions to P153 commented specifically on education. It was generally agreed that education was an important component of any health claims system that may be permitted. A number of public health and consumers groups supported a coordinated approach to nutrition education, involving current public health initiatives, and asked that relevant groups be considered and consulted about education initiatives to accompany a health claims system. However, some food companies expressed the belief that the introduction of health claims should not be contingent on a national nutrition education campaign. They expressed reluctance to contribute to the funding of a national nutrition education program, to place the health claims in context and to promote generic health claims that support dietary guidelines. Industry groups generally believed that such education is the responsibility of the public sector. A number of food companies made the point that education could be left to the relevant food companies as they generally provide this information.

11.5 Summary of issues raised in the process evaluation of the folate pilot

Some informants from the public health sector strongly supported well-resourced public education campaigns for each health claim, in order to support the achievement of anticipated public health benefits. In contrast, key informants from the food industry did not support mandatory public education campaigns for each health claim. While supportive of the Code of Practice guidelines, which encouraged food companies to produce education materials to provide additional nutritional information to their customers, the food industry was concerned about the costs and diversion of resources from the regulatory issues, which they perceived as the central focus of a health claims system.

Key informants from the public health sector indicated that if public health education campaigns are required for future permitted health claims, then considerable resources would be needed to ensure such campaigns deliver a sustainable impact on the target group.

Key informants from the public health sector indicated that the appropriate education role for ANZFA in a future health claims system, was to focus on consumer education about food labelling rather than public health education campaigns.

There was strong support across all sectors for food industry education activities associated with the use of a health claim. Food companies participating in the pilot indicated that it was appropriate that the Code of Practice for using health claims encourages companies to provide consumers of their products with access to additional information about the health claim within the context of a healthy diet.

11.6 Issues raised by SIGNAL

Most members of the Strategic Intergovernmental Nutrition Alliance (SIGNAL) group felt that approval of health claims should be contingent on accompanying education. There was a wide range of views expressed on who should be paying for and responsible for educating consumers. This depended on the type of claim and aspect. For example, ANZFA is responsible for educating consumers about health claims and labelling generally, government may pay for generic claims and industry for specific claims.
11.6.1 Assessment of issues

As commented in submissions, it is proposed that education will be an integral part of any health claims system that will be permitted. The strategy proposed in Approach 1 would not involve incorporation of health claims into current public health initiatives, however it would involve forming strategic alliances to aid in the dissemination of material about health claims. A concern of some groups is that if health claims are incorporated into current public health initiatives, current initiatives may be compromised.

Some submissions suggested that ANZFA consult with relevant groups in the development of an education strategy to accompany any health claims that may be permitted. As part of developing the full assessment report for P153, an Expert Working Group has been consulted on education initiatives to support health claims. The report and membership of this group is at Appendix 3 of Attachment 5. In addition, ANZFA met with the Strategic Intergovernmental Nutrition Alliance (SIGNAL) and a report of the outcome meeting with SIGNAL is at Appendix 5 of Attachment 5. A number of food companies suggested that education could be left to the food industry. ANZFA’s preferred approach involves food companies carrying out specific education on the respective health claims.

Key informants from the public health sector indicated that an appropriate education role of ANZFA was to focus on education about food labelling. ANZFA’s preferred approach is limited to education about changes to the food label as a result of the joint Code.

11.7 Alternative approaches for educating consumers on health claims

Two alternative approaches are presented for education initiatives to accompany a health claims system. The type of education will differ depending on whether health claims are viewed as a regulatory tool for food companies to make balanced, substantiated claims or as a public health intervention.

In the case of health claims being a purely regulatory mechanism, a general approach to education may be sufficient to ensure the protection of public health and safety.

However, if health claims are viewed as a public health intervention tool a greater level of education will be necessary and health claims should both complement and be complemented by current public health initiatives. The aim of this approach is that education is not solely on health claims, but that it is part of broader education on the role between diet and disease.

The potential scope of educational activities that could occur to accompany health claims is described in the figure below. Under Approach 1, only strategies 1, 2 and 5 would routinely occur, whereas under Approach 2, all 5 strategies detailed would occur.

Strategy 3 is not core to all claims, but may be critical to the acceptance of some claims and therefore the need to adopt the activities under strategy 3 will need to be considered on a case by case basis. For example, if a claim were to be approved on the relationship between saturated fatty acids and heart disease, the activities under strategy 3 may not be required because of the existing high level of public knowledge about the relationship. Conversely, a claim on the relationship between plant sterols and cholesterol levels may require accompanying education specific to the claim as the level of public knowledge about the relationship may be low.
<table>
<thead>
<tr>
<th>Strategy</th>
<th>Potential mechanisms</th>
<th>Responsibility</th>
<th>Included in Approach 1?</th>
<th>Included in Approach 2?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Information about the food labels and its changes as a result of the joint Code</td>
<td>Fact sheets for dissemination to professional and non-government organisations. Website.</td>
<td>ANZFA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2. Information about the health claims system as a whole – how it operates; how claims are substantiated; how to make a complaint etc</td>
<td>As above.</td>
<td>ANZFA</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3. Information about each individual claim that is approved – the relationship between the food/component and disease; sources of the component; importance of dietary variety; links to food selection guides etc</td>
<td>Pamphlets, booklets, posters etc specific to the claim. Linkages to other activities, such as educational activities related to food guides.</td>
<td>Governments; non-government organisations; industry (preferably in partnership)</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4. Linking the information on individual claims into broader, on-going national public health nutrition strategies in both countries</td>
<td>Information on the claim built into large-scale national campaigns.</td>
<td>As above</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5. Information about individual claims in relation to specific foods</td>
<td>Activities as determined by individual companies.</td>
<td>Industry</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

NB Strategies that would occur under Approach 1 are bolded. Strategies 1-5 would all occur under Approach 2.
Approach 1 (preferred approach)

This approach would focus on strategies to ensure public health and safety is protected and that consumers have enough information to make informed choices.

Advantages:

- Would educate consumers on what health claims are, in the context of other label changes and broader dietary guidance.
- Would not be too resource intensive.
- Would increase consumer literacy skills in relation to food labelling.
- Industry would be required to contribute to education in the form of education about individual claims.
- Would provide the opportunity to develop stronger links between food companies and public health organisations.
- Could be sustainable.

Disadvantages

- There may be limited education on individual claims.
- The promotion of individual claims may not be incorporated into current public health initiatives.

Approach 2

This approach would involve all the education strategies outlined under Approach 1 as well as incorporation of the claims, where appropriate, into the public health initiatives of government and non-government organisations.

Advantages:

- Education on individual claims will be incorporated into current initiatives – reinforcing public health messages.
- Would educate consumers on what health claims are and reinforce this with examples.
- Would provide the opportunity to develop stronger links between food companies and public health organisations.
- If incorporated into public health initiatives, education on health claims is likely to be more sustainable.
- If education is ongoing, it may effectively lead consumers to make appropriate dietary choices, resulting in improved health.

Disadvantages

- Would be very resource intensive to undertake for each claim.
- Could compromise current public health initiatives, by diverting current resources into the promotion of health claims.
- It would require greater coordination between ANZFA and other agencies that are potential partners in education.
Part B- Strategies to ensure the communications effectiveness of health claims

11.8 Introduction

Communication effectiveness is the process whereby, prior to allowing a health claim, steps are taken to find out about the knowledge of consumers regarding the diet-disease relationship which is the subject of the claim, and their perceptions regarding the best way to communicate this relationship. This process is important to ensure that consumers are not misled by health claims. It determines the way the claim should be worded so that the relationship between the food and disease is accurately conveyed. This can prevent consumer deception and ensure that claims do not provoke consumer anxiety or lead to diet distortions. It also ensures that the claim contains sufficient information to allow consumers to make an informed choice.

11.9 The preferred approach for implementation of a communications strategy for health claims

The preferred approach is Approach 1; mandate certain required elements of the claims. The mandated elements could be determined from findings of consumer testing. Companies would be allowed to develop their own wording that incorporates these required elements.

11.10 Objectives

One of the objectives proposed for health claims outlined in the Section 4 was that health claims must include key components of information as determined for each individual claim. The following principles are proposed in relation to ensuring this objective is met:

1. Health claims should assist consumers to select a healthy, balanced diet.
2. Claims should clearly and succinctly convey the relationship between the food/nutrient and disease/health-related condition.
3. Claims should recognise the multi-factorial nature of the disease mentioned.
4. Claims must not provoke anxiety or lead to diet distortions.
5. Claims must include a reference to dietary variety.
6. Claims should make reference to the minimum amount of the food/nutrient necessary to have the desired effect.
7. The claim should contain sufficient information to allow consumers to make an informed choice.

11.11 Submissions to P153

Communications effectiveness was not discussed as such in P153. However, a number of submissions suggested that the wording for health claims must be simple, specific, flexible.
11.12 Approaches for communication strategies to accompany health claims

Approach 1 (preferred approach)

Mandate certain required elements of the claims, determined by focus group testing. Allow food companies to develop their own wording that incorporates these required elements (This was the system used in the folate pilot).

Advantages:
• As certain elements would be mandated, this would mean that ANZFA could ensure that consumers are provided with important information.
• It gives food companies flexibility; they can then do their own consumer research and find out what wording is the most effective.
• It allows food companies to distinguish their claim from their competitors.
• Food companies can use shorter claims if desired, which would be better for products with limited label space.
• It would allow consumer testing to determine whether the claims are understood and used appropriately.

Disadvantages:
• Consumer testing is expensive.
• It may lead to confusion, since consumers would not be getting a consistent message.
• It would be more difficult to ensure that required terms are included if the wording is not mandated. The folate pilot has shown that often in the first instance some food companies did not read/understand that there were certain required terms that needed to be included in the claims (refer Appendix 1 of Attachment 4).

Approach 2

Mandate certain required elements of the claims. The mandated elements could be determined from findings of the previous folate focus groups and American and Canadian research. Allow companies to develop their own wording that incorporates these required elements.

Advantages:
• It would be less costly than Approach 1, as there would be no consumer testing.
• As certain elements would still be mandated, this would mean that ANZFA could ensure that consumers are provided with important information.
• It gives food companies flexibility; they can then do their own consumer research and find out what wording is the most effective.
• Food companies can use shorter claims if desired, which would be better for products with limited label space.
Disadvantages:

• Consumer testing is important to ensure that the claim is understandable.
• May lead to confusion since consumers would not be getting a consistent message.
• It would be more difficult to ensure that required terms are included if the wording is not mandated. The folate pilot has shown that often in the first instance some food companies did not read/understand that there were certain required terms that needed to be included in the claims (refer Appendix 1 of Attachment 4).
• May make monitoring more difficult if there is no baseline knowledge of consumer understanding of the relationship that is the subject of the claim against which to measure.
12. ASSESSMENT -FRAMEWORK ELEMENT 4 - MONITORING INITIATIVES TO SUPPORT HEALTH CLAIMS

12.1 Introduction

Monitoring of the impact of health claims on consumer knowledge, attitudes, and behaviour and product composition will provide valuable information about the impact of health claims on consumers and on industry. It is particularly important to design a system that evaluates the public health and safety impact of a health claims system. Monitoring can provide valuable information that can be used to alter a health claims system if necessary. ANZFA is recommending a number of changes to provisions in the joint Code to provide adequate, useful and truthful information for consumers. There will need to be some form of monitoring to determine the impact of these label and advertising changes on consumer knowledge, attitudes and behaviour and industry. This can be done using existing monitoring strategies and by developing new strategies where necessary.

12.2 The preferred approach for implementation of a monitoring strategy for health claims

The Authority is proposing that Approach 1 below is the preferred approach for monitoring strategies to accompany health claims. Under this approach, monitoring of health claims would occur as part of the proposed monitoring of the joint Code in Australia and New Zealand.

12.3 Objectives

One of the objectives proposed for health claims outlined in the Section 4 was that health claims must be monitored and evaluated at regular intervals. The following principles are proposed in relation to ensuring this objective is met:

1. At a minimum, monitoring must be undertaken to ensure that health claims are not causing harm, that is, causing anxiety in consumers, distorting diets or causing dietary trade-offs.
2. Monitoring of health claims should be incorporated into broader monitoring of the impact of label changes, due to the adoption of the joint Code in Australia and New Zealand.

12.4 Submissions to P153

Monitoring and evaluation was only discussed in ten submissions. There was general agreement in these submissions that there should be ongoing monitoring and evaluation if health claims are to be permitted. One food company indicated that monitoring and evaluation should only involve identifying changes in food sales and consumer understanding and suggested that longer term impacts on public health outcomes would be difficult to demonstrate. Another food company pointed out that the food industry has data that could contribute to the monitoring and evaluation of health claims. A number of submissions commented that an independent expert agency should undertake any monitoring and evaluation in order to maximise credibility.
One major discussion point was who will resource the operation - government alone or government and industry? Opinions were divided on this issue. Public health and consumers felt that food companies should fund monitoring and evaluation as they wanted health claims, but industry felt that for generic claims it was up to public health and government to ascertain any benefits on public health.

12.5 Issues raised in the process evaluation of the folate pilot

- ANZFA should develop a program evaluation plan for the health claims program covering the implementation and overall impact of the regulated approval of health claims, with performance indicators for monitoring the implementation and overall impact of the health claims program and strategies for the collection of performance data;
- ANZFA should also plan for periodic independent evaluations of the health claims program to allow comprehensive assessments of its implementation and impact, including the overall impact of health claims as a tool to educate consumers about nutrition;
- To ensure accountability of a health claims program, ANZFA should produce and publish an annual report on the implementation and impact of the health claims program including relevant performance information and findings from periodic program evaluations;
- There is a need to develop guidelines on monitoring and evaluation activities required for each individual health claim, in line with ANZFA’s health claims policy. The guidelines would specify the situations, if any, in which a monitoring and evaluation strategy was required for a particular health claim and the scope and focus of such a strategy; and
- Monitoring and evaluation activities should link with the broader food and health monitoring systems across Australia and New Zealand.

12.5.1 Assessment of issues

Submissions suggested that there should be ongoing monitoring and evaluation of any health claims system that may be permitted. One submission suggested that ANZFA should not try to monitor the long-term impacts on public health. ANZFA’s preferred approach does not include strategies to monitor long-term impacts on public health. One food company suggested that the food industry may be able to provide data for monitoring. The proposed Code of Practice for Health, Nutrition and Related Claims About Food will request that the food industry make available any data they have that may be beneficial to monitoring the impact of health claims. It is proposed that an independent agency will be responsible for collating and analysing the data to monitor the impact of health claims. Resourcing issues are discussed in further in Section 13.1.

It is proposed that guidelines for monitoring and evaluation strategies will be developed if the decision to allow health claims is made. ANZFA’s preferred option incorporates monitoring and evaluation activities into existing monitoring systems in Australia and New Zealand.
12.6 Approaches for monitoring impact of health claims

Approach 1 (preferred approach)

Under this approach, monitoring of health claims would occur as part of the proposed monitoring and evaluation of the joint Code in Australia and New Zealand. However, before any “monitoring” as such occurs, there needs to be uptake of claims by industry and products carrying claims widely available in the marketplace. The types of monitoring that would then need to occur can be grouped as:

1. Surveys to determine the food industry’s response to changes to the joint Code. In particular there would be a need to determine:
   - The impact that the changing compositional requirements as a result of deregulation have had on the food supply.
   - The impact of label changes on the composition of products.

2. Assessment of whether products comply with the eligibility criteria for health claims and contain levels of the nutrient/active ingredient in the amount stated and necessary to see the desired effect. This is particularly important in a system where a product by product approval mechanism is not used.

3. Consumer surveys to determine consumer understanding of the label changes would be an integral part of determining the success or otherwise of the joint Code. Questions of interest may include:
   - What information do consumers read on the label?
   - Do they understand what labelling information means and how do they use it?
   - Is there too much information on the label?

Specifically in relation to health claims, questions of interest include:
- Do consumers place too much emphasis on the role of individual foods in the development of major diseases?
- Do consumers believe that the food/food component can prevent disease rather than reduce the risk?
- Do consumers understand the concept of upper limits of safety?
- Do consumers understand the importance of eating a wide variety of foods?
- Does the mention of the health claims cause any anxieties in consumers?
- Do consumers perceive the nutrition and health properties of foods with health claims as accurately as products without health claims?
- Do they buy and consume products carrying claims?

Potential Mechanisms

1. ANZFA may be able to contract independent consultants or groups to carry out consumer surveys on consumer understanding of the label changes. One such group may be the National Nutrition Monitoring Unit in Australia. An independent contractor may need to be sought to carry out consumer surveys in New Zealand to answer the above questions.
2. ANZFA’s Monitoring and Surveillance program already carries out extensive work on the composition of foods. With the introduction of the joint Code, this role could be expanded to answer questions such as:
   1. The impact the changing compositional requirements as a result of deregulation have had on the food supply.
   2. The impact of label changes on composition of products.
In addition, dietary modelling could be carried out to estimate the effect of the changes in product composition on dietary intakes.

3. At present, the National Nutrition Monitoring Unit in Queensland is carrying out a variety of monitoring programs for the Commonwealth Department of Health and Aged Care. It may be possible to use some of the data they have collected for the purposes of monitoring the effect of changes in food regulation on industry and consumers, and in particular, the impact on public health and safety. In New Zealand, the Ministry of Health has indicated that they currently collect some general nutrition and health status data for New Zealand and this information could be used in the monitoring of the effect of changes in the food regulation, where appropriate.

4. ANZFA’s Monitoring and Surveillance Program is currently coordinating a bi-national surveillance and enforcement strategy. Under this system, information about products carrying health claims could be collected by the States, Territories, and New Zealand, and collated and analysed under the bi-national surveillance and enforcement strategy.

Advantages
- The least resource intensive option.
- Monitoring of health claims will be in context of all label changes.
- Would ensure health claims are not doing harm

Disadvantages:
- Would not monitor whether health claims are a successful public health intervention tool.

Approach 2

As for Approach 1, but in addition monitoring would incorporate strategies to evaluate if health claims are of any public health benefit.

In addition, to the questions posed above in Approach 1, answers would also be sought to questions such as:

1. Are consumers aware of the link between the nutrient/active ingredient and the disease?
2. Where do consumers get their information about the nutrient/disease?
3. Do consumers believe the health claim applies to them?
4. Are consumers perceiving the nutrition and health properties of foods with health claims more accurately than foods without health claims?
5. Do consumers read the label on food products?
6. Are consumers looking for the health claim and buying one product over another because it carries a health claim?
7. Do health claims help consumers identify foods that are good sources of nutrients?
8. How frequently do consumers purchase and consume products with health claims on them?
9. Is there an improvement in intakes of the nutrient with which the health claims is associated?
10. Do rates of disease change?

The type of monitoring systems used could be similar to those outlined above in Approach 1.

**Advantages**
- Has the capacity to determine the public health benefit, if any, of health claims

**Disadvantages**
- Very resource intensive and costly as would require the development of specific methodologies to determine whether claims are leading to positive changes in nutrient intakes, and ultimately changes in disease outcomes.
13. ASSESSMENT - OTHER ISSUES RAISED IN SUBMISSIONS

13.1 Resourcing

Twenty eight submissions commented on resourcing issues relating to health claims. Many submissions acknowledged that substantial resources would be required if health claims were to be permitted and that funding must be justifiable on a public health and safety basis. Many submissions supported joint industry/government funding for a health claims system.

A number of other organisations (mainly government and community organisations) commented that industry should be responsible for funding of a health claims system. Two New Zealand advertising organisations supported industry funding for regulation of a health claims system. There were a number of differing views about who should be responsible for funding specific areas of the management framework e.g. monitoring and evaluation and education.

Two submissions suggested a registration system, which effectively allows companies to buy rights to use health claims for a fixed period e.g. $500 for a generic claim and $1000-2000 for a specific health claim. Another company commented that a licensing system should ensure that the company who undertakes the original research to substantiate claims, receives fees from other producers. The Australian Food Standards Council (subgroup of Australian Food and Grocery Council) commented that cost recovery should only apply where there is a captureable commercial benefit.

One submission requested heavy fines for those transgressing from a health claims standard.

13.1.1 Assessment

Some of the key issues that will affect the cost of a health claims system include:

- Whether we have product-by-product approval.
- Whether we require monitoring and evaluation for each claim as extensive as that used in the pilot.
- Whether we intend to undertake a broad evaluation of the effectiveness of the system 3-5 years after its introduction (and at regular intervals thereafter).
- Whether ANZFA will repeat its extensive involvement in education activities with any future health claims as it did in the pilot.
- Whether an element of establishing the communications effectiveness of each claim will be included in the assessment process.
- The number of applications received/proposals raised.

The issue of resourcing has been addressed in part by the folate pilot. The pilot cost approximately $1.1 million to implement, including in-kind contributions. Of this, the following amounts were spent on each element of the proposed management framework for health claims:

- Substantiation 7%
- Regulatory processes 17%
- Surveillance and enforcement 7%
- Education and communication 56%
Industry contributed approximately 50% of the funds for the pilot through voluntary contributions. Other than the funding provided by AFGC and the Horticultural Research Development Corporation, the industry contributions were made as part of the process of individual product-by-product approval.

However, there are several factors that need to be kept in mind when considering the utility of the results of the folate pilot in the context of a ‘real life’ health claims system:

- If claims are permitted, they will be driven either by applications from external groups, or proposals raised internally. ANZFA will not be able to control the number of applications received for claims. (However, the amendments to the Act will give ANZFA greater ability to develop a work program to manage applications).
- After a period of time, there will be several claims in operation at once, making the resourcing and coordination of monitoring and education activities much more complex than in the pilot.
- The substantiation process required for each application or proposal will be significantly greater than in the pilot.
- It has been decided to not retain the individual product-by-product approval process as used in the pilot. This approach will reduce the burden on ANZFA, as staff will not have to assess products. However, this will also restrict our ability to receive voluntary contributions from industry.

The provisions in the amendments to the ANZFA Act that permit ANZFA to cost recover are very limited. Essentially ANZFA will only be able to charge for applications where:
- the applicant wants their application progressed more quickly than ANZFA’s work plan will allow; or
- where the application is considered to provide the applicant with an exclusive captureable commercial benefit.

It is not likely that many, if any, applications for health claims will fall into the latter category, particularly in the first instance. This may change over time as more functional foods are developed using patented ingredients.

An industry contribution to monitoring and evaluation and education and communication has been discussed the relevant Assessment Sections, Sections 11 and 12.

The approach proposed in Assessment Sections 7-12 needs to be considered in relation to respective roles and responsibilities. ANZFA clearly has a key role in ensuring that the way in which claims are regulated protects public health and safety, and that consumers receive adequate information about claims to make informed choices.

The proposed approach also needs to be considered in the context of resourcing. ANZFA has limited resources, and these resources need to be allocated to the development and maintenance of the joint Code as a whole. Health claims, should they be permitted, will form just one component of this activity.

Given the potential public health impact of claims, there may be a role for other parts of government to be involved in different elements of the management framework. Similarly, given the benefits that may accrue to industry through the use of claims in the marketing of
products, consideration needs to be given to their role in supporting and resourcing the proposed health claims management framework. Other agencies, such as those in non-government organisations, may also have an interest in participating in educational or monitoring activities in relation to specific claims.

Given ANZFA’s existing and projected budgetary situation, if health claims are permitted in the future, and if adequate resources from other sources to support the proposed framework are not forthcoming, ANZFA may need to consider alternative ways in which to manage health claims.

Two potential options, both of which would require amendments to the ANZFA Act, include

- Increasing ANZFA’s cost recovery capacity to enable ANZFA to recoup the costs associated with substantiating claims, and with the education and monitoring undertaken in support of claims.
- Limiting the number of permitted claims and their implementation. Applications received for health claims could be limited to a certain number per year, and prioritised according to national health priorities in both countries.

A further option is also possible without requiring amendments to the ANZFA Act. Under this option, ANZFA could focus its efforts on ensuring public health and safety are protected through the substantiation process and place very minimal effort in the areas of education and monitoring.

In terms of fines for food industries that breach Standard 1.2.7, Health, Nutrition and Related Claims About Food, fines are already predetermined under the relevant Food Acts in the States, Territories and New Zealand and it is beyond the scope of this proposal to address this.

13.2 Advertising

The main concern of the New Zealand Advertising Standards Authority, the Advertising Agencies Association of New Zealand Inc and the Association of New Zealand Advertisers was that the current prohibition should be removed as it contravenes the New Zealand Bill of Rights 1990 and the Commerce Act 1986. Submitters commented that the current standard is nonsensical as many advertisements already use the word “health” in advertising. One submitter said that health claims should be permitted in advertisements, but if challenged should be able to be substantiated. The submitters also strongly advocated a self-regulated regime for health claims (as currently practised in New Zealand) and suggested a preventing system to ensure compliance prior to completing advertisements. A copy of the World Federations of Advertisers Congress about self-regulation and advertising was enclosed.

Three broad categories for regulating health claims were suggested including:

- General health claims – would need to comply with an advertising Code of Practice, vetted by the media authorities and heard by the Advertising Standards Complaints Board.
- New but generalised health claims – this category would relate to new scientific knowledge and be managed by ANZFA and industry, after which the advertisement would revert to the procedure in outlined under general health claims.
Therapeutic food products – claims to cure/alleviate/prevent disease are scrutinised by an appropriate authority in an efficient manner, after which the advertisement would revert to procedure outlined under general health claims.

In addition, a concern was raised that it would be difficult to control claims made on the internet.

13.2.1 Assessment

Clause 8 of Standard 1.1.1 of the joint Code states that: ‘Advertisements for food must not contain any statements, representations, claims, information, designs, words or references which are prohibited by this Code from being included in the label on a package of that food.’ As such, the prohibition on health claims, unless specifically permitted in Standard 1.2.7, also applies to the advertising of food. Further comment on the issues raised above is also being sought from the New Zealand government.

A further problem is regulation of claims over the internet. This problem is not unique to foods and would occur anyway, regardless of whether health claims regulation was changed or not. In terms of the current regulation of claims made on the internet, any companies advertising in Australia, whether Australian or overseas companies need to comply with the Trade Practices Act and the Food Standards Code. The same fines apply to products advertised on the internet as to all products.

13.3 Therapeutics versus foods

Many submissions commented that care should be taken when considering foods at the interface between therapeutic goods and foods and that clear parameters for foods and medicines are needed to prevent confusion. Several submissions commented that linking a product to reduction of a disease risk does not belong on food labels. Some submissions commented that health claims should not be therapeutic claims which involve prevention, treatment or cure of diseases. Other submissions opposed medicalisation of the food supply and requested regulation under the Therapeutics Goods Administration.

One company indicated that claims on medical foods (e.g. for lactose intolerance) should not be considered to be health claims or require pre-market approval. Another company also commented that they wished to make claims on foods manufactured for special metabolic disorders.

The TGA had significant comments on this area. There was concern about the potential harm if foods with health claims are promoted e.g. consumption levels of specific nutrients may rise inordinately resulting in toxic side effects. In addition, the TGA commented that drug/nutrient interactions and the whole diet are not well understood and were concerned that foods currently considered to be therapeutic products could reposition themselves as foods should health claims be permitted e.g. herbal products.

Another concern is that manufacturers may move products to food regulation carrying “preventative therapeutic claims” thereby avoiding quality manufacturing practice standards for therapeutic goods, rigorous substantiation of efficacy including dose response, toxicity and efficacy and TGA national enforcement. The TGA commented that the Complementary Medicines Advisory Committee has been established to regulate products at the drug/food
The Therapeutic Goods Advertising Code prohibits all disease claims and aims to protect consumers from self-diagnosis and medication.

13.3.1 Assessment

Therapeutic claims which involve prevention, treatment or cure of disease will continue to be prohibited in the joint Code. Foods in Standard 2.9 of the joint Code will be prohibited from making health claims, this includes claims on medical foods.

The TGA’s criteria for substantiating claims on therapeutic goods has been noted and taken into account in developing the levels of evidence required for health claims and nutrition function claims. Where possible, ANZFA has tried to be consistent with their approach. The substantial difference is that ANZFA is proposing to prohibit claims that calcium will reduce the risk of osteoporosis and folate will reduce the risk of neural tube defects unless an expert committee has evaluated the evidence and rules that the evidence supports the claim whereas TGA would allow the sponsor to hold the evidence and produce it on demand. Therefore, if anything, ANZFA is proposing a more strict substantiation criteria for health claims, hence allaying fears that therapeutic goods will position themselves as foods in order to be subject to less rigid substantiation criteria.

There was concern about the potential harm of foods with health claims are promoted. ANZFA is proposing the health claims will be subject to an independent evaluation by an expert committee before they will be allowed. As part of this, the committee will address any safety issues. In addition, ANZFA is proposing that monitoring and evaluation will be an important part of any health claims system, to ensure health claims do not cause harm.

13.4 Generic versus specific claims

The Preliminary Assessment report for P153 canvassed opinion on three possible categories of claims:

- generic health claims open to all qualifying foods;
- generic health claims tailored to the requirements of specific products; and
- specific health claims for specific products.

13.4.1 Assessment

This concept has not been pursued as it is encompassed within the definition of health claims and it is not intended to regulate these claims in different ways.

13.5 Issues raised in P169

13.5.1 Introduction

In addition to the broader health claims issues being considered a number of issues were raised in Proposal 169 Representational issue – Claims About Food that were referred to P153 for consideration and review.
In particular three areas were specifically raised:

(1) Endorsements on the labels and advertising of food by organization whose name includes a disease.
(2) Claims about not promoting tooth decay.
(3) Slimming and weight-reducing claims.

### 13.5.2 Endorsements

ANZFA proposes to continue to prohibit any representation on foods that suggest that the food has a particular approval or endorsement that may convey a claim that would otherwise be prohibited within the Standard. The Standard provides for an exemption to this prohibition provided the organisation making the endorsement has had the criteria for the endorsement program approved and listed in the Table to clause 9 in the Standard. The foods carrying an approved endorsement must meet the generic eligibility criteria for health claims as specified in clause 6. In addition, the label of any foods carrying an approved endorsement must also include a nutrition information panel and a statement on the importance of dietary variety.

### 13.5.3 Claims about tooth decay

ANZFA supports that claims such as “does not promote tooth decay” would not be considered health claims and would be permitted within the relevant Australia and New Zealand Regulations providing they were not false, misleading or deceptive.

Claims that a product “helps prevent tooth decay” would be considered health claims and would need to meet the substantiation criteria and associated regulatory controls proposed for health claims including being listed in Standard 1.2.7 of the Food Standards Code.

### 13.5.4 Weight loss and slimming claims

ANZFA proposes to retain the prohibition on the use of slimming claims (Standard A1 (9)) unless claims are specifically permitted via the ANZFA application process for a health claim and listed in Standard 1.2.7 of the Food Standards Code. The application process would identify the essential criteria products must meet should any products be permitted to make such a health claim.
14. ANZFA’S SECTION 10 OBJECTIVES

14.1 Protection of public health and safety

The fundamental aim of a health claims framework is the protection and promotion of public health. It is to this end that messages may be given, in the context of general nutrition education and claim specific promotion, about the consumption of foods that may reduce the risk of disease.

The proposed framework for health claims will be based on significant scientific agreement as to the veracity of the claim and the absence of risk to non-target groups. Nutrient and food ingredient qualification criteria as well as exclusion of inappropriate food categories define the foods appropriate to bear the health claim. While the evidence of health claims achieving substantial changes in public health outcomes is as yet unknown, the promotion of consumption of these foods would facilitate the achievement of target nutrient intakes, and would not conflict with general advice about a healthy diet.

Health claims will be monitored to ensure they do not cause harm and to determine their impact on knowledge, attitudes and behaviour in relation to approved claims. Changes to food product formulation as a result of allowed health claims will also be monitored. Co-regulatory guidance for food product promotion and provision of information about the subject of the claim will be broadly disseminated, and administered and monitored by a co-regulatory group.

14.2 Provision of adequate information to enable consumers to make informed choices and to prevent fraud and deception

Consumers would be informed about the subject of the health claim by several mechanisms.

Food labels will carry the claim and additional information. The nutritional content of the product in which the contribution of a serve of the food to the target intake for all nutrients considered to be of public health significance will also be required. Participating companies will be encouraged to engage in the provision of ancillary information about the subject of the claim in their product promotion. In addition, general nutrition education initiatives to heighten awareness and encourage behaviour change will be implemented concurrent with the introduction of health claims, in the context of broader information on the label.

14.3 Promotion of fair trade

Constraints on the management framework for health claims mean that arrangements for the proposed health claims system will confer market advantages on those companies that choose to use approved health claims.

14.4 Promotion of trade and commerce

The potential for certain foods to bear a health claim offers relevant companies the opportunity to promote consumption of their products in new ways. In addition, it may also encourage the fortification of products with permitted nutrients.
14.5 Consistency with international standards

Few countries have adopted health claims and the US has the most comprehensive of any system. Codex provides individual countries with the option to implement a national system of health claims.
15. WTO NOTIFICATIONS

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

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

Matters relating to public health and safety are notified as a Sanitary or Phytosanitary (SPS) notification, and other matters as a Technical Barrier to Trade (TBT) notification.

It is proposed that this matter be advised to the WTO as a TBT notification. Although the provisions in question are voluntary, the preferred option is a significant departure from current requirements and may be construed as a technical barrier to trade.

In the case of the preferred option - Option C, the current prohibition on health and related claims would be revised and exemptions to this general prohibition would be added to permit certain claims that have been assessed and approved by ANZFSC.

This option is being recommended in the interests of providing informed choices for consumers. ANZFA considers there is scope for claims linking a particular food to health/disease outcomes to be provided on food labels and, that such claims bear the potential to support national public health and nutrition initiatives. Although it may be considered there may be barriers to trade, it should be noted that one of the most significant stakeholders, the United States, already allow some health claims on foods. Canada has also made a policy decision to allow health claims and is currently considering a framework for managing a health claims system. A system for allowing health claims is also being developed in the United Kingdom, and health claims are permitted in Japan, Sweden, the Netherlands and South Africa. Within the Australian and New Zealand food industry, the smaller businesses are likely to incur the greater relative costs of implementation. However, as this is a voluntary provision, there is no requirement for them to use health claims.
16. REFERENCES


Commonwealth Department of Health, Housing and Community Services. Food and nutrition policy. Canberra. AGPS. 1992


FDA Federal Register CFR 101.70.


Levy, A and Derby, B. The impact of the NLEA on consumers: recent findings from FDA’s food label and nutrition tracking system. Food and Drug Administration, Consumer Studies Branch, Center for Food Safety and Applied Nutrition, Washington, 1996.


Public Health Association Australia. Policy discussion paper: Health claims. 2000


Strategic Intergovernmental Nutrition Alliance. Eat Well Australia – the agenda for action in public health nutrition (DRAFT) 2000.


The International Association of Consumer Food Organisations. functional foods. public health boon or 21st century quackery? 1999


The role of epidemiology in determining when evidence is sufficient to support nutrition recommendations. American Journal of Clinical Nutrition 1999;69 (suppl): 1297S-1367S.

Van Duyn, M; Scott, V; Allen, J. Focus groups with Australians and New Zealanders on a folate health claim. Australia New Zealand Food Authority, Canberra, 1998.


Williams, P. Health claims and functional foods and time for a regulatory change. Australian Journal of Nutrition and Dietetics. 1998;55(2): 87-90

ATTACHMENTS

1. Draft Standard 1.2.7
2. Draft Inquiry report for P170, pilot for management framework for health claims
3. Summaries of submissions
   Appendix 1 – P153
   Appendix 2 – A399
4. Evaluation reports of the folate pilot
   Appendix 1 – Process Evaluation
   Appendix 2 – Outcome Evaluation
5. Background to Section 7.2 (Framework elements)
   Appendix 1 – Regulation
   Appendix 2 – Substantiation
   Appendix 3 – Education and communications effectiveness
   Appendix 4 – Monitoring and evaluation
   Appendix 5 – SIGNAL
6. International regulation of health claims
7. Comparison of regulatory provisions in A1(19), A399 and P153
Standard 1.2.7
Health, Nutrition, and Related Claims About Food

Purpose

This Standard prohibits the making of certain claims about food and permits the making of other claims on the label of food or in advertisements for food, provided certain conditions are met. This Standard should be read in conjunction with Standard 1.2.8.

Table of Provisions

1 Application
2 Interpretation
3 General prohibition on making health claims
4 Prohibition on claims of therapeutic/prophylactic action and advice of a medical nature
5 Prohibition on claims including the word ‘health’
6 Permitted health claims
7 Nutrition content claims and nutrition function claims
8 Additional requirements for making health claims etc
9 Endorsements about food

Clauses

1 Application

Unless expressly prescribed or permitted elsewhere in this Code, the prohibitions in this Standard apply in relation to food.
Editorial Note

For example, clause 29 of Standard 2.9.1, Infant Formula Products, provides that where an infant formula product is labelled with a claim that the product is suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions the label must include, amongst other things, a statement indicating the condition, disease or disorder for which the food has been specially formulated. Because clause 29 expressly prescribes that information, the prohibitions in this Standard do not apply.

2 Interpretation

In this Standard -

claim means any statement, representation, design or information in relation to food which is not prescribed by this Code, and includes an express or implied claim.

in relation to food means –
(a) on the label of a package of food;
(b) on the label on or in connection with the display of unpackaged food; or
(c) in an advertisement for food.

enhanced function claim means a claim about the specific beneficial effects of a food or constituent of a food on the physiological, psychological or biological functions other than the role of the nutrient or biologically active substance in the normal growth, development, maintenance and other like functions of the human body.

health claim means a claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a -
(a) enhanced function claim;
(b) reduction of disease risk claim; and
(c) claim that a food is a slimming food or has intrinsic weight-reducing properties;

but excludes a –
(d) nutrition function claim; and
(e) nutrition content claim; and
(f) claim of therapeutic or prophylactic action.

nutrition content claim means a claim in relation to food which describes or indicates the presence or absence of a nutrient, energy content or biologically active substance in that food.

Editorial Note:

‘Biologically active substance’ is defined in Standard 1.2.8.
**nutrition function claim** means a claim in relation to food which describes the physiological role of a nutrient, energy content or biologically active substance in the food, in the growth, development, maintenance and other like functions of the human body.

**prophylactic action** means the prevention of an abnormal physiological state or disease, but does not include the maintenance of normal physiological function.

**reduction of disease risk claim** means a claim in relation to food that a relationship exists between the consumption of a food or food constituent and the reduced risk of developing a disease or health related condition.

**therapeutic action** means action relating to preventing, curing or alleviating a disease, ailment, defect or injury.

---

**Editorial Notes:**

Standard 1.1.1 provides that any claim which is prohibited on a label of food under this Code is also prohibited in an advertisement for food.

An example of a nutrition content claim is “this product is low in fat”. This type of claim is permitted under this Standard, provided clause 8 is satisfied.

An example of a nutrition function claim is “Calcium is important for strong bones”. This type of claim is permitted under this Standard, provided clause 8 is satisfied.

An example of an enhanced function claim is “iron reduces tiredness”. This type of claim is prohibited under this Standard unless specifically permitted in the Table to clause 6.

An example of a reduction of disease risk claim is “fruit and vegetables may reduce the risk of developing some cancers”. This type of claim is prohibited under this Standard unless specifically permitted in the table to clause 6.

---

3 **General prohibition on the making of health claims**

Subject to clause 6, a health claim must not be made in relation to a food.

4 **Prohibition on claims of therapeutic/prophylactic action and advice of a medical nature**

A claim, either express or implied –

(a) for therapeutic or prophylactic action; or
(b) that could be interpreted as advice of a medical nature from any person;

must not be made in relation to food.
5 **Prohibition on claims including the word ‘health’**

A claim in relation to food must not include the word ‘health’ or any word of similar effect as part of or in conjunction with –

(a) the name of food;
(b) any generic or specific description of food; or
(c) the trade name or trade mark of any food;

unless the food contains, per serve as specified in the nutrition information panel –

(d) no more than 3 g of fat;
(e) no more than 1.5 g of saturated fat;
(f) no more than 500 mg of sodium; and
(g) no less than 10% of the Recommended Dietary Intake of a nutrient, prior to fortification, other than sodium and potassium.

6 **Permitted health claims**

A health claim may be made in relation to food, other than food standardised in Parts 2.7 and 2.9, provided the –

(a) food contains, per serve as specified in the nutrition information panel –

   (i) no more than 14 g of fat, of which no more than 5 g is saturated fat;
   (ii) no more than 500 mg of sodium; and
   (iii) no less than 10% of the Recommended Dietary Intake of a nutrient, prior to fortification, other than sodium and potassium; and

**Editorial Note:**

The reference to ‘the Recommended Dietary Intake (RDI) of a nutrient’ is a reference to the RDI listed in the Schedule to Standard 1.3.2, but does not include a reference in that Schedule to ‘Estimated Safe and Adequate Daily Intake’ (ESADDI).

(b) claim is listed in column 1 of the Table to this paragraph, the food meets the criteria specified in column 2 of the Table, and any special conditions specified in Column 3 are met.
### Table to paragraph 6(b)

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permitted health claim</td>
<td>Eligibility criteria</td>
<td>Special conditions</td>
</tr>
<tr>
<td>A claim which states – (a) that increased maternal folate consumption in at least the month before and 3 months following conception may reduce the risk of fetal neural tube defects; and (b) the recommendation that women consume a minimum of 400 micrograms folate per day in at least the month before and at least 3 months following conception</td>
<td>Contains at least 40 micrograms folate</td>
<td>Excludes – (a) soft cheeses and pate; (b) foods standardised in Part 2.7 and Standards 2.9.1, 2.9.2, 2.9.3, 2.9.5 and 2.9.6.</td>
</tr>
</tbody>
</table>

Where this claim is made on the label of packaged food or on or in connection with the display of unpackaged food, –

1. The label must contain a statement of particular storage, handling or cooking requirements, if the ability of the food to contain at least 40 micrograms folate per each serving depends on those requirements;

2. The nutrition information panel must contain – (a) the average quantity of folate in one serving of the food beside the proportion of the RDI of folate contributed to by one serving of the food; and (b) an asterisk accompanying the word ‘folate’ which refers to a footnote advising that the RDI of 200 micrograms referred to is for adults, whereas for women, at least one month before and during pregnancy, the recommended folate intake is 400 micrograms per day.

### 7 Nutrition content claims and nutrition function claims

Subject to clause 8, a nutrition content claim or nutrition function claim may be made in relation to food.

### 8 Additional requirements for making health claims etc

1. Where a health claim, nutrition content claim or nutrition function claim appears on the label of packaged food or on the label on or in connection with a display of unpackaged food, the label must contain a nutrition information panel in accordance with Standard 1.2.8.
Where a permitted health claim or a nutrition function claim in relation to a food is made, the claim must be accompanied by a statement that it is important to maintain a varied diet.

9 Endorsements about food

The label on a package of food or on or in connection with unpackaged food must not include any representation that the food has a particular approval or endorsement conveying a claim which would otherwise be prohibited by this Standard from an organisation unless –

(a) the organisation is listed in Column 1 of the Table to this clause and the food meets any eligibility criteria, specified in column 2;
(b) the requirements specified in clause 8 are met; and
(c) the food meets the requirements specified in paragraph 6(a).

Table to paragraph 9(a)

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permitted Endorsing Organisation</td>
<td>Eligibility criteria</td>
</tr>
</tbody>
</table>
The folate health claim pilot was initiated by the direction given in March 1998 by the Parliamentary Secretary to the Minister for Health and Family Services under section 11 of the Act, ANZFA is obliged to hold an inquiry in relation to the draft variation to Standard A1, prepared in relation to the Proposal, which it would otherwise be required to do under section 24 of the Act.

The Australian Food Standards Code was amended as follows:

To Commence: 1 July 1998  To Cease: 31 December 1999 (subsequently amended to August 2002)

**Standard A1** is varied by inserting after subclause (19)(d)-

(e) (i) The Table to this subclause sets out permitted health claims that may be made in respect of food listed in the Table which meets the qualifying and disqualifying criteria specified; and which also meets the eligibility criteria set out subclause (ii).

(ii) A food meets the eligibility criteria of this subclause if it is a primary food as defined in Standard A9, or else if it contains, in each serving as specified in the nutrition information panel, not more than-

(A) 14 g fat;
(B) 5 g saturated fat;
(C) 500 mg sodium;
(D) 10 g in total of added sugars and honey.

(iii) The label on or attached to a package of food in respect of which a health claim set out in the Table has been made must include a nutrition information panel in accordance with clause (13), provided that in relation to the claim for "Folate and Neural Tube Defects" the entry in the nutrition information panel should be based on a recommended dietary intake (RDI) of 400 µg folate rather than the 200 µg specified in Standard A9.

(iv) The label on or attached to a package of food must present the health claim in the context of the need for a varied diet.

(v) Where the ability of a food to meet the qualifying criteria set out in the Table depends on particular storage, handling or cooking requirements, the label on or attached to a package containing the food for which a health claim is made must include a statement of those requirements.
### TABLE TO SUBCLAUSE (19)(e) - PERMITTED HEALTH CLAIMS

<table>
<thead>
<tr>
<th>Food</th>
<th>Criteria</th>
<th>Permitted Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOLATE AND NEURAL TUBE DEFECTS (Foods to be listed here)</td>
<td>Qualifying Criteria: At least 40 µg folate. Disqualifying Criteria: None</td>
<td>A claim which states-&lt;br&gt; (a) the link between increased maternal folate consumption in the month before and 3 months following conception and a reduction in the risk of foetal neural tube defects; and &lt;br&gt; (b) the recommendation that women consume at least 400 µg folate per day in the month before and 3 months following conception.</td>
</tr>
</tbody>
</table>

**Editorial Note:** Subclause (e) implements a pilot trial of a management system for health claims. The outcomes of the pilot will be used to assist in the evaluation of a proposal to allow wider use of health claims in food labels and advertisements. The subclause ceases to have effect on 31 December 1999.

**Discussion**

This proposal established a health claims management framework using a folate/NTD health claim. Amendment to the Food Standards Code was approved in June 1998 and the first round of products approved to carry a folate/NTD health claim in November 1998. The progress and outcome of the folate pilot was integral to the broader review of health claims (P153 – Health and Related Claims).

As part of the folate pilot, an evaluation took place to determine the appropriateness of the proposed health claims management framework (process evaluation) and whether the health claim had any socio-cultural impact such as consumer awareness and knowledge regarding folate and health claims (outcome evaluation). The executive summaries of the process and outcome evaluations are at Attachment 4 of this report. The full reports can be obtained from ANZFA.

**Public Submissions**

In order to undertake the Inquiry, public comments are sought as to the appropriateness of the pilot.
1. Submissions to P153

LIST OF SUBMITTERS TO P153

Sanitarium Health Food Company Ltd - Colin Keene
Kellogg Australia Pty Ltd - M J Olsen
QUF Industries Ltd - R D Mcbean
Confectionary Manufacturers of Australasia - Jennifer Thompson
HJ Heinz Company Australia Ltd - Kim Tikellis
Goodman Fielder - Frank Lee
Palatinit Sussungsmittel GmbH Mannheim - Jane Barnes (from Foodsense on behalf of Palatinit Sussungsmittel GmbH Mannheim)
Nestle Australia Ltd - Vince Bolkard
Uncle Toby’s Co Ltd - Robert G Ganly
Distilled Spirits Industry Council of Australia Inc - Gordon J Broderick
The Proprietary Medicines Association of Australia Inc - Bronwyn Capanna
The Wrigley Company Pty Ltd - Anthony O’Donnell
New Zealand Dairy Foods Ltd (Part of NZ Dairy Group) - Carol Wham
Institut Penyelidikan Minyak Kelapa Sawit Malaysia - Datuk Dr. Yusof Basiron
Axiope Pty Ltd
(on behalf of Toothfriendly Sweets International) – D L Bill
Blake Dawson Waldron - Belinda Findlay
Advertising Agencies Association of NZ Inc– David Innes
(representing 42 members)
Australian Dairy Products Federation - Helen Dornon
Australian Iron Status Advisory Panel - Tony Helman
Australian Meat and Livestock Corporation - Andrea Mortensen
Australian Nutrition Foundation Inc - Nola Caffin
Bread Research Institute Ltd - Monique Ivanhoe
Association of New Zealand Advertisers Inc Member of the Advertising Standards Authority NZ - Jeremy Irwin
Bristol Myers Squibb – Tony Perriam
Monsanto /Nutrasweet Kelco, a division of Monsanto
Submission from the US office - Maureen McKay
Wyeth Australia Pty Ltd - Natalie Touzell
Australian Food Council (now the Australian Food and Grocery Council)– Geoffrey Annison
Wine Makers Federation of Australia Inc - Stephen Stachan
New Zealand Grocery Marketers Association – Brenda Cutress
New Zealand Advertising Standards Authority Inc - Glenn Wiggs
New Zealand Dairy Board - Joan Wright
Nutritional Foods of Australia - Val Johanson
(health food manufacturers, retailers, naturopaths serves on TGA committee)
Informed Systems Ltd, New Zealand - John Birkbeck
Milk Marketing NSW - Sarah Pennell
Food Technologist’s Association of Victoria - Elaine Conroy
Australian Consumer’s Association and Consumer Institute of NZ- Matt O’Neil
Elaine Attwood (individual)
Dr Beverley Wood (individual)
Mark Lawrence (individual) - NHMRC research scholar, Deakin University
Rosemary Stanton
Diabetes Australia - B E Thorpe
Dietitians' Association of Australia and Dietitians of Diabetes Australia - Sandra Capra
Center for Science in the Public Interest (US consumer organisation) - Bruce Silverglade
Home Economics Institute of Australia Inc - Rosemary Cramp
National Council of Women of Australia Inc Ltd - Valerie Cocksedge
Environmental Health, Food and Nutrition Branch - NSW Health Department – John McMahon
Queensland Environmental Health Unit Food Services Division - R V Holmes
New Zealand Ministry of Health – Heather Wilson
New Zealand Ministry of Agriculture
Royal Women’s Hospital, Melbourne
Consumer Information Group on Pregnancy and Childbirth Folate – MJ Watson
HealthCare Otago Ltd (NZ Public Health Service) – Lynette Finnie
University of Wollongong
Department of Biomedical Science - Peter Howe
Community and Health Services, Tasmania
Public and Environmental Health Branch - Mark Jacobs
University Of New South Wales - Peter Baume And Leah Bloomfield
School of Medical Education
Auckland Health Care
Largest Health Care Organisation in NZ - Jenny Yee, Elizabeth Stewart
CSIRO Division of Human Nutrition - Richard Head
Public Health Association of Australia
Commonwealth Dept of Health and Family Services Public Health Division - Liz Furler
Therapeutic Goods Administration (TGA)
Dept of Health and Family Services
PART A – OVERALL COMMENTS

In August 1997, ANZFA circulated the P153 (Health and Related Claims) for public comment. The proposal recommended that a review of health claims be undertaken and that it should proceed in three stages e.g. Stage 1 - Policy Analysis, Stage 2 - Resourcing Issues, Stage 3 - Development of Framework. Fifty nine submissions were received in response to the Preliminary Assessment P153, many of which contained extensive references supporting their comments.

Of the 59 submissions received, 28 were from industry, 14 from government/regulatory bodies and 17 from consumers. In total, 50 submissions generally supported the review of health claims, however 11 of these submissions had some concerns. Twenty seven of the submissions who generally supported the review were from industry, 11 from government/regulatory agencies and 12 from consumer groups.

Eight submissions did not support the review or the introduction of health claims and one submitter did not support or oppose the review. One industry submission, 3 government/regulatory agencies and 4 consumer groups did not support the review or the introduction of health claims.

In general, issues raised in submissions have been categorised into policy, management framework and resource issues.

Policy related issues (Part B) focussed mainly on who supported or disapproved of the review of health claims.

Submissions addressing management framework (Part C) were broad and varied. Issues in this category included the need for definitions of nutrition messages versus health claims, use of the word “health” in labels and advertising, the need for mandatory nutrition labelling, types of health claims e.g. specific and generic and how they should be regulated, the need for scientific substantiation of claims, qualifying and disqualifying criteria, mechanisms for approving and regulating health claims (e.g. codes of practice, fair trading law), the need for education campaigns and monitoring and evaluation, advertising relating to health claims and the relationship between therapeutic goods and foods.

Submissions addressing resourcing issues (Part D) related to who should bear the specific and overall costs of developing and implementing a health claims system and who should be responsible for regulating health claims. Other submissions questioned how resourcing costs would affect small businesses and whether funds would be diverted from other public health budgets to fund a health claims system. Issues such as buying rights to health claims and licensing health claims, the relevance of captureable commercial benefit and fines were also raised.
PART B - POLICY

1. GENERAL

Most of the 59 submissions received commented on policy issues. Many submissions provided extensive reference material to support their views relating to policy issues. Issues were classified under the following headings.

2. GENERAL SUPPORT FOR THE REVIEW OF HEALTH CLAIMS

Sanitarium Health Food Company, Kellogg (Australia) Pty Ltd, QUF Industries Ltd, the Confectionary Manufacturers Australasia, HJ Heinz Group Australia, Palatinit Sussungmittel GmbH Mannheim, Goodman Fielder, Nestle Australia Ltd, Distilled Spirits Industry Council of Australia, Wrigley Company Pty Ltd, the New Zealand Dairy Foods Ltd, the University of Wollongong Department of Biomedical Science, Blake Dawson Waldron, the Advertising Agencies of New Zealand Inc, Auckland Health Care, the Australian Dairy Products Federation, the Australian Iron Status Advisory Panel, the Australian Meat and Livestock Corporation, the Australian Nutrition Foundation Inc, the Bread Research Institute Ltd, the Association of New Zealand Advertisers Inc, CSIRO, the Diabetes Australia, Dietitians Association of Australia, the Milk Marketing, the New Zealand Dairy Board, Nutritional Foods of Australia, the Commonwealth Department of Health and Aged Care, Bristol Myers Squibb, Monsanto/Nutrasweet Kelco, Wyeth Australia Pty Ltd, Axiome Pty Ltd, Food Technology Australia, the Queensland Environmental Health Unit, the Royal Women’s Hospital Melbourne, Marjo Roshier, the Australian Food Council, the Therapeutic Goods Administration and the New Zealand Grocery Marketers Association division generally supported a review of the standard relating to health claims. However, Heinz commented that general prohibitions on health claims should be maintained for some specific food categories e.g. infant foods.

Many of the submissions also specifically supported the proposed policy principles for reviewing health claims. The Australian Iron Status Advisory Panel commented that without a policy background, health claims could be abused. The Nutritional Foods of Australia commented that any system for health claims should not favour large companies. Although the Association of New Zealand Advertisers Inc generally supported the review, they commented that reference to advertising needs to be removed from the standard as it conflicts with the Bill of Rights 1990 and the Commerce Act 1986 in New Zealand. The Australian Dairy Products Federation also commented that advertising should be looked at separately.

The New Zealand Dairy Board suggested that ANZFA did not take into account the fair trading objectives under Section 10 and suggested the objective would capture the unfair disparity in use of health claims in food and health shops and regular food and misinformation through print and electronic media.

Reasons for supporting the review were varied and included:

- the current standard is confusing, restrictive, inhibits dissemination of national nutrition messages and denies consumers the opportunity to make healthy choices;
- the current standard inhibits product development and research and is a major disincentive for marketers;
• the standard creates confusion for consumers by promoting an environment in which misinformation is widespread;
• there are links between foods and health which have already been substantiated and which should be able to go on labels;
• the enforcement and interpretation of the current standard is inconsistent;
• allowing health claims will permit agencies to target dietary advice to the community e.g. ethnic groups, those at higher risk of chronic disease;
• health claims are an important means of communicating useful information about diet and disease to consumers and may impact positively on the community;
• provides manufacturers with a secure environment to commit resources for product development and allows innovation;
• successful health claims systems are working overseas;
• health claims recognise the scientific and technological advances in nutrition science and food technology;
• foods currently on the market, which have health benefits are unable to make health claims and should not be underestimated e.g., dairy products and osteoporosis, isomalt, “toothfriendly initiative” which may benefit public health.
• the current standard presents an artificial barrier between foods and therapeutic goods; and
• the standard would provide a yardstick against which health messages can be measured.

3. GENERALLY SUPPORT REVIEW BUT WITH CAUTION

The Proprietary Medicines Association of Australia Inc, NSW Health Department, Environmental Health Food and Nutrition Branch, Mark Lawrence, the Australian Consumer’s Association and Consumers’ Institute of New Zealand, the New Zealand Ministry of Health, the New Zealand Ministry of Agriculture, Home Economics Institute of Australia Inc, Informed Systems, the New Zealand Advertising Standards Authority Inc, Institut Penyelidikan Minyak Kelapa Sawit Malaysia and the Public Health Association of Australia expressed some reservations about the review of health claims. The following submitters encouraged a cautious approach to health claims and expressed concern about the proposed review.

The Proprietary Medicines Association of Australia Inc submitted that if claims are permitted, they should be consistent with other countries and fair to all manufacturers. They also commented that consistency needs to extend to efficacy, safety, advertising controls and surveillance.

The NSW Health Department, Environmental Health, Food and Nutrition Branch supported the proposed review commented that total deregulation is not an option as nutrition is a changing and contentious science and any new claims need scientific validation before being permitted. The Environmental Health, Food and Nutrition Branch, also believed that the current provisions should be maintained and enforcement of this provision improved.

The Australian Consumers Association and the Consumers Institute of New Zealand had three main concerns including there is:
• a lack of conclusive evidence between health claims and public health benefit;
• a lack of national public health nutrition policy which may cause the process to be
taken over by food manufacturers;
• the potential for market failure e.g. there is lack of enforcement.

They also expressed concern that industry may attempt to undermine or weaken the
provisions e.g. as in the USA.

The Home Economics Institute of Australia Inc commented that in order to validate health
claims will become broad and are unlikely to benefit consumers. Also the extent of variation
from person to person adds to the complexity. They also commented that the drive for people
to buy a product could compromise the health message. They also commented that if health
claims are allowed then they should be subject to regular review in light of the latest research.

Institiut Penyelidikan Minyak Kelapa Sawit Malaysia commented that there may be a need to
regulate health claims on food labels to some degree and they may contribute to consumer
education in nutrition and dietary guidelines.

The Public Health Association commented that ANZFA needs to prevent the medicalisation
of the food supply and at the same time encourage innovative food product research and
development. They also commented that they would support a revised label format
encompassing A1 Clauses (13), (19) and (22).

4. STRONGLY OPPOSE THE EFFECTIVENESS OF HEALTH CLAIMS

Health Care Otago Ltd, University of New South Wales School of Medical Education,
Beverley Wood, Rosemary Stanton, Community and Health Services Tasmania, Public, the
Wine Makers Federation of Australia and Environmental Health Branch, the Center for
Science in the Public Interest (US consumer organisations), the National Council of Women
of Australia strongly opposed or were concerned about the proposed review.

Main reasons of concern included:
• current permissions already provide consumers with the information they need to make
an informed choice about a healthy diet. The proposed changes may lead to consumer
confusion;
• health claims will lead to an inappropriate focus on certain products;
• total diet is more important than individual foods. Diet related problems are
multifactorial;
• excessive consumption of one product may occur;
• there is concern about ongoing validity of claims and liability issues;
• believe that health claims will impact middle to upper socio-economic groups, e.g.
people who are already high consumers of dietary supplements;
• inappropriate encouragement of health claims may lead to over use of fortified products
with the potential for nutrient imbalance or overload;
• health claims have the potential to reduce the visibility and effectiveness of government
health promotion schemes and may increase the promotion of packaged food;
• health claims may disadvantage unpackaged food;
current regulatory regimes relating to health claims are ineffective and there is lack of industry compliance;
• a generic approach to health claims will lead to gradual introduction of specific health claims e.g. as in the USA;
• the potential for positive nutrition messages has not been fully recognised.
• information does not lead to changed behaviour and may not necessarily affect public health. There is no evidence to show health claims affect public health;
• health claims will not be suitable for all of the population and may lead to increased food costs;
• health claims, in isolation, will be counterproductive to health;
• consumer health is a public responsibility and should not be left to marketing specialists;
• our knowledge of human nutrition is incomplete;
• enforcement will be impossible;
• the nutrient actually identified in the food may actually just be a marker for the active ingredient.

Wine Makers Federation of Australia do not support health claims on alcoholic beverages because of the potential to cause harm.

5. OTHER ISSUES

Uncle Toby’s Co Ltd stated that if A1(19) is to be retained, then 19(b) needs to be moved elsewhere in the Code. The Distilled Spirits Industry Council of Australia questioned whether the P153 encompassed negative claims e.g. that some foods may cause health problems. Wrigley Company Pty Ltd submitted that ANZFA should develop a process for challenging or prohibiting claims which are misleading or do not have scientific support. The Advertising Agencies of New Zealand commented that it would like to appear at any hearing relating to health claims.

PART C - MANAGEMENT FRAMEWORK

1. GENERAL

The majority of submitters commented on the management framework for health claims. Many of the submissions, in particular the submission from the Australian Foods Standards Council, provided substantial references to support their comments. A number of submissions also commented that the wording for health claims must be simple, specific, flexible and generally commented that a speedy completion to the review is necessary. Kellogg (Australia) Pty Ltd and the Commonwealth Department of Health and Aged Care, Public Health Division suggested a staged introduction of health claims. However, Kellogg (Australia) Pty Ltd also recommended immediate adoption of claims permitted in the USA.

HJ Heinz Group Australia, Goodman Fielder, Milk Marketing NSW, NSW Health Department, and the Environmental Health Food and Nutrition Branch specifically supported the key elements for the management framework for health claims.
The Dietitians of Diabetes Australia and the Dietitians' Association of Australia implied that they would support a framework, which could improve diabetes management and improve public health.

The Australian Meat and Livestock Corporation commented that allowing health claims meets the two primary objectives under Section 10 of the ANZFA Act. Both the Australian Meat and Livestock Corporation and Monsanto/Nutrasweet Kilcoy suggested that the framework should be undertaken with the Australian Food Council as the lead negotiator.

The Australian Consumer’s Association and Consumers’ Institute of New Zealand commented that health claims should be considered along with the review of all relevant food label information e.g. nutrient claims, nutrition messages, ingredient lists and the nutrition information panel etc. They were also concerned the current laws were being flouted, stating there is no reason to expect manufacturers to abide by more liberal rules in future. The New Zealand Dairy Board and Milk Marketing NSW suggested that the current prohibition limits access to valuable information by consumers and favours misinformation through irresponsible journalism and fad diet books. The Australian Dairy Products Federation were also concerned that media information can be incorrect. Informed Systems requested regulation to cover labelling, advertising, electronic print and all sales promotion relating to health claims. HJ Heinz Group Australia suggested that a reference to where people may find further information to support claims should be indexed on the label.

2. DEFINITION OF NUTRITION MESSAGES VERSUS DEFINITION FOR HEALTH CLAIMS

Eight submissions commented on definitions relating to health claims. Sanitarium, Uncle Toby’s Co Ltd, the Australian Nutrition Foundation Inc, the Confectionery Manufacturers Association and Monsanto/Nutrasweet Kilcoy commented that the definitions for nutrition messages and health claims should be clarified to avoid inconsistencies and confusion. Sanitarium Food Company commented that nutrition messages are unhelpful to consumers. Monsanto/Nutrasweet Kilcoy favoured the Codex definition for health claims. Wyeth Australia Pty Ltd requested a definition for structure function claims. The Public Health Association recommended that ANZFA consider disease claims versus health claims. The Proprietary Medicines Association of Australia Inc commented that there needs to be definitions for functional foods and nutraceuticals.

3. USE OF THE WORD “HEALTH”

Informed Systems Ltd commented that use of the word “health” should remain in the standard. Community and Health Services, Tasmania and Marjo Roshier commented on the widespread and inappropriate use and abuse of the word “health” which is not enforced and which can cause confusion for consumers. Marjo Roshier submitted that the use of the word may mislead consumers to think that such products play a role in a healthy diet. The Association of New Zealand Advertisers commented that the current standard and advertising practice relating to the word “health” contravenes existing legislation and is nonsensical.
4. **MANDATORY NUTRITION LABELLING**

HJ Heinz Group Australia recommended a mandatory nutrition information panel where a health claim is used on a food label.

5. **TYPES OF HEALTH CLAIMS**

5(a) **General**

Nestle Australia Ltd were opposed to a closed list of authorised claims such as the US approved claims and indicated that the standard should allow product specific claims as well as generic claims. Nestle Australia Ltd suggested that the following types of claims should be permitted: claims for nutrient, ingredient or non-nutritional substance related to health effects, claims related to the reduction of a disease risk, claims related to healthy eating patterns. The Australian Meat and Livestock Corporation supported generic and specific health claims and an industry code of practice, particularly in relation to iron.

The Dietitians' Association of Australia, the Dietitians of Diabetes Australia, The New Zealand Ministry of Agriculture, the New Zealand Ministry of Health Nestle Australia Ltd and Milk Marketing NSW commented that any new permission for a health claim should be science based and require information to be placed in context of the overall diet. The New Zealand Ministry of Health and Ministry of Agriculture and Queensland Environmental Health Unit, Food Services Division, and the Australian Dairy Products Federation also emphasised the importance of total diet. The Dietitians' Association of Australia wanted to ensure that fresh fruit and vegetable consumption is not compromised as a result of a health claims system. The Institut Penyelidikan Minyak Kelapa Sawit Malaysia submitted that total factors relate to disease not individual foods. The Commonwealth Department of Health and Aged Care submitted that a caveat is essential to ensure that the claim is put into the proper context of multifactorial lifestyle risk factors for disease.

The NSW Health Department, Environmental Health, Food and Nutrition Branch specifically emphasised the need for pre-market evaluation for claims. Wrigley Company Pty Ltd commented they did not agree with pre-market approval by ANZFA.

The Advertising Agencies of NZ Inc recommended that advertising of health claims should be assessed in three broad categories. ‘General Health Claims, Generalised Health Claims and Therapeutic Food Products. Details of these categories are included in the submission.

5(b) **Specific Health Claims**

Fifteen submissions specifically commented on specific health claims. Goodman Fielder, the Public Health Association of Australia and the Dietitians of Diabetes Australia commented that specific health claims should be evaluated on a case-by-case basis. Uncle Toby’s Co Ltd did not believe that specific health claims should not be part of the urgency of P153. The Bread Research Institute specifically supported specific health claims. The Public Health Association of Australia commented that specific, allowable claims are seen as part of a broader review of a new informative and educational food label.
The Commonwealth Department of The Australian Consumer’s Association and Consumers’ Institute of New Zealand submitted that it is unlikely that manufacturers would benefit from generic health claims but that specific health claims would be highly desired from a marketing point of view.

A number of submissions commented on claims which they believed would be beneficial to consumers. The Australian Iron Status Advisory Panel considered that the following health claims relating to “bioavailable” iron would be of considerable public health benefit “Lack of iron can cause anaemia. X is a good source of absorbable iron”. The Australian Iron Status Advisory Panel also commented that health claims should not mislead and that the role of iron in the diet rather than dietary supplements should be encouraged. It was recommended that any such claim is restricted to foods with a designated % of the iron RDI for reproductive age females, with bioavailability incorporated into the claim. The submission provided numerous references on iron status. The Australian Meat and Livestock Corporation also had a specific interest in claims about bioavailable iron. Axiome Pty Ltd explained that use of the logo for “tooth friendly” products should be permitted for sale in Australia and sought clarification from ANZFA about whether it is currently prohibited under Standard A1(19). The Australian Dairy Federation commented that the dairy industry are interested in claims relating to calcium/osteoporosis/hypertension, folate/neural tube defects, dairy/dental health and probiotics/gut health. Mark Lawrence supported health claims relating to folate and neural tube defects.

The New Zealand Ministry of Health and the Australian Nutrition Foundation did not generally support specific health claims. The Australian Nutrition Foundation commented that if a specific claim were to be allowed, then they must be put in the context of other risk factors. The Consumers Institute of NZ and the Australian Consumer’s Association strongly opposed the introduction of specific health claims before a system of generic claims had been evaluated and the claims shown to be compelling and not misleading. The National Council of Women of Australia did not support specific products linked with improved health, but welcomed resourcing by the food industry in ‘broad nutrition education’. The Public Health Association of Australia made recommendations about the claims themselves in terms of use and meaning.

5(c) Generic/Model Health Claims

Sixteen submissions specifically commented on either model or generic health claims. Sanitarium Health Company commented that if model health claims are pursued, they should be concise, understandable and the framework should be flexible to allow new claims as new evidence becomes available. The Australian Food Council submitted that health claims, which are permitted, should be model generic health claims and allow alternative wording in accordance with an industry Code of Practice. The Australian Nutrition Foundation considers there is a strong case for generic health claims/messages and that logos and non-verbal messages should be evaluated. The Australian Dairy Products Federation, the Bread Research Institute and Wyeth Australia Pty Ltd supported the use of generic claims. Monsanto /Nutrasweet Kilcoy, the Bread Research Institute and Wyeth Australia Pty Ltd recommended that Dietary Guidelines provide the basis for the establishment of generic health claims. The Australian Food Council, Queensland Environmental Health Unit, and the Proprietary Medicines Association of Australia Inc stated that if health claims are permitted, they should be model generic health claims.
The New Zealand Ministry of Agriculture commented that health claims should be generic
(not specific), positive, scientifically valid, and emphasise the importance of the total diet.
They should not include the word ‘disease’.

The Dietitians of Diabetes Australia requested clear guidelines for generic health claims. The
Australian Consumer’s Association and the Consumers’ Institute of New Zealand requested a
pilot study of generic claims prior to national health claims legislation.

The Australian Meat and Livestock Corporation commented they believe that health claims
should not only focus on risk reduction by indicating the relationship between a nutrient and
a health-related condition. The Commonwealth Dept of Health and Family Services. Public
Health Division submitted that classes of foods where health claims are permitted, need to be
identified.

The Therapeutic Goods Administration, Commonwealth Department of Health and Aged
Care submitted that consideration should be given as to whether a general claim can be made
for consumption of any amount mixed in a diet or whether the effect is dose responsive.

The Bread Research Institute Ltd supported the CAFTA paper of 1991 and suggested that
mandatory fortification requirements should automatically allow health claims; e.g. thiamin
in bread making flour. They recommend mandatory folic acid fortification as in the USA as a
public health measure. The Public Health Association also suggested that ANZFA develop a
separate nutrition information food standard similar to the NLEA. The Wine Makers
Federation of Australia did not support health claims on alcoholic beverages.

6. SCIENTIFIC SUBSTANTIATION

Sanitarium Health Food Company, the Australian Meat and Livestock Corporation, HJ Heinz
Group, the New Zealand Grocery Marketers Association, the Australian Food Council,
Informed Systems, the Dietitians’ Association of Australia, the Confectionery Manufacturers
Australia and the Association of New Zealand Advertisers Inc agreed that scientific
substantiation of health claims via expert panels was needed. Most of those who commented
indicated that the expert groups were necessary and that relevant representation, transparency
and efficiency were essential to ensure consumer confidence. Nutritional Foods of Australia
suggested an evaluation process similar to the Complementary Medicines Evaluation
Committee.

The Commonwealth Department of Health and Aged Care commented that substantiation
should be discussed by the nutrition community. They also stated that evidence should be
from controlled human intervention trials, epidemiological data, animal models and other
biological evidence. The Home Economics Institute of Australia Inc commented that
consumer representation should help the food industry and ANZFA to manage the
framework. The Therapeutic Goods Administration submitted that scientific substantiation
must evaluate nutritional criteria, dose specificity and directions for use. Nestle Australia Ltd
did not support a joint government and scientific body to arbitrate should contentious issues
arise.
The Commonwealth Department of Health and Aged Care also recommend that ANZFA collaborate with SIGNAL to consider and sign off substantiation criteria. The New Zealand Grocery Marketers Association stated the degree of substantiation needs further consideration by ANZFA.

HJ Heinz Group and the Australian Food Council commented that substantiation must be supported by national nutrition policy. Nestle Australia Ltd commented that substantiation of claims should be open to manufacturer flexibility as to how the claims are justified. The Wrigley Company Pty Ltd submitted that the onus should be on manufacturers to scientifically substantiate their claims. Milk Marketing NSW believes that nutritional science is advanced and there is scientific evidence to substantiate claims.

The Australian Consumer’s Association and Consumer Institute of New Zealand, CSIRO, Therapeutic Goods Administration, Dietitians' Association of Australia and the Australian Nutrition Foundation supported case-by-case evaluation. Goodman Fielder, the Public Health Association of Australia and the Dietitians of Diabetes Australia commented that specific health claims should be evaluated on a case-by-case basis. The Australian Consumer’s Association and Consumer Institute of New Zealand supported the case-by-case evaluation in the Keystone report and expressed concern about the consumer’s right to informed choice without being mislead. They also commented that potential claims should require vigorous independent testing and pre-market approval. CSIRO commented that case-by-case evaluation must prioritise perceived nutrition problems in Australia and New Zealand, RDIs of other nutrients in the food and possible negative attributes. CSIRO strongly recommend the development of guidelines for substantiation. Nestle Australia Ltd was opposed to funding arrangements between ANZFA and manufacturers in relation to case-by-case assessment of applications for claims. Nestle Australia Ltd did not support pre-market clearance and believe it could compromise the relationship between ANZFA and the industry.

The Bread Research Institute offered its services for scientific review of claims.

7. ELIGIBILITY CRITERIA

There were eight submissions relating to eligibility criteria. The Australian Consumer’s Association and Consumers Institute of New Zealand and the Australian Food Council specifically supported a framework with qualifying and disqualifying nutrient levels. The Dietitians' Association of Australia commented that the eligibility criteria should be consistent with the national dietary guidelines. The Australian Meat and Livestock Corporation and CSIRO Division of Human Nutrition pointed out that nutrient bioavailability needs to be taken into account in the development of health claims (see comments under 5(b)).

HJ Heinz Group Australia stated that if criteria are developed, they should be relevant to the nutrient relationships associated with the particular claim and apply to food categories only (to avoid the good food/bad food scenario). Goodman Fielder did not believe that health claims should be subject to pre-determined qualifying and disqualifying criteria. Goodman Fielder commented, there are four considerations when setting eligibility criteria and that the criteria should be set out on a food by food or group by group basis, for example:
1. the food must provide adequate nutritional sustenance;
2. other components must not counteract the claim;
3. other components must not increase the risk of other diet-related health problems;
4. the context of eating the food must be consistent with the claim.

Wyeth Australia Pty Ltd supported the consideration of “disqualifying attributes” (in Step 3(b)) but oppose the setting of “disqualifying levels” of some negative nutrients. They also oppose the NLEA/FDA because of disqualifying attributes.

8. MECHANISMS FOR APPROVING AND REGULATING HEALTH CLAIMS

Many submissions provided substantial references to support their submissions.

8(a) Standards or Codes of Practice?

The Australian Food Council recommended a prohibition on health claims except where permitted in the joint Code. It suggested that industry develop a supporting Code of Practice, which provides alternative wording for claims and guidance to industry about dissemination of nutrition/lifestyle information.

HJ Heinz Group commented that ANZFA consider a number of mechanisms for approving/regulating health claims but favoured an overarching Nutrition Information Food Standard or separate Act of Parliament. Goodman Fielder submitted that Clause A1(19) should include provision for exemptions, and ideally would be moved to another area of the Code. The Department of Health and Aged Care, Public Health Division submitted that it did not believe in exemptions to the current prohibition other than those relating to folate. The Commonwealth Department of Health and Aged Care recommended retention of the prohibition with introduction of exemptions.

Kellogg (Aust) Pty and the Confectionery Manufacturers Australasia suggested that ANZFA review the operation of the Code of Practice on Nutrient Claims. Kellogg (Australia) Pty Ltd also suggested that ANZFA review the Swedish food industry’s self regulation program for health claims before establishing a new standard. The New Zealand Diary Board, QUF Industries, Palatinit Sussungsmittel BmbH Mannheim, Nestle Australia and Blake Dawson Waldron suggested that ANZFA needs to consider whether general fair trading legislation concerning misleading and deceptive conduct together or industry guidelines or similar non-mandatory measures are sufficient to protect public health.

Wrigley Company Pty Ltd submitted that ANZFA should consider recognition of claims allowed in other countries. Goodman Fielder, Kellogg (Australia) Pty Ltd, Queensland Environmental Health Unit, Food Services Division, Australian Dairy Products Federation, Australian Nutrition Foundation, Public Health Association, Bread Research Institute, Wyeth, Uncle Toby’s Co Ltd, the Australian Food Council and Wyeth Australia Pty Ltd either referred to the Keystone analysis of the US NLEA or suggested that ANZFA should consider the current USA system for regulating health claims. Monsanto/Nutrasweet Kelco and the Australian Meat and Livestock Corporation did not support the USA NLEA system. The Centre for Science in the Public Interest urged ANZFA not to permit health claims based on the USA NLEA system as they may mislead consumers, multinational companies have lobbied the USA Congress to weaken NLEA requirements and permission to allow health claims is still under consideration internationally.
Nutritional Foods of Australia suggested that the NFAA Code of Practice on the Marketing of Health and Nutrition Products could provide ANZFA with a model for approving health claims. Palatinit Sussungsmittel GmbH Mannheim also recommended a government approved code of conduct. The Australian Nutrition Foundation recommended a code of practice to provide companies with guidance on types of claims which should be permitted.

The Australian Consumer’s Association and Consumer Institute of New Zealand submitted they would prefer to see health claims under the jurisdiction of the National Public Health Nutrition Strategy Group within the National Public Health Nutrition Partnership (neither which are established). Australian Consumer’s Association and Consumer Institute of New Zealand and the Commonwealth Department of Health and Aged Care also said health claims should be considered in context with dietary reference tools e.g. guidelines, national food selection guide, RDI’s food endorsement programs, food industry nutrition education initiatives also.

The Association of New Zealand Advertisers Inc. commented that Standard A1(19) could be incorporated in the Advertising Industry Codes of Practice.

9. EDUCATION

Nineteen submissions specifically commented on education relating to health claims. The Environmental Health, Food and Nutrition Branch, the Ministry of Health, the Ministry of Agriculture, the University of Wollongong Department of Biomedical Science, Healthcare Otago Limited, Australian Consumer’s Association and Consumers’ Institute of New Zealand, the Dietitians' Association of Australia, the Australian Iron Status Advisory Panel, the Home Economics Institute of Australia Inc, the Australian Nutrition Foundation Inc, the Public Health Association of Australia the Therapeutic Goods Administration and the Bread Research Institute Ltd specifically supported education (either prior to or in conjunction with the introduction) as an essential part of a health claims system. The Home Economics Institute of Australia Inc submitted that education be based on the total diet and not individual foods. The New Zealand Dairy Foods Ltd commented that education should be ongoing and explained that industry groups are taking effective education campaigns about health claims e.g. the Dairy Advisory Bureau.

The New Zealand Ministry of Health and the Ministry of Agriculture supported a co-ordinated approach to a nutrition education program. The University of Wollongong Department of Biomedical Science commented that education is essential to avoid the “some is good, more must be better” attitude. The Australian Consumer’s Association and Consumers Institute of New Zealand commented that the education initiative should be coordinated with the introduction of the national Food Selection Guide and that initiatives should be aimed at health educators to ensure accurate dissemination. The Australian Nutrition Foundation requested that informatics be considered in the educational process. The Dietitians' Association of Australia supported a national nutritional education campaign approach involving dietitians. The Public Health Association of Australia opposed regulation that permits certain claims without resource being made available for education.

The Dietitians of Diabetes Australia, the Australian Nutrition Foundation and the CSIRO, Division of Human Nutrition offered to discuss this matter further with ANZFA.
The Dietitians of Diabetes Australia requested that nutrition education proposals accompany all applications and that offered their services at the food company/regulatory interface as experienced professionals. The Commonwealth Department of Health and Aged Care, Public Health Division advised that comprehensive consumer testing of an education campaign to coincide with the Gazettal of the revised Standard A1(19)(or the release of a food with a health claim) is necessary. They also commented that commitment to public education must be assured. The Environmental Health, Food and Nutrition Branch recommended that targeted education is required, particularly for ethnic sectors, in addition to general nutrition education.

The Therapeutic Goods Administration supported public education of public health professionals and requested that complementary practitioners e.g. herbalists, aroma therapists, acupuncturists, chiropractors etc be included. They also requested adverse effects reporting from all health professionals.

Kellogg (Aust) Pty did not believe that broad nutrition education in association with health claims was necessary, as the food industry generally provide this information. Goodman Fielder and New Zealand Dairy Foods also indicated that where education is needed, the food industry is well placed to provide it. Wyeth Australia Pty Ltd submitted that labelling and advertising is nutrition education for consumers at industry’s expense. CSIRO did not support national nutritional education and commented that education should focus on the meaning of the health claim alone.

Heinz commented that education in support of health claims needs to incorporate the messages in approved health claims, increase awareness of food labels and motivate consumers to read the label. Goodman Fielder commented that permission for claims should not be contingent on the conduct of national nutrition education campaigns. The National Council of Women of Australia supported a general nutrition education campaign accessible to all ethnicities and socio economic levels.

10. MONITORING AND EVALUATION

Eleven submissions specifically commented on monitoring and evaluation of health claims. The Australian Meat and Livestock Corporation, the Australian Nutrition Foundation Inc, the Confectionery Manufacturers Australasia, CSIRO the University of Wollongong, Department of Biomedical Science and the Dietitians of Diabetes Australia generally supported ongoing monitoring and evaluation if health claims are to be permitted. CSIRO agreed with monitoring and evaluation of specific claims over a specified timeframe, in order to detect emergence of discernible changes. The Home Economics Institute of Australia Inc indicated that monitoring and evaluation programmes should include provision for periodic revision. The Public Health Association Australia indicated they would strongly oppose regulation that permits certain health claims without monitoring and evaluation strategies. The Commonwealth Department of Health and Aged Care, Public Health Division had a similar view to the PHAA but stated that a monitoring and evaluation system must be in place before an exemption to the existing prohibition is made. They also indicated that an organization other than ANZFA should undertake the process to maximise credibility.
Kellogg (Aust) Pty commented that monitoring and evaluation should identify changes in food sales and consumer understanding and suggested that longer term impacts on public health outcomes will be difficult to demonstrate as they are influenced by many variables. HJ Heinz Group Australia commented that the food industry has data, which will contribute to the monitoring and evaluation of health claims.

11. ADVERTISING

The Association of New Zealand Advertisers commented that their submission should be read in conjunction with the Advertising Standards Authority and the Advertising Agencies’ Association submission. The Association of New Zealand Advertisers Inc registered interest in discussing a development framework with ANZFA to ensure that advertising conforms with the food standards health and medical claims.

The New Zealand Advertising Standards Authority Inc propose a self regulated regime, which they claim is effective and in line with current Government policy in New Zealand. They also state they are willing to include amendments relating to advertising of health claims in their Therapeutics Code. The Association of New Zealand Advertisers Inc suggested a pre-vetting system to ensure compliance prior to completing advertisements relating to health claims and offered to discuss the development of a framework with ANZFA. Informed Systems Ltd commented that regulation of health claims should cover both advertising and labels. The Association of New Zealand Advertisers believe the current provisions should be removed from food standards legislation as they contravene the NZ Bill of Rights and Commerce Act 1986.

12. RELATIONSHIP BETWEEN THERAPEUTIC GOODS AND FOODS

Many submissions commented that care needs to be taken when considering foods at the interface between therapeutic goods and foods. The Institiut Penyelidikan Minyak Kelapa Sawit Malaysia submitted that claims linking a food product to risk reduction for a disease condition are medical claims, and do not belong on food labels. Nestle Australia commented that claims that a food can treat or cure a disease should not be allowed. The University of New South Wales, School of Medical Education also commented that foods, which have therapeutic benefits, should be regulated as therapeutic goods. Informed Systems Ltd commented that promotional material should not imply medical advice and that dietary supplements should be subject to the same regulation for health claims.

Monsanto /Nutrasweet Kelco indicated that health claims should not suggest that foods can prevent, treat, or cure disease, as this is the role of drugs. They also proposed that health claims can convey that they can reduce the risk for certain diseases, assuming there is appropriate scientific substantiation. Or could say that a product is “suitable”. The Therapeutic Goods Administration commented that health claims should not be therapeutic claims which involve prevention, treatment or cure of diseases. TGA believes that health claims should, incorporate nutrition messages.

The New Zealand Grocery Marketers Association said that there needs to be clear parameters for foods and medicines to prevent confusion and requested consideration of the NZ Medicines Act interface. The Proprietary Medicines Association of Australia submitted that there needs to be a clear hierarchy of claims with associated level of substantiation that is consistent across the food therapeutic interface.
Diabetes Australia commented there were inconsistencies between the Therapeutics legislation and the food legislation in relation to claims. The Therapeutic Goods Administration and the Proprietary Medicines Association of Australia Inc indicated that there needs to be a new or revised standard to ensure that there is a clear distinction between health claims versus disease prevention claims which are therapeutic and regulated by the TGA. The Proprietary Medicines Association of Australia Inc gave the example that use of a therapeutic claim on a food product should not cause that food to be reclassified as a therapeutic good.

The National Council of Women of Australia commented on functional foods and enclosed a previous submission to ANZFA which opposed the medicalisation of the food supply and requested regulation under the Therapeutics Goods Administration. Informed Systems Ltd supported a new standard for health claims and proposed that it cover all dietary supplements not covered by the TGA legislation.

The Nutritional Foods Association commented that ANZFA and the TGA will need to work together with industry to ensure the frameworks work well together and that foods are not allowed to make claims at a therapeutic level. Wyeth Australia Pty Ltd requested that “disease management” claims on medical foods (e.g. lactose intolerance) should not be considered to be health claims or require pre-market approval. Bristol Myers commented that they wish to include claims about special metabolic disorders.

The Therapeutic Goods Administration cited antioxidant claims as potential preventative claims which encourage changes in population consumption. The TGA warns of the potential harm if foods are promoted so that consumption levels of specific nutrients rise inordinately with toxic side affects. The TGA also warned that drug/nutrient interactions and the whole diet are still not well understood. They commented that care should be taken should health claims be permitted, as therapeutic products may reposition themselves as foods e.g. some herbal products. The TGA also attached a list of stakeholders as part of the submission and recommends close liaison between ANZFA and TGA in this review.

The TGA’s submission presented the following outline of the TGA’s regulation of therapeutic claims to assist ANZFA understand the regulatory processes which it meets at the interface.

The harmonisation at the National level between Australia and New Zealand is contingent on interpretation on the place of the New Zealand dietary supplements, which are regulated separately in New Zealand and not in Aust. In Australia products at the interface of food and therapeutic goods are regulated as one or the other. A review of the legal definition is in process.

The draft [Oct 97] of Arrangements for Complementary Medicines and Related Matters relates Schedules listable products, low risk] & 14 [registrable products] of TGA regulations to claims for ‘complementary’ products, which make preventive claims. If regulated under TGA, the onus of proof of a preventive claim is higher than that of an ordinary treatment. The TGA is concerned that some manufacturers may move products to food regulation carrying ‘preventive therapeutic claims,’ thereby avoiding quality manufacturing practice standards for therapeutic goods, rigorous substantiation of efficacy including dose response, toxicity and efficacy, and TGA national enforcement.
The Therapeutic Goods Administration commented that ANZFA relies on the State and Territories enforcement for foods, benchmarked by each state. The Complementary Medicines Advisory Committee, a newly established expert committee, will regulate products at the drug/food interface e.g. its first task in Feb 98 is to evaluate royal jelly, ginger and kava in therapeutic goods. The validity of therapeutic claims is part of the risk assessment. The Therapeutic Goods Advertising Code is prohibitive on all disease claims on the assumption that consumers need protection from self-diagnosis and self-medication, in this case possibly using diet and self-prescribed medicines, instead of seeking medical attention for potentially serious conditions.

PART D - RESOURCES

1. GENERAL

Twenty eight of the 59 submissions received, specifically commented on resourcing issues. Many submissions acknowledged that substantial resources would be required if health claims are to be permitted. Several submissions commented that funding needs to be justified on a public health and safety basis, be transparent, practical, and simple. The Centre for Science in the Public Interest commented that resourcing is seen as beyond “their brief”. The Australian Dairy Products Federation submitted that the lack of resources for enforcement for the current legislation is working against fair trading. The New Zealand Dairy Board and the Nutritional Foods Association of Australia signalled interest in discussing resourcing issues with ANZFA. Monsanto/Nutrasweet Kilcoy indicated that it agreed with the Australian Food Council’s submission on health claims. Submissions could be divided under the following headings 2-8.

2. COST OF DEVELOPING AND IMPLEMENTING HEALTH CLAIMS

Less than half of the 59 submissions received, commented on who should bear the cost of developing and implementing health claims. Some submissions generally referred to resourcing of the health claims framework as a whole. Other submissions commented on who should resource specific areas of the health claims framework. Community and Health Services Tasmania commented that the significant resources required do not warrant investment.

2(a) Who should bear the overall cost of a health claims system?

Sanitarium, HJ Heinz Group Australia, the Australian Consumer’s Association, the Consumers’ Institute of New Zealand, New South Wales Health Department, Dietitians' Association of Australia and the Australian Food Council supported joint industry/government funding of a health claims system. Although the Australian Food Council supported joint funding for practicality reasons, comment was made that it should be the governments responsibility. HJ Heinz Group Australia suggested that there should be some degree of user pays and commented that ANZFA should fund administrative and financial costs associated with evaluating whether the proposed policy guidelines can be met. The Australian Consumer’s Association and the Consumers’ Institute of New Zealand commented that the Ministry of Health did not have the resources to fund the health claims system.
The Ministry of Agriculture, Ministry of Health, The Royal Women’s Hospital, the University of Wollongong, the National Council of Women of Australia and the Commonwealth Department of Health and Aged Care supported either substantial or sole industry funding of a health claims system. Nestle Australia Ltd believed that industry as a whole, rather than individual manufacturers, should fund health claims. The New Zealand Grocery Marketers Association requested a cost benefit analysis prior to any industry involvement in funding. Monsanto/Nutrasweet Kilcoy suggested that resourcing should be discussed with the Australian Food Council. The New Zealand Ministry of Health and the Ministry of Agriculture commented that independent management of industry funding would be essential to avoid a conflict of interest.

The Advertising Standards Authority Inc (NZ) supported industry funding for regulation of advertising. The Advertising Agencies of NZ Inc advocated self regulation of advertising for health claims and discussed the mechanism for self regulation in New Zealand and how it is working effectively e.g. complaints go to the Advertising Standards Complaints Board. The submission indicated that successive governments in New Zealand have endorsed self-regulation and recommends a three broad categories for regulating health claims (see management framework summary).

2(b) Submissions on who should bear specific costs related to health claims

The University of Wollongong and the Australian Nutrition Foundation Inc commented that industry should be responsible for the costs related to substantiation. The Dietitians Association of Australia stated that applications to permit health claims should be funded by applicants and that an external independent organization should be responsible for monitoring health claims. The Australian Nutrition Foundation Inc commented that government should be responsible for monitoring and evaluation. The New South Wales Health Department questioned whether NHMRC funding should be available for monitoring and evaluation. Goodman Fielder commented that monitoring and evaluation should be largely public funded.

The Australian Nutrition Foundation Inc, Uncle Toby’s Co Ltd and the Public Health Association commented that government and industry should be responsible for education about health claims. The Australian Nutrition Foundation Inc suggested that ANZFA build on the current FDA position. The Public Health Association suggested co-funding of the National nutrition education initiative, tied to an agreement on co-regulation as in the NLEA model to precede the label changes. The Public Health Association also made recommendations on funding of national education monitoring and enforcement. The Ministry of Health see substantiation, monitoring and surveillance of claims as being problematic and expensive.

3. WHO SHOULD BE RESPONSIBLE FOR REGULATING HEALTH CLAIMS?

Several submissions specifically commented on who should be responsible for regulating a health claims system.

The New Zealand Advertising Standards Authority, The Association of New Zealand Advertisers Inc and the Advertising Agencies Association were in favour of self regulation of advertising relating to health claims.
The Association of New Zealand Advertisers Inc considered that the management of regulations by ANZFA or appropriate Government organizations will slow the process down. The submission enclosed a copy of the World Federations of Advertisers Congress about self-regulation and advertising.

HJ Heinz Group Australia favoured co-regulation or self regulation by industry. Kellogg (Aust) Pty Ltd favoured industry self regulation with rational government enforcement against false, misleading or unsubstantiated claims. The Australian Meat and Livestock Corporation submitted that self-regulation can be used to enforce health claims e.g. code of practice or law enforcement officers. The Australian Consumer’s Association, the Consumers’ Institute of NZ, the Public Health Association of Australia, Monsanto/Nutrasweet Kilcoy, the New Zealand Grocery Marketers Association and NSW Health Department supported a co-regulatory approach. Monsanto/Nutrasweet Kilcoy suggested a co-regulatory approach using a code of practice. The Dietitians' Association of Australia recommends a review of the Code of Practice on nutrient claims to see if a co-regulatory approach works. However, the Australian Consumer’s Association and the Consumers’ Institute of NZ were concerned about the current lack of enforcement.

The Australian Nutrition Foundation Inc recommended regulation by ANZFA and the NHMRC which builds on the current FDA position. The Public Health Association of Australia and Dietitians' Association of Australia indicated that ANZFA should manage resources and co-ordinate expert panels. The Home Economics Institute commented that funding arrangements should have consumer representation. The Royal Women’s Hospital and Wrigley Company Pty Ltd commented that ANZFA should maintain overall control to ensure effective, regulation, monitoring and resourcing. The Confectionary Manufacturers Australasia were particularly concerned about enforcement of health claims.

The Therapeutic Goods Administration requests that ANZFA and the TGA enforce permitted health claims regardless of whether the product is a food or a therapeutic good. The TGA state that this will require greater enforcement resources and a changed enforcement structure.

4. RESOURCING COSTS FOR SMALL BUSINESSES

The New Zealand Advertising Standards Authority and the Bread Research Institute commented that small businesses may be disadvantaged by the bureaucracy and expense of a health claims system.

5. DIVERSION OF FUNDS FROM OTHER PUBLIC HEALTH BUDGETS

The Australian Consumer’s Association, the Consumers’ Institute of New Zealand and Diabetes Australia were concerned that current health promotion and public health budgets may be diverted to fund a health claims system.

6. BUYING RIGHTS TO HEALTH CLAIMS AND LICENSING HEALTH CLAIMS

Goodman Fielder and Uncle Toby's Co Ltd suggested a registration system whereby a company effectively buys rights to health claims. Uncle Toby's Co Ltd suggested a registration system whereby companies would buy rights to use a particular claim on a product group for a fixed period, at around $500 per generic claim and $1000-2000 for a specific claim.
The Nutritional Foods Association of Australia suggested a licensing system whereby the company who undertakes the original research to substantiate claims receives fees from other producers wishing to use the approved claims.

7. CAPTUREABLE COMMERCIAL BENEFIT

The Australian Food Standards Council commented that cost recovery for health claims should only be applied where related to approval of specific health claims and where there is an exclusive captureable commercial benefit and that cost recovery should not be sought to increase public awareness.

8. FINES

The Australian Consumer’s Association and the Consumers’ Institute of New Zealand requested heavy fines for transgressions, should a standard be developed.
2. A399 - review of standard A1(19) - claims made about foods

A SUMMARY OF SUBMISSIONS IN RESPONSE TO THE PRELIMINARY ASSESSMENT REPORT OF A399

List of Submitters

National Council of Women of Australia - Elaine Atwood
Consumers' Association Of South Australia – Jill Bailey
Nestle Australia Ltd – Robyn Banks
Diabetes Australia – Alan Barclay
New Zealand Dairy Board – Julie Beagley
InforMed Systems Limited – John Birkbeck
McCain Foods Asia Pacific – David Boyle
Complementary Healthcare Council of Australia – Paul Bryden
Department of Public Health & Community Medicine – Alan Coates
Food Technology Association (FTA - VIC) – Elaine Conroy
Consumer Food Network – Dick Copeman
HEIA Inc. – Rosemary Cramp
Australian Food and Grocery Council – Tony Downer
Kelloggs – Efi Farmakalidis
Blake, Dawson & Waldron – Belinda Findlay
Public Health Association of Australia Inc. – Lynne Flemming
Phillips Ormonde & Fitzpatrick – John Gibbs
National Heart Foundation – Mareta Grundy
Queensland University of Technology, Brisbane – John Harrison
Heyhoe & Associates – Tom Heyhoe
Smart Foods Centre – Peter Howe
Bread Research Institute of Australia (BRI) – Monique Ivanhoe
Department of Health & Aged Care – Eric Johnson
The Proprietary Medicines Association of Australia Inc. – Zephanie Jordon
Sanitarium – Colin Keene
Goodman Fielder – Frank Lee
Unilever Foods – Julie Newlands and Donella Peters
Ministry of Health and Manatu Hauora – Gail Powell
Weekes Preston – Chris Preston and Diane Redmond Heath
Dairy Farmers – Norm Reynolds
Australian Dairy Corporation (ADC) – Phillip Richardson
National Food Processors Association – Peggy Rochette
Queensland Health – M P Smith
Confectionery Manufacturers of Australasia (CMA) – Jennifer Thompson
Angas Park Fruit Company Pty Ltd – Brain Thorn
Advertising Standards Authority Inc – Glenn Wiggs and Beverly Wood
Australian Cancer Society – L Wright
INTRODUCTION

An application has been received from NSW Health (Application A399), supported by all other enforcement agencies in Australia and New Zealand, to immediately review Standard A1(clause 19) of the Food Standards Code.

There has been concern for several years about the wording of the current Standard. The wording is sufficiently vague as to make uniform interpretation and application of the Standard very difficult for enforcement agencies. Some industry groups have also reported experiencing difficulty in interpreting the standard for food labelling and advertising purposes.

This situation has contributed to the recent release of several products whose labelling and advertising are considered to be in breach of the spirit of the Standard. While the issue of whether or not the statements are technical breaches of the standard can be debated, it is clear that they go against what is intended by A1(19). These products contain statements in their labelling and advertising that have the potential to mislead consumers about the role the products can play in reducing their risk of developing disease.

In response to A399, ANZFA decided that urgent clarification of Standard A1(19) was required in order to avoid a compromise of the following statutory objectives of the ANZFA Act, specifically:

a) the protection of public health and safety; and
b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception.

A Preliminary Assessment of A399 has been undertaken by ANZFA in which a number of options for progressing A399 have been outlined. These include:

Option 1 - review A1(19) as proposed by the applicant;
Option 2 - make no amendment to A1(19); or
Option 3 - impose no regulation (discard A1(19)).

Public comment has been sought in Australia and New Zealand in the form of written submissions in response to the Preliminary Assessment Report of A399.
A total of 45 submissions were received by ANZFA in response to the Preliminary Assessment Report of A399.

Of the 45 submissions, 18 submissions were received from the food industry/retail sector, 14 from non-government organisations (NGOs), five from individual submitters, four from universities, three from National/State Health Departments and one from the Office of Regulation Review.

In response to the options provided in the Preliminary Assessment Report, 14 submitters preferred option one, 26 preferred option two, three preferred option three and two did not specify an option. Of the three that gave option three as their first preference, one gave option two as their alternative preference.

Key issues raised in the submissions received have been categorised in terms of their relevance to the three possible options listed in the Preliminary Assessment Report: to review A1(19) as proposed by the applicant; to make no amendment to A1(19); or to impose no regulation.

**Option 1 - Review A1(19) as proposed by the applicant**

Fourteen submissions as listed in Attachment 1, supported the immediate review of A1(19) as proposed by the applicant. Key issues that were raised in justifying such action are as follows:

*The need to protect public health and safety.*

The majority of submitters that supported option one felt that there was strong justification in undertaking an immediate review of A1(19) in order to protect public health and safety. Diabetes Australia however, provided in principle support to A399 based on a number issues, one of which was whether there was any evidence “that public health and safety is at risk by the foods currently sold in Australia that breach the spirit of the standard”.

No direct evidence to suggest that public health and safety is at risk has been provided by the applicant or in any of the submissions in response to A399.

*The need to clarify current prohibitions and thereby decrease current ambiguity within A1(19).*

It was suggested that by clarifying and decreasing the ambiguity within A1(19), both the food industry and enforcement agencies would benefit. In relation to enforcement agencies, it was suggested that clarification of the Standard would more easily enable action to be taken by enforcement agencies against illegal claims.

It was noted however, by the Complementary Healthcare Council of Australia (CHC), that if Standard A1(19) is reviewed as suggested, enforcement agencies also need to be adequately resourced to enable them to undertake necessary enforcement action.
Diabetes Australia also noted that currently there seems to be problems associated with enforcing the Code and whilst supporting A399, questioned whether a review of A1(19) will result in more effective enforcement. If not, Diabetes Australia believes a review of the Standard will achieve little.

**Overall opposition to the introduction of health claims.**
A number of organisations such as the Public Health Association of Australia (PHAA) remain opposed to the introduction of health claims. The PHAA viewed the proposed review of A1(19) as potentially enabling stricter control of claims made in Australia and New Zealand and therefore supported A399.

**The need for consistency between the regulation of claims on food products and therapeutic goods.**
The CHC noted that for therapeutic goods, a strong advertising regime exists that is strictly policed. CHC maintained that there needs to be such a regime in place for managing the advertising of food products and hence equity across the marketplace between food products and therapeutic goods.

**Limiting the competitive advantage obtained by companies using potentially illegal claims.**
The Confectionery Manufacturers of Australasia (CMA) supported an immediate review of A1(19) as they believed that “companies are fast concluding that health claims are permissible”. The CMA supported an immediate review in order to ensure that “law-abiding food manufacturers and marketing companies are not further competitively disadvantaged in the Australian market place”.

Whilst a number of submitters agreed with the immediate review of A1(19), a proportion of submitters supported A399 in principle, although held reservations with regard to specific issues. The Proprietary Medicines Association of Australia Inc (PMAA) for example, noted that they support a review of A1(19) provided it is undertaken as an interim measure whilst the general work on health claims is being undertaken and that there is a commitment to its completion by the end of 2000. Similarly, Diabetes Australia queried whether it is worthwhile to undertake such a review given that P153 is due for completion by the end of 2000. Diabetes Australia also raised the issue of whether it may be worthwhile to establish a pre-approval process for products/labels prior to going to market.

### Option 2 - Make no amendment to A1(19)

Twenty-six submissions as listed in Attachment 1 supported option two, to make no amendment to A1(19) at this stage. A number of these submissions however supported a review of A1(19) done in conjunction with P153.

Key issues that were raised in opposition to undertaking a review of A1(19) at this stage were as follows:

**Associated cost to industry.**
A key issue that was raised in submissions opposing a review of A1(19) as proposed, is the cost that will be faced by industry, particularly if undertaken prior to the completion of P153. It has been suggested that the costs will be incurred in two specific areas: changes to existing labels and changes to trade names/trademarks.
A number of companies claimed that the most significant costs will be associated with “establishing new brand names if current brand names are deemed illegal”. The Australian Food and Grocery Council (AFGC) suggested that companies face establishment costs of trade names/trademarks of up to $2.5 million and maintenance costs of $1-1.5 million. If A399 is accepted, companies will waste this investment and be forced to reinvest in establishing new labels.

It is suggested that labels containing nutrition messages would need to be changed in order to avoid being regarded as implied health claims and in Goodman Fielder’s case, it is claimed that this would affect 70% of labels with an associated cost of $2.5 - $2.8 million. AFGC claimed that a range of incidental and intangible costs will also be incurred by factors such as ‘loss of reputation, change over costs and new product numbers (barcodes)’.

A concern raised by Blake Dawson Waldron regarding costs is that if A399 proceeds prior to the completion of P153, many product labels may become unlawful under A399. However, if P153 results in a relaxation of the current prohibition of health claims, a number of products would then need to make further changes to their labels. Hence, a manufacturer may face the added cost of re-establishing a product line that it previously had to abandon. Johnson & Johnson also noted that not only will this be expensive to industry but also confusing to consumers. AFGC maintained that it will need to be demonstrated as to how the benefits of the proposed change will provide public health and/or other benefits that will exceed the costs to industry.

In addition to the costs incurred by industry, Phillips Ormonde and Fitzpatrick submitted that if the right to use trade marks that include the word ‘health’ is revoked by the proposed change to A1(19), the Government may have to provide compensation to those companies owning the trademark.

A further issue raised by Blake Dawson and Waldron together with the National Food Processors Association, US (NFPA), was whether the proposed changes to A1(19) will be compliant with WTO obligations. They suggested that the costs associated with changing labels and trademarks amount to a trade restrictive obligation, as companies exporting products to Australia that bear a trademark incorporating the word ‘health’, will be required to change that trademark.

Inefficient and inappropriate to proceed prior to the completion of P153

Many submitters maintained that to proceed with A399 ahead of P153 would be inappropriate. In particular, they felt that proceeding with an immediate review of A1(19) would:

- lead to confusion within industry about the use of health claims;
- potentially result in the need for not only one but two label changes (if the outcome of P153 is to allow specific health claims); and
- be an inefficient use of resources particularly if resources were to be diverted from P153 to inhibit its completion by end 2000.
Those submitters that did not support A399 being advanced prior to the completion of P153 included: Weekes Preston; New Zealand Ministry of Health; Unilever Foods; the Smart Food Centre; Sanitarium; the National Heart Foundation; the Australian Dairy Corporation; Johnson & Johnson; Naturally Good Food Products; AFGC; Nestle; the New Zealand Dairy Board; the Dietitians Association of Australia; Blake Dawson and Waldron; and the Angus Park Fruit Company. Diabetes Australia, whilst generally supporting option one, also felt it would be inappropriate to review A1(19) prior to the completion of P153.

A lack of evidence to:

1. **Demonstrate that current practices are posing a threat to public health and safety and potentially misleading consumers.**

AFGC maintained that no evidence has been provided to demonstrate that ANZFA needs to act urgently or indeed at all to alter A1(19). They also maintained that the concept of the ‘spirit’ of a Standard is not a valid reason for making regulatory changes.

A number of other submitters also suggested that without evidence to demonstrate that A1(19), as it is currently worded poses a threat to public health and safety, action to alter A1(19) should not be taken at this stage, particularly not by using the provision of Section 37 of the ANZFA Act.

AFGC claimed that ANZFA ‘has not demonstrated how the amendment will support any of the objectives listed in Section 10 of the ANZFA Act, cannot demonstrate a cost/benefit and has not investigated alternatives’. It maintained that ANZFA will need to demonstrate that the benefits of the proposed change will provide health and/or other benefits that will exceed the anticipated costs to industry.

2. **Demonstrate that current legislation is inadequate to deal with the problem outlined in A399.** Weekes Preston, the AFGC and Kellogg’s claimed that the applicant has failed to demonstrate that existing law is not sufficient to deal with the issue raised in protecting public health and safety. The Smart Foods Centre suggested that numerous food products currently use ‘health’ as part of their name, so why not prosecute under the current Standard if this is considered a threat to public health and safety?

The proposed amendments extend A1(19) not clarify it.

A number of submitters believed that the proposed amendment to A1(19) will make the Standard too restrictive. They claimed that nutrition messages and nutrient claims, that ANZFA has encouraged the food industry to use, will become illegal. These concerns have been expressed by a large number of submitters including AFGC, Blake Dawson Waldron, Nestle, Australian Dairy Corporation, the National Heart Foundation, Sanitarium, the Smart Foods Centre, Unilever Foods, the New Zealand Ministry of Health and the Dietitians Association of Australia.

Specific views in relation to how the proposed drafting extends A1(19) have been outlined in the following ‘Critique of the proposed draft variation to A1(19)’.

The National Heart Foundation (NHF) submitted that the proposed amendment to Standard A1(19) institutes a prohibition on nutrition claims relating to health maintenance or enhancement and will not only constrain industry, but will also constrain opportunities for public health education and therefore hinder the potential for informed consumer food choices.
In turn, this action also takes away the incentive for food industry to invest in the development of new, more nutritious food products and modification of existing products by prohibiting food industry, particularly law abiding companies to make nutrition messages and nutrient claims.

The NHF had a specific concern that A399 will prohibit the operation of the Tick Food Information Program.

Sanitarium suggested that in any review of A1(19) a definition of prohibited ‘health claim’ messages and a definition of permitted ‘nutrition messages’ should be included. They suggested that at present it is difficult to draw a boundary between the two and may be impossible to do so as statements can be worded to lie along a continuum. They list the following example:

Foods high in calcium:

<table>
<thead>
<tr>
<th>Nutrition message</th>
<th>Health Claim,</th>
</tr>
</thead>
<tbody>
<tr>
<td>- help build strong bones and teeth</td>
<td>- help to prevent osteoporosis</td>
</tr>
<tr>
<td>- help to maintain proper bone density</td>
<td></td>
</tr>
<tr>
<td>- help to prevent loss of bone density</td>
<td></td>
</tr>
<tr>
<td>- help to prevent weakening of the bones</td>
<td></td>
</tr>
</tbody>
</table>

The AFGC also suggested that clarification of Standard A1(19) can be achieved by developing a set of guidelines that define nutrition messages, nutrient function messages and health claims. They claimed that this will ensure that valuable information about how foods can contribute to healthy diets can be provided to consumers, without breaching the Standard.

Consumers will have access to only limited nutrition information

As a result of the imposed restriction on nutrition messages and nutrient claims, many submitters believed that the draft Standard inhibits advice being provided to consumers by food companies about how their products can be incorporated into a healthy diet.

Kellogg’s stated that ‘consumers are entitled to obtain information about nutritional benefits of products to allow them to make informed choices’. They claimed that ‘further prohibition on nutrition information proposed by A399 will disadvantage consumers who are already confused by nutrition and health information and seeking clarification to assist them in selecting a healthy diet’.

In addition to this, a number of submitters were concerned that changes in the information that is provided to consumers will arouse uncertainty and confusion amongst consumers.

It is more appropriate to defer to alternative legislation or competitors (self regulation)

A number of submitters including Kellogg’s, the Australian Dairy Corporation, and Weekes Preston believed that rather than imposing a more prescriptive Standard, the difficulties that are being experienced, can be adequately dealt with by deferring to other legislation such as the Trade Practices Act, Fair Trading Legislation or Food Acts. Some viewed the proposed Standard as an additional and unnecessary layer of legislation. It was claimed by Kellogg’s that if indeed public health and safety is being compromised by claims that are misleading or deceptive, that such claims should be in the domain of the Trade Practices Act, yet there is no evidence that any action has been taken in relation to this.
**A399 is in conflict with the objectives of the Review of the Food Standards Code**

Phillip Ormonde and Fitzpatrick, on behalf of Coles Myer Ltd submitted that the proposed clause 19(c) is contrary to the 'spirit' of the first, third and fifth objectives of the Food Standards Code Review.

In relation to the first objective, ‘to review all regulation to ensure that it is the minimum necessary to achieve the desired outcomes, takes account of existing legislation, and avoids duplication where possible’ they maintained that the Trade Practices Act and Fair Trading Legislation provide adequate regulation.

Regarding the third objective, “to remove rigidly prescriptive requirements which make no contribution to public health and safety, nutrition or consumer protection, but which restrict manufacturers from varying their products to match changing market requirements including new consumer tastes” they claimed that the wording of 19(c) is too prescriptive because it seeks to prevent any use of the word ‘health’.

In relation the fifth objective, ‘to help discharge Australian and New Zealand obligations as members of the World Trade Organization, which provide that member countries must not use measures such as food standards to impose barriers to trade unless such requirements can be fully justified for specified reasons such as the protection of public health and safety’ they claimed that 19(c) will prevent the importation of any food product bearing the word ‘health’.

**A399 will result in discrimination against industry over other organisations and information sources.**

AFGC claimed that A399 will be discriminatory as other organisations are able to make nutrition messages and nutrient claims.

Heyhoe and Associates, on behalf of Johnson and Johnson suggested that the proposed changes will cover food labels and advertising but will not cover:
- general media coverage;
- advertisements for dietary supplements; and
- information provided on the internet.

Given this, they believed that all the Standard will do is ‘hamper food manufacturers and marketers in their attempts to provide relevant information about their products to consumers’ and not achieve the objective of ‘protecting public health and safety’.

Similarly, it was noted that it would be inconsistent and unfair if foods are sold as ‘health foods’ in health food stores as generally they are not labelled whereas other foods that are equally as ‘healthy’ are subject to A1(19).

**The proposed Standard is inconsistent with international legislation and the Therapeutic Goods Administration legislation.**

Heyhoe & Associates, on behalf of Johnson & Johnson, submitted that A399 is totally inconsistent with approaches taken by:
- the United States and in Japan where health claims are allowed; and
- by the TGA where ‘the new Standard for advertising of non-prescription medicines will have truth and safety as its priorities’.

29
Approval Process
A number of submitters including the Dietitians Association of Australia and Diabetes Australia have suggested that an approval process where food product manufacturers submit their product/label for pre-market review/approval. It was felt that such a process could help clarify the interpretation of the Code before a product was released on the market.

Option 3 - Impose no regulation (discard A1(19))

Three submissions, as listed in Attachment 1, supported option three, to repeal A1(19) as it currently stands.

The primary issues raised to justify why A1(19) should be discarded were as follows:

That the issues dealt with by A1(19) can be more appropriately dealt with by the Trade Practices Act and State Fair Trading Legislation or competitors (self regulation)
Blake Dawson and Waldron submitted that fair trading laws and the Trade Practices Act maintain consumer health and safety as a primary goal. They also suggested that the ‘immediate need’ for action is unfounded as avenues currently exist under fair trading laws for ensuring that false, misleading and deceptive statements are not made.

John Harrison, Queensland University of Technology argued that the proposed regulation imposes greater complexity with potentially increased costs to industry. Given this, he suggested that either enforcement can be undertaken by the ACCC by deferring to the Trade Practices Act. As an alternative, he suggested allowing a greater measure of self-regulation within industry.

Encouragement of the use of health claims
Blake Dawson Waldron maintained that there is a public health benefit to making medical claims and that there is an incentive for companies to create products that will assist consumers from a health and medical perspective.

The Advertising Standards Authority, New Zealand (ASA), maintained that Standard A1(19), as it stands and with the proposed variation, disadvantages consumers as it is in their interests to be fully informed about foods which contribute to a healthy diet. As an alternative, the ASA proposed that a Code of Advertising be introduced and to remove all reference to advertising in Standard A1(19).

CRITIQUE ON THE PROPOSED DRAFT VARIATION TO A1(19)

Clause 19(a)

The main comment regarding Clause 19(a) was in relation to the foods it covered. It was suggested that it was necessary to have a definition of ‘particular foods’ and ‘classes of foods’. The PMAA recommended that the Standard apply to ‘all foods’.
Clause 19(aa)

A large proportion of submitters that opposed A399 do not agree with the change proposed in 19(aa). Specifically, AFGC noted that the result of defining ‘claim’ as ‘any statement, representation, design or information which is not prescribed by this Code, and includes an express or implied claim’ widens the application of A1(19) and will have the unintended consequence of prohibiting widely used legal claims that are nutrient claims or nutrition messages. Many submitters agreed with this point of view, specifically in relation to the use of the word ‘implied’ because this will cause difficulties in health promotion organisations working with food industry partners to disseminate food and health messages to the public. They felt that widening the application changes the intent of A1(19) rather than clarifying it.

The NHF specifically opposed the use of ‘statement, representation or design’ as this restricts the use of drawings, figures (including the healthy food pyramid), emblems and logos (including the NHF tick logo) and that these items are important in nutrition education.

The NFPA suggested that it would be appropriate to define an ‘express claim’ and an ‘implied claim’ as done by the US Food and Drug Administration.

Clause 19(b)

A general concern raised in relation to Clause 19(b) was that the problem created by altering the definition of ‘claim’ in 19(aa) becomes apparent as 19 (b)(1) ‘prohibits any claim (with extended meaning) for therapeutic or prophylactic action’.

A specific concern raised by Dr Richard Head, CSIRO is that the scope of the word ‘prophylactic’ in 19(b)(1) is unclear. He suggested that it may be beneficial to include the following: ‘for the purpose of this clause, the term “prophylactic action” refers specifically to the prevention of an abnormal physiological state or disease and does not refer to the maintenance of normal physiological function’.

Clause 19( c)

A number of submitters acknowledged and gave their support to the prohibition of the word ‘health’ as stated in Clause 19( c), however, a large number of submitters objected to the proposed restriction placed on the use of the word ‘health’.

Submitters objected to 19( c) (ii) ‘Any label on or attached to a package of food or any advertisement for food must not include the word ‘health’ or any word of similar effect as part of or in conjunction with any generic or specific description of food’ as this will effectively rule out any statements that are currently made about foods which are nutritional messages rather than health claims. AFGC provided an example of this as ‘fruit and vegetables are essential for a healthy diet’. NHF gave a similar example, that ‘high fibre foods should be part of any healthy diet’.

Submitters particularly objected to 19(c ) (iii), ‘Any label on or attached to a package of food or any advertisement for food must not include the word ‘health’ or any word of similar effect as part of or in conjunction with the trade name or trade mark of any food’. Opposition to this subclause appears to exist primarily due to the costs involved in implementing changes to these items.
It has been queried whether the proposed change will offer any increased benefit to public health and safety and is argued that the Trade Practices Act is able to regulate ‘health’ used as part of a trade name or trademark if it is considered false or deceptive.

As stated in an earlier point regarding discrimination against the food industry, Sanitarium noted that it is inconsistent to permit products to be classified as ‘health foods’ by being sold in health food shops or in the health food section of a supermarket but not to permit products to be labelled in such a way as to communicate their suitability to be included as part of a healthy diet via the use of the word ‘health’ in a company brand/trade name.

Blake Dawson Waldron claimed that there exists at least 129 registered or pending trade marks containing the word ‘health’ in relation to classes 29 and 30 under the Trade Mark Act 1995. The proposed alteration to A1(19) will render these trademarks unlawful. In addition to this, a large number of companies and businesses include the word ‘health’ in their name and these organisations would be prevented from using that name on their food products or in connection with the promotion of their products.

A suggestion given by both the Food Technology Association, Victoria and the NFPA is that a ‘grandfather’ clause be introduced to allow for the continued use of any current trade names/trade marks whilst not permitting any new ones in the future. The NFPA suggested that several US food companies utilise the word ‘health’ and have trade marked brand names that are exported globally. They submitted that ‘failure to provide “grandfathering” for these products would be inequitable and discriminatory’.

Clause 19(d)

Some concern has been expressed that there will be confusion over the definition of ‘physiological condition’.

Dr Richard Head, CSIRO, suggested that as it stands, ‘physiological condition’ could refer to a normal situation such as the growth of pregnancy. The Smart Food Centre suggested that there continues to be a misuse of the word ‘physiological’ when clearly ‘pathophysiological’ is intended.

A number of submitters claimed that the proposed changes to 19(d) also extend Clause A1(19) unnecessarily. For example, the phrase ‘helps keeps you regular’ on a high fibre food would be prohibited as it is an implied reference to the disorder of constipation.

CONCLUSION

Submissions in response to A399 have raised many issues that need to be considered prior to progressing the Application. The issues raised can be thought of in terms of:

• whether it is appropriate to undertake a review of A1(19) immediately, in the future or at all; and
• if A1(19) is reviewed, how would the current wording of the Standard be altered?
**The review of A1(19)**
Whilst strong support exists for going ahead with the review of A399 immediately as suggested in the Application, many submitters opposed the Application. Of those who opposed the Application however, many supported the review of A1(19) at a later date either as part of P153 or following its completion.

**The draft variation of A1(19)**
Many issues have been raised in relation to the proposed draft variation as listed above. Whilst those submitters who supported the immediate review of A1(19) and accepted the proposed drafting, the majority of submitters have concerns in two key areas. The major concerns are in relation to:

- extending Clause 19(aa) to include claims that are currently legal, that is nutrient claims and nutrition messages. This problem could potentially be overcome by providing a definition and examples of legal claims such as nutrient claims/nutrition claims and illegal health claims; and
- prohibiting the use of the word ‘health’, particularly in trade names and trademarks. Amongst other concerns, this is seen to:
  - impose considerable cost on industry by making it necessary to modify labels and/or trade names/trademarks; and
  - potentially create a trade barrier by restricting importation of food products that currently bear a trade name/trademark including the word ‘health’.
### Submissions that support Option 1, Option 2 or Option 3 as outlined in the Preliminary Assessment Report of A399

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Review A1(19) as proposed by the applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consumers’ Association of South Australia</td>
</tr>
<tr>
<td></td>
<td>Dr Richard Head, CSIRO</td>
</tr>
<tr>
<td></td>
<td>Public Health Association of Australia</td>
</tr>
<tr>
<td></td>
<td>National Council of Women of Australia</td>
</tr>
<tr>
<td></td>
<td>Consumer Food Network of Australia and New Zealand</td>
</tr>
<tr>
<td></td>
<td>Diabetes Australia</td>
</tr>
<tr>
<td></td>
<td>Complementary Healthcare Council of Australia</td>
</tr>
<tr>
<td></td>
<td>Home Economics Institute of Australia</td>
</tr>
<tr>
<td></td>
<td>The Proprietary Medicines Association of Australia</td>
</tr>
<tr>
<td></td>
<td>Donella Peters</td>
</tr>
<tr>
<td></td>
<td>Dr Beverley Wood</td>
</tr>
<tr>
<td></td>
<td>Dept. Health and Human Services, Tasmania</td>
</tr>
<tr>
<td></td>
<td>Queensland Health</td>
</tr>
<tr>
<td></td>
<td>Confectionary Manufacturers of Australasia</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option 2</th>
<th>Make no amendment to A1(19)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Phillips Ormonde &amp; Fitzpatrick</td>
</tr>
<tr>
<td></td>
<td>Weekes Preston</td>
</tr>
<tr>
<td></td>
<td>Prof. Alan Coates, University of Sydney</td>
</tr>
<tr>
<td></td>
<td>National Heart Foundation</td>
</tr>
<tr>
<td></td>
<td>Food Technology Association Victoria</td>
</tr>
<tr>
<td></td>
<td>InforMed Systems</td>
</tr>
<tr>
<td></td>
<td>Dietitians Association of Australia</td>
</tr>
<tr>
<td></td>
<td>Smart Foods Centre</td>
</tr>
<tr>
<td></td>
<td>David Hughes</td>
</tr>
<tr>
<td></td>
<td>Ministry of Health, NZ</td>
</tr>
<tr>
<td></td>
<td>Australian Food and Grocery Council</td>
</tr>
<tr>
<td></td>
<td>Unilever Foods</td>
</tr>
<tr>
<td></td>
<td>Angus Park Fruit Company</td>
</tr>
<tr>
<td></td>
<td>Heyhoe &amp; Associates (Healthy Co (Aust))</td>
</tr>
<tr>
<td></td>
<td>Heyhoe &amp; Associates (Johnson &amp; Johnson Pacific)</td>
</tr>
<tr>
<td></td>
<td>Heyhoe &amp; Associates (Naturally Good Products)</td>
</tr>
<tr>
<td></td>
<td>National Food Processors Association, US</td>
</tr>
<tr>
<td></td>
<td>New Zealand Dairy Board</td>
</tr>
<tr>
<td></td>
<td>Nestle Australia</td>
</tr>
<tr>
<td></td>
<td>BRI Australia Ltd</td>
</tr>
<tr>
<td></td>
<td>Australian Dairy Corporation</td>
</tr>
<tr>
<td></td>
<td>Goodman Fielder</td>
</tr>
<tr>
<td></td>
<td>Kellogg’s</td>
</tr>
<tr>
<td></td>
<td>Sanitarium</td>
</tr>
<tr>
<td></td>
<td>Dairy Farmers</td>
</tr>
<tr>
<td></td>
<td>McCain Foods Asia Pacific</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Option 3</th>
<th>Impose no regulation (Discard A1(19))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blake Dawson Waldron</td>
</tr>
<tr>
<td></td>
<td>Advertising Standards Authority, NZ</td>
</tr>
<tr>
<td></td>
<td>Dr John Harrison -Queensland University of Technology</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No specific option chosen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of Regulation Review</td>
</tr>
<tr>
<td>Mrs Diane Redman-Heath</td>
</tr>
</tbody>
</table>
SUMMARY OF PROCESS AND OUTCOME EVALUATIONS

MANAGEMENT FRAMEWORK FOR FOLATE/NEURAL TUBE DEFECT
HEALTH CLAIM PILOT

INTRODUCTION

In March 1998, ANZFA raised a proposal (P170) to conduct a pilot of a management framework for health claims. The experiences from proposal P170 were intended to feed into the review of P153 which reviews the prohibition on health claims. The pilot aimed to obtain a clearer, more practical understanding of the regulatory, social and public health impact of health claims and specifically focused on the benefits of folate in reducing the incidence of neural tube defects in babies. ANZFA proposed to use the experience gained from conducting the pilot on folate to guide further planning, development and decision-making, if health claims are to be permitted in future.

The pilot had two primary objectives which were to trial the use of the proposed management framework for health claims using a folate/neural tube defect health claim and to address a significant public health problem.

The management framework was comprised of five components including:

1. **regulatory systems** – regulatory and practical arrangements for approval of products to carry a health claim. A co-regulatory approach was taken where the regulation of the folate health claim in the Food Standards Code was supported by an Interim Code of Practice;

2. **scientific assessment/substantiation** - mechanisms for how claims are substantiated, who should substantiate claims and systems for setting qualifying and disqualifying criteria for food products using the claim;

3. **education and communication** - strategies to support and promote health claims;

4. **monitoring and evaluation** – mechanisms for assessing and monitoring the outcomes associated with health claims; and,

5. **surveillance and enforcement** - mechanisms to ensure compliance with the regulatory system for health claims.

ANZFA commissioned ARTD Research Consultants to undertake a “process” evaluation of the pilot. The process evaluation focused on how to undertake and manage health claims. It did not determine whether health claims should be permitted or whether the folate health claims had any impact on public health. ANZFA also commissioned MJ and LF Watson (from the Royal Women’s Hospital and Centre for the Study of Mothers’ and Children’s Health) to undertake a separate “outcome” evaluation to examine the sociocultural and other impacts of the pilot, such as changed buying and consumption patterns or changed knowledge and attitudes toward foods that are rich sources of folate.
1. Executive summary of the process evaluation of the folate pilot

**Pilot of a management framework for health claims**

To obtain a clearer, more practical understanding of the regulatory, social and public health impact of health claims, in March 1998 ANZFA raised a proposal (P170) to conduct a pilot of a management framework for health claims, using a health claim about the benefits of folate in reducing the incidence of neural tube defects. The framework comprises five components:

1. scientific assessment
2. regulatory systems
3. surveillance and enforcement
4. education and communication
5. monitoring and evaluation.

**Process evaluation of the pilot**

The terms of reference for the evaluation focus on assessing and making recommendations about how experience gained from conducting the pilot should guide further planning, development and decision-making, if health claims were permitted more generally (see section 1.3). As a process evaluation, the focus is on ‘how to do health claims’ rather than the impacts associated with the folate health claim. ANZFA is undertaking a separate outcomes evaluation to examine the public health and other impacts of the pilot.

The experiences and perceptions of key stakeholders from government, industry, consumer, community and professional organisations were collected over two rounds of consultations using interviews (60 stakeholders) and written feedback (30 submissions).

**Overall effectiveness**

The management framework used in the pilot provided a sound basis for the appropriate, effective and efficient management of the folate health claim. Thus, the pilot has successfully demonstrated that it is possible to effectively manage a single health claim within the current Australian and New Zealand regulatory and public health environment.

This is not to say that the folate health claims pilot has achieved all its intended outcomes. Such judgements will need further data from the outcomes evaluation, due for completion in January 2000.

The extent to which the management framework provides a basis for managing other health claims is less certain. Key informants across all sectors expressed reservations about the generalisability of findings, noting:

- substantiation of the folate claim was relatively straightforward and non-controversial;
- slow uptake of the folate health claim on products and associated advertising;
- limited practical application to date of the surveillance and enforcement element of the management framework;
- key partners had inadequate time to prepare and plan for the pilot because of the requirement on ANZFA to establish the folate pilot as a matter of urgency;
- the slower uptake of pilot activities in New Zealand limited insights about the management framework in the New Zealand context.
Implementation of the pilot
Preparation for the pilot began in March 1998, with folate health claims being permitted on eligible foods from November 1998 to February 2000.

To date, ANZFA has approved the use of the folate health claim on over 100 products, including 28 primary foods and 72 processed foods from 10 food manufacturers and five fresh produce organisations. As at the end of May 1999, 10 products carrying a folate health claim were ‘on-the-shelves’ in retail outlets, with a further four to six of the currently approved products expected to use the health claim by the end of the pilot. The use of the folate health claim varied significantly between Australia and New Zealand, and between food sectors and companies.

Management of the pilot
The pilot is being managed by ANZFA with the support of an intersectoral Steering Committee.

Key informants from all sectors acknowledged the professionalism of ANZFA staff and their partners in establishing and implementing the pilot. However since April 1999, with the departure of a number of key project staff from ANZFA, informants noted an apparent decline in the responsiveness and support available from ANZFA staff.

Suggestions to improve ANZFA’s management of the pilot included:
• involving stakeholders (particularly New Zealand stakeholders) in the planning of the pilot;
• keeping stakeholders informed about the progress of the pilot using a format that is clear and concise;
• giving greater notice about upcoming pilot events, particularly media events.

Costs associated with the pilot
Over its full period, the folate pilot will cost around A$1.1 million to fully implement, including in-kind contributions, with 80% of the expenditure managed by ANZFA.

A number of different strategies for reducing the costs associated with the management framework processes were identified (see Section 8.4). However, the appropriateness of these strategies and the overall resource implications for any health claim system is dependent on ANZFA’s future approach to health claims. For example, costs would vary greatly depending on whether public health campaigns and comprehensive evaluations were required for all health claims.

However, it is clear from the pilot that there are significant costs associated with a health claims system and that these costs will be primarily borne by ANZFA. Given that no allocation has been made for such costs in the current ANZFA budget, additional funding will be needed from government appropriations or user pay contributions.

Improving the management framework
The consultants identified seven key strengths of the framework - namely:
• the five elements of the management framework adequately covered the main areas and issues which needed to be addressed in managing the folate health claim;
• it ensured that relevant partners were engaged in elements of the framework that related to their needs and issues;
• expert committees provided a credible, independent basis for substantiating the health claim and establishing the eligibility criteria for approved foods;
• the co-regulatory system achieved a balance between industry self-regulation and legally-binding enforcement of the Food Standards Code by government agencies;
• the individual product approval system was administratively simple and efficient;
• the Code of Practice Management Committee provided a mechanism for industry involvement in ensuring compliance with the Interim Code of Practice for the Communication of the Health Benefits of Food Products and maximised the efficient use of existing infrastructure;
• the monitoring strategy involved the collection of an appropriate range of process and short-term outcomes data, taking advantage of existing nutrition and health surveys and industry data.

The consultants identified seven areas where the framework needed strengthening - namely:
• greater integration of the differences in the policy and industry context between Australia and New Zealand. In the pilot this resulted in much lower levels of interest and engagement of New Zealand industry in the first half of the pilot;
• need for detailed guidelines on the requirements and standards for scientific substantiation of claims;
• need for a public consultation process to consider the divergent views about the rationale and merits of each health claim;
• need to better promote the role and functioning of the Code of Practice Management Committee to avoid current confusion between self-regulation and co-regulation;
• need to clarify the interface between the responsibility of the Code of Practice Management Committee in enforcing the Code of Practice and the responsibilities of New Zealand and Australian State/Territory government agencies in enforcing the Food Standards Code;
• sustainability of the public education campaign; and,
• resolve uncertainties in the comparability and usefulness of monitoring data in establishing the outcomes of the pilot.

Implications for future use of the management framework
A key policy issue for ANZFA to consider is the relative importance of the public health and regulatory focus of a health claims system - that is, the relative importance of health claims as a public health intervention versus a regulatory system to allow food companies to make balanced substantiated claims.

Given the divergent views about the rationale and merits of health claims, ANZFA will need to develop a health claims policy which articulates the basis on which the relative benefits of individual health claims will be assessed. Such a policy would be used to guide decisions following a public consultation process and also refine the scope and extent of public education and evaluation strategies.

Scientific assessment
A strong, independent scientific assessment process is required to ensure public confidence in the integrity of a health claims system. This requires the adjudication of the scientific evidence used to substantiate a health claim by a suitable expert panels convened by ANZFA or out-sourced to a research body such as the NHMRC.
To assist applicants to prepare a case for scientific substantiation there is a need to develop guidelines and procedures on requirements for scientific substantiation.

An expert panel would also establish the eligibility criteria for foods including both qualifying and disqualifying criteria. In line with the guidelines used in the pilot, approved foods should support the aims of the Australian National Food and Nutrition Policy, New Zealand Plan of Action for Nutrition, the Dietary Guidelines for Australians and the New Zealand Food and Nutrition Guidelines.

**Regulatory systems**
A co-regulatory system for the management of health claims is appropriate. This system encompasses legally-binding rules specified in the Food Standards Code, supported by an industry code of practice which provides additional information and guidelines on the use of health claims. The concept of co-regulation is not well understood, particularly in Australia, where it is confused with self-regulation and needs further explanation to stakeholders.

Co-regulatory processes would include amendments to the Food Standards Code for each permitted health claim, an administratively simple pre-market approval process based on individual product applications from food companies and associations to ANZFA, and a *Code of Practice for the Communication of the Health Benefits of Food Products* which provides best practice guidelines for companies and organisations wanting to use approved health claims.

A critical factor in the success of the co-regulatory system will be an appropriately resourced public consultation process for each health claim proposal.

**Surveillance and Enforcement**
A Code of Practice Management Committee would provide the primary mechanism for surveillance and enforcement of a *Code of Practice for the Communication of the Health Benefits of Food Products*. The Committee would include members of the food industry, community and consumer organisations, ANZFA and New Zealand and Australian State/Territory regulatory authorities.

It will be necessary to promote the role and functioning of the Committee including procedures for making complaints and attempting resolution of alleged breaches and complaints.

A future health claims program will need to examine the resource implications for New Zealand and Australian State/Territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee.

**Education and Communication**
Education and communication strategies are an integral component of a health claims system, although guidelines are needed on the requirements for public health campaigns that support health claims, in line with ANZFA’s health claims policy. The guidelines would specify the situations, if any, in which public health campaigns would be required and the scope of such campaigns.

Food companies and associations making health claims for their products would be required as part of the *Code of Practice* to ensure that consumers can access information and education materials about the health claim within the context of a healthy diet.
ANZFA would be responsible for consumer education about food labelling as part of any health claims program, which includes information about changes to the Food Standards Code, how to read food labels and interpreting health claim messages in general.

**Evaluation and Monitoring**

Monitoring and evaluation strategies are an integral component of a health claims system. ANZFA should develop a broad evaluation plan for any health claims system covering the implementation and overall impact of the regulated approval of health claims. To ensure accountability of any health claims system, ANZFA should produce and publish an annual report on its implementation and impact including relevant performance information and findings from periodic program evaluations.

There is a need to develop guidelines on monitoring and evaluation activities required for each individual health claim, in line with ANZFA’s health claims policy. The guidelines would specify the situations, if any, in which a monitoring and evaluation strategy was required for a particular health claim and the scope and focus of such a strategy.

Monitoring and evaluation activities should link with the broader food and health monitoring systems across Australia and New Zealand.
2. Executive summary of the outcome evaluation of the folate pilot.

This report is concerned with the monitoring and evaluation component of the Folate/Neural Tube Defect (NTD) Health Claim Pilot. This is an important element in framework for the Australia New Zealand Food Authority (ANZFA) P153 to determine whether there is scope for properly substantiated health claims on food labels to deliver a public health benefit.

Health claims are an innovation in food regulation that enables elaboration of the nutrition message on a label attached to a food to include a link to a named disease. This is seen as more specific than a simple nutrition message and provides an impetus for the food industry to produce and promote products likely to benefit public health nutrition. Approval for the Folate/NTD health claim as a pilot in a wider review of health claims was granted in November 1998.

The evidence for the role of folate in the aetiology of neural tube defects is strong. This evaluation confirms that while most Australian women of child-bearing age have heard of folate, they remain unclear as to its role in the reduction of risk of NTDs. As the dietary intake of folate of most Australian women is below that recommended, means to better inform them about periconceptional folate is important.

The outcome evaluation of the Folate/NTD health claim pilot was substantially based on a series of surveys conducted prior to (1998) and after the implementation of the pilot (1999). These surveys elicited information on knowledge relating to folate and attitudes to this health claim. Information was also available from other sources including the food industry.

Of the four consumer surveys conducted (South Australian Health Monitor, Eat Well Tasmania Survey, Australian Supermarket Institute and CSIRO National Nutrition Survey) only the first three were provided in unit record format for comprehensive analysis. The summary following refers to this. Summary findings from the CSIRO National Nutrition Survey are presented in Section 4.1.
Knowledge of folate

- In 1998, the proportion of women of child-bearing age who had heard of folate was high (82%) and increased significantly in the 1999 surveys, to 89%.
- Significant and independent socio-demographic factors affecting having heard about folate are education, income level and marital status. Age, metropolitan/rural residence or occupational status were not associated with having heard of folate when adjusted for other factors.
- State of residence was a significant factor; respondents from South Australia and Western Australia, both of which have had active folate awareness campaigns, were more likely to have heard of folate, than respondents from other states.
- The same factors remained significant when the analysis of the data was restricted to women between 17 and 45 years of age.
- The percentages of women having heard of folate increased significantly over the period of the survey in Victoria, Queensland and Tasmania.

Knowledge of the folate/birth defects relationship

If folate awareness is defined as specific knowledge of the relationship between folate and birth defects, which is seen as a key for women of child-bearing age to enact appropriate behaviour change, then many fewer women are folate aware than have heard of folate. In 1998, in the subgroup of women who had heard of folate, 40% of women of childbearing age knew of the folate/birth defects association. By 1999 this had increased significantly to 46%. For all women of childbearing age the proportions were less. These changes were significantly different.

- Factors significantly associated with knowing of the folate/birth defects association were age group, education level and state of residence.
- There were significant increases in folate awareness in New South Wales, Western Australia and Tasmania over the survey period.
- In 1999, post trial, 23% of women who had heard of folate did not know why folate was important.
- About 20% of women gave vague, imprecise or inaccurate reasons for folate’s importance, citing reasons such as anaemia and related disorders and “requirement for healthy bones”.

Key results with respect to folate awareness and related knowledge are:

Sources of folate information

- Respondents who had heard of folate reported a variety of sources of information.
- Written material including newspapers and pamphlets was the most commonly cited source of folate information (43%). Other sources cited were doctors (27%), television (20%) and families and friends (13%). These percentages did not change during the survey period.
- About 25% of women indicated that folate information had encouraged them to eat foods containing folate and this was highest in the 25 to 34 years age group. This decreased significantly over the study period in the South Australian survey but increased in the Tasmanian survey.
- Over 70% of those answering the question on the preferred method of receiving the folate/birth defects message ranked education material first. Less than 15% ranked messages on a food label as first preference. These preferences did not change over time.
Messages on foods about the amount of folate or about added folate.

- In 1998 41% of women of child bearing age reported having seen messages about folate on foods and this increased significantly to 51% in 1999.
- Cereals, Ready To Eat (RTEC) or unspecified were the most commonly cited type of foods on which messages were seen. This source was cited by 15% in 1998 and 28% in 1999, a significant increase.
- Less than 1% reported having seen messages on fresh vegetables and fruit and this did not change during the survey period.
- Less than 1% reported foods that were incorrect.
- Where respondents were asked which foods contained folate (Australian Supermarket Institute survey only) 40% in 1998 and 52% in 1999 cited leafy green vegetables, a significant increase over time.
- Similarly cereal-based foods were cited by 26% and 49% as a source of folate.
- Also more respondents named *both* leafy green vegetables *and* cereal-based foods as a sources of folate, increasing from 13% at baseline to 31% at the end of the survey period.

Health claim message - linking folate to birth defects - on foods

- Only in the Australian Supermarket Institute (ASI) surveys were respondents asked if they had seen three different messages on food labels. One of these was the specific Folate Health Claim message ‘This food contains folate. A diet rich in folate may help prevent birth defects like Spina Bifida’. In 1998, 11% of women claimed to have seen this message compared to 29% in 1999.
- However in 1998 only 9% of all female respondents who had heard of folate, actually specified particular foods where the message relating folate to birth defects had been seen; this increased to 17% in 1999, a significant increase. Cereals (unspecified) and RTEC were cited in more than 85% of these responses. Some foods cited were incorrect.

Changes in food purchasing patterns

- In the ASI surveys respondents were asked if the folate food messages would affect their purchases. In 1998, 45% of women respondents stated that it would encourage them to purchase foods, increasing to 49% in 1999, a non significant change.
- Behaviour change associated with the health claim message was also investigated by estimates of changes in market share from 1998 to 1999 of RTEC and fresh food products that had a health claim. These estimates did not support the above hypothetical question as there was no evidence that the buying practices of respondents of these foods changed over the study period, the market share having decreased by 3-5% between 1998 and 1999.

Conclusions and recommendations:

The results of the surveys indicate that the proportion of people who have heard of folate and are aware of the folate/birth defects association increased over the survey period; this was more pronounced in women between the ages of 18 and 45 years.

However, while more than 80% of female respondents have heard of folate, in all cases only a minority were able to link birth defects with folate; to recall having seen foods with folate labels; to know which foods contained folate; or to be encouraged to change their purchasing behaviour.
The absence of any change in the sales of approved products also confirms there were probably no substantial changes in dietary behaviour during the survey period.

The small changes that occurred between the 1998 and 1999 surveys may reflect the influence of food label messages and other food industry actions including folate promotion associated with the pilot health claim. There were also other additional factors independent of the health claim pilot such as state health promotional campaigns on folate, distribution of folate fact sheets in doctor’s waiting rooms, or word of mouth between peers which would have contributed to such changes.

It was interesting that 64% of young females (the 17 to 24 year age group) in the ASI 1999 survey stated that they would be encouraged to purchase foods with folate messages. These women were the main shoppers in their households and may not be representative of the whole female population in this age group. However as women in this age group are at the beginning their child bearing period, they are the group for whom this knowledge has most relevance. The increase in knowledge in population groups with low folate awareness (Tasmania) and in young women suggests that the health claim did impact on difficult-to-reach population groups. Knowledge of food sources of folate increased during the survey period for both leafy green vegetables and breakfast cereals suggesting that consumers understood the importance of natural folate sources as well as fortified sources.

Education material, particularly written material was preferred for conveying the information, rather than food labelling. This confirms that the effectiveness of interventions will be greater if they are underpinned by presenting nutrition information with an educational format.

Nevertheless, our analyses show that the young, less well educated and those with low incomes are the groups that are least likely to be aware of folate, and therefore fortification of staple foods with an explicit health claim may be the most expedient way of reaching these groups.

The results highlight a limitation of the folate health claim, namely that it is relevant to only a small proportion of the population: 30% of this survey population were women of child-bearing age, less than 5% of whom are likely to be in the critical peri-conceptional period. Further, NTDs are a rare (albeit severely adverse) outcome. Hence the folate health claim lacks specificity, although it is however a method for reinforcing the message in the community and it has encouraged initiatives in the food industry.

There is justification for a folate health claim based on the strong evidence associating folate with NTDs. This evaluation has shown positive outcomes with respect to knowledge during the survey period but it is uncertain as to the extent to which they can be attributed to the folate health claim per se. There have been no identifiable changes to food purchases either self-reported by the survey respondents or in point of sale estimates.

This health claim is very specific and to extrapolate many of the findings of this evaluation to other health claims seems inappropriate.
1. REGULATION

1.1 Recommendations from previous working groups

In 1997, a working group met to discuss a regulatory framework for health claims if they were to be permitted and estimate the costs of developing and implementing a regulatory system. The Working Group based their recommendations on the following:

- The development of such a regulatory framework is based on the premise that exemptions would be provided to the current prohibition on health and related claims in the Food Standards Code, as part of the review of Standard A1(19); and
- Any regulatory framework developed would include the four major elements identified by ANZFA as essential components to aid in ensuring an effective and credible health claims system. These elements are: a food standard (or standards) to regulate claims, systems for establishing the scientific substantiation and qualifying/disqualifying criteria for each claim, monitoring and evaluation, and an education campaign.

1.1.1 Regulation of ‘generic’ claims

Three major options for a regulatory framework for generic (dietary guideline-based) health claims emerged from the discussion of the working group. These are described below:

a) The first option was a prescriptive stand alone standard which offered no leeway for the wording of claims. Monitoring and evaluation and education were not to be mandated under this option. Pre-market notification would be prescribed by the standard, as part of the monitoring and evaluation plan for health claims.

b) The second option allowed for the development of “tailor made” claims and enforcement by government enforcement agencies. It did not mandate monitoring and evaluation or education. Pre-market notification would be prescribed by the standard, as part of the monitoring and evaluation plan for health claims.

c) The third option allowed for tailor made claims and incorporated two sub-options. Both sub-options included industry signing on to agreed systems for monitoring and evaluation and education. The first sub-option depended upon pre-market notification and industry self-regulation. The second sub-option had three models based on pre-market clearance of claims. One model relied on clearance and enforcement by government enforcement agencies. The second suggested clearance by an independent expert panel with the main enforcement emphasis being on industry self regulation. The third model suggested a system that was enforceable through being mandated in toto by the Food Standards Code.

1.1.2 Regulation of ‘specific’ health claims

The working group considered that there might be four types of specific claims:

---

5 NB – this framework was subsequently modified for the folate/NTD health claim pilot to include an element on surveillance and enforcement – refer page 5 of the overview paper at appendix 1.
Two potential models for the regulation of these claims were discussed and it was acknowledged that specialist legal advice would be required to establish whether or not the second option was legally viable.

Option 1 - approval by the Australia New Zealand Food Standards Council (ANZFSC) after application to ANZFA. Under this option, specific health claims would be approved by ANZFSC on the basis of an application to ANZFA to vary the Food Standards Code. Approved claims would be listed in the Code, and would be enforced by government enforcement agencies.

Option 2 - approval by ANZFA. Under this option, claims would be approved directly by ANZFA, which would generally be a more rapid process than the process mandated under the ANZFA Act, as potentially fewer rounds of public consultation would be necessary. This option would require delegation of power by ANZFSC to ANZFA, which may not be possible (it was considered that specialist legal advice would be needed to determine the viability of this option). A list of approved claims would be available to enforcement agencies and relevant industry bodies, for reference.

### 1.1.3 Appeals and conflict resolution

The Working Group considered that the Administrative Appeals Tribunal (AAT), through its normal procedures, would handle appeals for any process involving the approval of claims by ANZFSC/ANZFA.

For the options that suggested a mechanism for approving claims, that did not involve approval by ANZFSC, the Working Group recommended that the initial point of contact for appeals or conflict resolution should be the relevant government enforcement agency (States, Territories, NZ, AQIS). Where disputes could not be resolved at this level, they might be referred to an expert panel. Any problems that could not be solved by the panel would need to be converted into an application to ANZFA and to progress through the normal regulatory process for final approval by ANZFSC. (Appeals against the ANZFA/ANZFSC process may be dealt with by the AAT.)

### 1.2 The folate pilot

#### 1.2.1 Amendment to the Food Standards Code

In the folate health claims pilot, Standard A1 (19) of the Food Standards Code was amended in November 1998 to permit the use of one claim, a folate/neural tube defect health claim on approved foods. The amendment was time-limited and due to cease on 13 February 2000.

---

6 NB – legal advice indicates that ANZFSC cannot delegate this function to ANZFA.
7 Note that this timeframe has now been extended to permit the use of the claim until 13 August 2002
The amendment:

- provides for a list of products approved to carry a folate/neural tube defect health claim in the table to subclause (e) of Standard A1(19);
- specifies criteria for foods to be eligible to make a claim and those foods that are not eligible;
- clarifies how the entry for folate in the nutrition panel should be made;
- provides guidance on the use of folate/neural tube defect claims on unpackaged foods; and
- requires an accompanying statement that it is important to maintain a varied diet.

In New Zealand, the Medicines Act was also amended in December 1998 to permit the use of a folate health claim.

As with all product labelling and advertising, health claim information in Australia must comply with the *Food Standards Code* and the provisions of the Trade Practices Act (Aust), and be truthful and not misleading. In New Zealand, health claim information must comply with the *Food Standards Code*, the *New Zealand Food Regulations*, the *New Zealand Medicines Act* and the *New Zealand Fair Trading Act*. It is the responsibility of food companies to ensure that their products meet the requirements of the regulations.

1.2.2 Co-regulatory system

For this trial the *Food Standards Code* was supported by the *Interim Code of Practice for the Communication of the Health Benefits of Food Products* and regulatory arrangements for approving foods. The combined elements of the regulatory system, together with appropriate surveillance and enforcement mechanisms make up the ‘co-regulatory system’.

1.2.3 Interim Code of Practice for the Communication of the Health Benefits of Food Products

The Interim Code of Practice is intended to supplement the *Food Standards Code*. For the folate health claim pilot, the Code of Practice includes:

- guidelines for wording folate health claims so that the claims reflect the nature of the evidence and the claim made;
- restrictions on the use of health claims during the pilot;
- additional information which must be provided by companies for consumers when communicating the health benefits of foods;
- additional information which companies using health claims are encouraged to provide for consumers; and
- data which companies must provide to ANZFA for the purposes of monitoring the pilot study.

1.2.4 Pre-market approval for individual products

For the folate health claim pilot, food companies wishing to make the health claim on or about their products must seek pre-market approval from ANZFA. Companies must provide information as specified in the *Interim Code of Practice* and complete an application form.
As part of the regulatory arrangements, companies enter into a contract with ANZFA which entitles them to use the ANZFA folate health claim logo and encourages them to produce relevant accompanying nutrition education messages and materials along with broader healthy eating advice, and participate in associated monitoring activities.

Approved products are listed in Food Standard A1(19e), which is updated regularly. The assessment and approval process takes place approximately every three months.

Food companies are able to develop their own wording and format for the folate health claim, within the constraints of the Food Standards Code and the Interim Code of Practice. Model folate health claim statements have been drafted to guide the format, content and tenor of health claims made on food products or in advertisements. The model statements are included in the Interim Code of Practice.

1.2.5 Issues arising from the process evaluation of the folate pilot

1.2.5.1 Strengths and weaknesses of the management framework for health claims

The folate pilot tested a proposed framework for the management of a health claims system. The process evaluation showed that although there were some minor issues associated with the framework, it was generally sound and workable if health claims were permitted generally, and assuming the necessary resources were available. The consultants identified seven key strengths of the framework of which points 4-6 are particularly relevant for the work of this group. The seven key strengths are given below:

1. the elements of the management framework adequately covered the main areas and issues which needed to be addressed in managing the claim;
2. it ensured that relevant partners were engaged in elements of the framework that related to their needs and issues;
3. expert committees provided a credible, independent basis for substantiating the health claim and establishing the eligibility criteria for approved foods;
4. the co-regulatory system achieved a balance between industry self-regulation and legally-binding enforcement of the Food Standards Code by government agencies;
5. the individual product approval system was administratively simple and efficient;
6. the Code of Practice Management Committee provided a mechanism for industry involvement in ensuring compliance with the Interim Code of Practice for the Communication of the Health Benefits of Food Products and maximised the efficient use of existing infrastructure; and
7. the monitoring strategy involved the collection of an appropriate range of process and short-term outcomes data, taking advantage of existing nutrition and health surveys and industry data.

The consultants identified also seven areas where the framework needed strengthening of which points 4-5 are particularly relevant for the work of this group. These seven areas are given below:

1. greater integration of the differences in the policy and industry context between Australia and New Zealand. In the pilot this resulted in much lower levels of interest and engagement of New Zealand industry in the first half of the pilot;
2. need for detailed guidelines on the requirements and standards for scientific substantiation of claims;
3. need for a public consultation process to consider the divergent views about the rationale and merits of each health claim;
4. need to better promote the role and functioning of the Code of Practice Management Committee to avoid current confusion between self-regulation and co-regulation;
5. need to clarify the interface between the responsibility of the Code of Practice Management Committee in enforcing the Code of Practice and the responsibilities of New Zealand and Australian State/Territory government agencies in enforcing the Food Standards Code;
6. sustainability of the public education campaign; and
7. resolve uncertainties in the comparability and usefulness of monitoring data in establishing the outcomes of the pilot.

1.2.5.2 Public consultation

There was strong support for the current practice of two rounds of public consultation for any proposal to vary the Food Standards Code. In relation to health claims, key informants raised a number of areas that should be considered in these public consultation processes:

- industry interest in using the health claim;
- community understanding of the issues associated with the health claim;
- public health benefits and risks that could result from allowing the health claim; and
- costs and sources of funding for administering a management framework for the health claim.

1.2.5.3 Amendments to the Food Standards Code

The process evaluation report recommended that there is a need for simple amendments to the Food Standards Code for each health claim that may be permitted covering:

- the nutritional criteria that must be met by a food or food product in order to be eligible to make the claim;
- the mandatory elements which must be covered in the claim, including a statement that it is important to maintain a varied diet; and
- approved foods could be listed in a Register referred to in the Food Standards Code.

1.2.5.4 Pre-market approval

There were divergent views on the need for pre-market approval for individual products seeking to use a health claim. Key informants from the food industry, while generally positive about the food approval process used in the pilot, said that the process introduced an unnecessary additional layer in the regulatory process with associated costs. They indicated that any pre-market approval system should be administratively simple and free-of-charge.

Key informants from other sectors supported retention of the individual product approval system as an important element in building public confidence in the system of health claims.

---

8 NB – as a Register would have no legal standing, approved foods would also need to be listed in the FSC.
Guidelines should be developed for the pre-market approval process for products wanting to make approved specific health claims.

The costs associated with a pre-market approval process could be reduced by placing the onus on applicants to seek independent regulatory and technical advice before submitting an application for pre-market approval. ANZFA’s role would be limited to processing applications. Alternatively, if a significant advisory role were considered desirable for ANZFA, then additional resources beyond the budget for the regulatory component of the pilot would be required.

1.2.5.5 Code of Practice

The process evaluation report recommended that there is a need for the Food Standards Code to be supported by a Code of Practice for the Communication of the Health Benefits of Food Products which provides best practice guidelines for companies and organisations wanting to use approved health claims. The Code of Practice would cover:

- principles and practices governing the use of health claims in general, including the pre-market approval process, general restrictions on health claims such as not quantifying the risk reduction and marketing and advertising practices; and
- appendices specific to each health claim which provide additional information on eligibility criteria for products to carry the health claim, suggested wording or model claims and guidelines for education activities and the provision of information to consumers.

1.2.5.6 Specific health claims

In relation to dealing with specific health claims, key informants indicated that the approach to regulating specific health claims, where a particular company had an exclusive captureable benefit, would be different to general health claims. For example, key informants from the food industry believed that it would be appropriate for individual product approvals to be mandatory in relation to specific health claims.

1.3 The international perspective on regulating health claims

Systems used in other countries for regulating health claims are detailed in Attachment 6.


2. SUBSTANTIATION

2.1 Recommendations from the 1997 working group

As part of the proposed system to manage health claims, a Working Group was established in 1997 to provide cost estimates for the processes involved in developing and maintaining a health claims system for its first three years of operation. A Working Subgroup was established to specifically address scientific substantiation.

This working group used the concept paper developed by the ANZFA as the basis for their discussions. They agreed with the scientific validation provision of the US health claim regulations. Such provision requires that a health claim can only be authorised when, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner consistent with generally recognised principles) there is significant scientific agreement to support the claim among qualified experts. The working group also agreed that in addition to publicly available scientific evidence, other scientific evidence might also be appropriate in the evaluation process, including that provided in confidence for commercial reasons.

The group generally agreed that in the substantiation and safety of health claims there would need to be:

- A preference for human studies;
- Appropriate control groups for comparison;
- An assessment of the potential impact of the claim on total dietary intakes of nutrients and other food constituents and the implications for a healthy diet; and
- An appropriate number of subjects included in the studies.

It was recognised that the data and evaluation requirements associated with the scientific substantiation of health claims will vary depending on the nature and type of claim.

The working group recommended the establishment of a Scientific Substantiation Task Group to develop guidelines for scientific substantiation and to prioritise claims for substantiation. The membership of the Task Group was recommended as:

- Nutritional science (x2)
- Clinical nutrition
- Nutrition epidemiology
- Nutrition toxicology
- Food Science (x2)

The working group agreed that the Task Group should have oversight of the substantiation process but where specialist advice is required other working groups could be established.
2.2 Scientific Substantiation undertaken for the purpose of the Folate/NTD Health Claims Pilot.

2.2.1 The link between folate and neural tube defects

In terms of scientifically substantiating a link between folate and neural tube defects for the purpose of the pilot, substantial work had been undertaken in Australia and internationally. In particular, the substantiation of a health claim about folate/NTDs was expedited by the 1995 National Health and Medical Research Council report *Folate Fortification* (National Health and Medical Research Council, 1995) which confirmed a link between adequate maternal intake of folate and decreased risk of neural tube defects in the newborn.

In addition to this, ANZFA convened a meeting of independent experts to review scientific advancements on the relationship between folate and neural tube defects since the NHMRC made its recommendations in 1994.

This committee confirmed that it is now well established that folate plays an important role in reducing the risk of having a baby with neural tube defects.

2.2.2 Nutritional criteria

An independent expert group determined a set of nutritional criteria for foods and food products that wish to carry a folate/neural tube defect health claim. The criteria were based on the principles that approved foods should:

- support the aims of national nutrition policy;
- contribute to the Recommended Dietary Intakes of the nutrient in the target group and be commonly consumed by the target group; and
- not be usually consumed in amounts that would mean a risk of over-consumption of the nutrient by any segment of the community.

The criteria that foods/food products had to meet in order to carry a folate/NTD health claim were as follows:

One serving of the food carrying the health claim must contain:

- at least 40 micrograms of folate; and
- foods which are not primary foods as listed in Standard A9 of the *Food Standards Code* must not contain in one serving more than:

  14 g of total fat; or
  5 g of saturated fat; or
  500 mg of sodium; or
  10 g of added sugars (or honey)

Primary foods as defined in Standard A9 are: fruit, vegetables, grains, legumes, meat, milk, yoghurt, eggs, nuts, seeds and fish.
2.2.3  Summary of Issues raised from Process Evaluation of folate pilot

Some stakeholders did not believe that the folate pilot had adequately tested the substantiation part of the proposed framework as the substantiation had been previously confirmed by the NHMRC report on folate fortification. Concern was also voiced at the lack of differentiation between natural and synthetic forms of folate in substantiating the claim.

There was broad support for the principles used by working groups in establishing eligibility criteria for products to carry a folate health claim. Industry had concerns with the nutritional validity of more than 10 g of added sugar being a disqualifying criterion. Industry also believed that the context of supporting the dietary guidelines was simplistic and imposed a rigid framework. Health claims targeting specific population groups may not relate to the dietary guidelines.

Other issues raised that related specifically to the permission of health claims generally were:

- There was broad support of the use of expert panels to adjudicate scientific evidence. However members of panels would be judged by their professional reputation and independence.
- It was recommended that guidelines be developed which specify the requirements and standards for substantiation.
- It was pointed out that the level of substantiation required for each claim is likely to vary between claims depending on the availability of credible evidence and the perceptions of the issues associated with the claim.
- Epidemiologists raised concerns about the difficulty in establishing a causal pathway between food intake and risk of disease.
- Industry sought scientific processes that were administratively simple and timely.
- Industry supported that where substantiation had already been established by a credible organisation, for example the claims allowed in the US, the process should focus on checking appropriateness for Australia and New Zealand.
- Any process needs to support public confidence in a health claims system.


A Report of this group is in Appendix 2 to this Attachment.

The group decided that ANZFA should not adopt the US health claims ‘per se’ without review in the light of new evidence and their applicability to Australia and New Zealand. The reasons for this are:

- The majority of the US health claims were reviewed in the early 90s – there have been further studies and advances in nutritional science since this time;
- The US have different emphases on importance of different dietary factors. For example, limiting intake of dietary cholesterol is considered important for decreasing total cholesterol and hence risk of CHD whereas, in Australia and New Zealand, dietary fat is considered more important;
- There are differences in the food supply and in the characteristics of the two populations; and
• If ANZFA copies the American system without its own review, ANZFA would have no basis for responding if there is a complaint.

2.4 The international perspective on substantiation of health claims

Systems used in other countries for substantiating health claims are detailed in Attachment 6.

2.5 Standards for Levels and Kinds of Evidence to Support Claims for Therapeutic Goods in Australia

Therapeutic Goods in Australia are permitted to make claims about non-prescription medicines, and in particular, complementary health-care products. Any claims made about therapeutic goods must be capable of substantiation – that is, they must be true, valid and not misleading.

2.5.1 The kinds of evidence which may support a therapeutic good claim

There are two broad types of evidence that may be used to support claims. There are:

• Scientific evidence; and
• Evidence based on traditional use of a substance or product.

2.5.1.1 Claims based on scientific evidence

A draft national standard for rating the quality of scientific evidence has been suggested by the Complementary Medicines Evaluation Committee (CMEC) (Therapeutic Goods Administration, 2000). This standard has been adapted from the “Designation of Levels of Evidence” (National Health and Medical Research Council, 1998). The various kinds of scientific evidence are rated as follows;
### Table 1: CMEC Levels of Scientific Evidence

<table>
<thead>
<tr>
<th>Level</th>
<th>Type of evidence</th>
</tr>
</thead>
</table>
| **HIGH**    | Evidence obtained from a systematic review of all relevant randomised controlled trials, for example a Cochrane review  
OR          | Evidence obtained from at least one properly designed randomised controlled (preferably multi-centre) double blind trial. It is preferable to have data from at least two independent trials, but in some cases, one large well-conducted trial may suffice. (Advice should be sought from TGA in such cases). |
| **Medium**  | Evidence obtained from well designed controlled trials without randomisation. In the case of a homeopathic preparation, evidence from well-designed, controlled homeopathic proving.  
OR          | Evidence obtained from well designed analytical studies preferably from more than one centre or research group, including epidemiological cohort and case-controlled studies.  
OR          | Evidence obtained from multiple time series with or without intervention, including population and ecological studies. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940’s) could also be regarded as this type of evidence. |
| **General** | Descriptive studies or reports of relevant expert committees. Texts, such as TGA-approved Pharmacopoeias or monographs, or other evidence based reference texts, may be included in this level. |
| **Supporting evidence** | Non-human data, such as in vitro studies and animal studies, and non-clinical studies such as biochemical, nutritional and microbiological studies. This evidence does not stand alone and may only be used in conjunction with primary evidence. |
Claims that may be made about therapeutic goods in Australia are categorised into three levels – high, medium and general. Different levels of evidence are required to support each level of claim. Within these three broad levels there are several different types of claims that may be made. These are summarised below:

### Table 2: Levels and types of claims and the evidence required to support them

<table>
<thead>
<tr>
<th>Level of Claim</th>
<th>Type of Claim</th>
<th>Evidence required to support claim</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIGH</strong></td>
<td>• Treats/cures/manages any disease/disorder.</td>
<td>High level. Registration only – evaluated by CMEC, MEC or ADEC.</td>
</tr>
<tr>
<td></td>
<td>• Prevention of any disease or disorder.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment of vitamin or mineral deficiencies.</td>
<td></td>
</tr>
<tr>
<td><strong>MEDIUM</strong></td>
<td>• Health enhancement.</td>
<td>Medium level. Sponsor must hold the evidence for Listable goods.</td>
</tr>
<tr>
<td></td>
<td>• Reduction of risk of a disease/disorder.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reduction in frequency of a discrete event.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Aids/assists in management of a named symptom/disease/disorder.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Relief of symptoms of a named disease or disorder.</td>
<td></td>
</tr>
<tr>
<td><strong>LOW</strong></td>
<td>• Health maintenance, including nutritional support.</td>
<td>General level. Sponsor must hold the evidence for Listable goods.</td>
</tr>
<tr>
<td></td>
<td>• Vitamin or mineral supplementation.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Relief of symptoms (not related to a disease or disorder).</td>
<td></td>
</tr>
</tbody>
</table>

### 2.5.1.2 Registrable disease list

There is a list of diseases/disorders about which claims may be made only after evaluation of the product and the claims through Registration of the product. Where a sponsor seeks to mention a Registrable disease in what would have otherwise been categorised as a medium or general level claim, that claim would become Registrable and the product would require Registration (that is, evaluation by the TGA with the advice of the CMEC, MEC or ADEC). These are as follows:
Table 3: The Registrable disease list (for medicines)

<table>
<thead>
<tr>
<th>Disease/disorder/action –serious manifestation of</th>
<th>Disease/disorder/action –serious manifestation of (cont’d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abortifacient action.</td>
<td>Infectious diseases, including sexually transmitted diseases, but not: • symptomatic relief of upper respiratory tract infections; • management of cold sores; • the use of condoms to prevent transmission during sexual intercourse; or • topical treatment for non genital warts.</td>
</tr>
<tr>
<td>Cardiovascular diseases but not: • the use of devices to measure parameters or control circulation locally; or • reference to assistance of peripheral circulation.</td>
<td>Insomnia, persistent.</td>
</tr>
<tr>
<td>Dental and periodontal disease but not • dental caries</td>
<td>Mental diseases, ailments or defects, including substance abuse.</td>
</tr>
<tr>
<td>Disease of joint, bone, collagen, and rheumatic disease but not • relief of symptoms; • osteoarthritis, or • calcium for the prevention of osteoporosis.</td>
<td>Metabolic disorders.</td>
</tr>
<tr>
<td>Diseases of the eye or ear likely to lead to severe impairment, blindness or deafness.</td>
<td>Musculoskeletal diseases.</td>
</tr>
<tr>
<td>Diseases of the liver, biliary system or pancreas, but not • liver tonic or live formula.</td>
<td>Neoplastic disease (all cancers).</td>
</tr>
<tr>
<td>Endocrine diseases and conditions, including diabetes and prostatic disease, but not: • pregnancy testing.</td>
<td>Nervous system diseases, but not • folate for neural tube defects.</td>
</tr>
<tr>
<td>Gastrointestinal diseases or disorders, but not • relief of symptoms.</td>
<td>Renal diseases and diseases of the genito-urinary tract.</td>
</tr>
<tr>
<td>Haematological disorders and diseases.</td>
<td>Respiratory diseases, but not: • symptomatic relief of upper respiratory tract infections.</td>
</tr>
<tr>
<td>Immune disorders and diseases.</td>
<td>Skin diseases, other than relief of symptoms by topical treatment, with a warning not to use for long periods without medical advice.</td>
</tr>
</tbody>
</table>
3. EDUCATION AND COMMUNICATION

3.1 Recommendations from the 1997 working group

In 1997, an education framework and communications effectiveness working group met to identify and describe the potential components of a coordinated national nutrition education campaign to support health claims and estimate the costs of developing and implementing such an education program. They also discussed the most effective way of communicating health messages.

The working group suggested that central to the development and implementation of an effective nutrition education campaign for a health claims system would be the formalisation of strategic alliances between key stakeholders for this campaign. Key stakeholders would include:

- national, State and Territory governments;
- peak food industry bodies including producers, manufacturers, processors and retailers;
- peak consumer bodies; and
- non-government organisations and community groups (including academics) involved in health and nutrition education.

It was envisaged that a steering council with membership from key national and state/territory stakeholders would oversee the campaign. The council would be supported by ANZFA, but would form an independent body to guide the campaign’s development and implementation. The council would need to co-operate on developing:

- the key messages, themes and events for the national campaign; and
- the most effective methods/settings/channels for the delivery of these key messages.

The working group identified the following three elements that would underpin the organisational structure for the planning and implementing of the education campaign:

1. Development of nutrition promotion and educational materials and events based on agreed themes, by all relevant public and private bodies at all levels;
2. Supportive community-based initiatives; and
3. Supporting media campaign to underpin and reinforce elements 1 and 2.

The Working Group identified three educational phases for the nutrition education campaign. These phases are identified below:

Phase 1: Increasing people’s awareness and knowledge of health claims as being credible and a useful tool for making informed food choices when used in association with dietary guideline messages.
Phase 2: Motivating people to use information on food labels, including health claims and the nutrition information panel, to help make informed food choices which would result in a healthy diet.
Phase 3: Helping people to develop skills which would facilitate dietary change.

The working group decided that the structure of the health claims message was very important to the effective communication of the message. They believed that:
• the claims need to be as specific as possible to increase the chance of their uptake by the community;
• consumers need sufficient information to enable them to make an informed decision but there may be a need to avoid some of the wordy types of claims as used in USA;
• one model for health claims is that claims could consist of:
  - a short attention grabbing component;
  - extra information elsewhere on the label relating the claim to diet, nutrition and/or lifestyle, to provide context; and
  - a larger body of indirect information gained from magazines, advertisements, media, telephone information services and consumer information brochures;
• another model is that the majority of the necessary information should be contained within the one claim;
• health claims need to be inclusive in the way they are worded so as not to alienate particular sub-groups of the population.

The working group made the following points about the strategy for devising and implementing health claims:

• a strategy for the wording of health claims is needed which builds on consumer understanding, on what they believe and who they trust;
• consumers already have a background of nutrition knowledge but there will need to be a long term process of sustained consumer education so that increasingly more people will understand, use and benefit from health claims;
• it was suggested that generic claims be introduced first with set wording, then consideration could be given to industry proposals for other similar consistent claims based on application to and approval by ANZFA.
• there needs to be provision for product specific health claims developed for specific foods (but also based on application to, and approval by, ANZFA); and
• there is a need to determine whether a "disease prevention" or "health promotion" orientation for messages is the best mechanism to ensure consumer understanding of health claims.

The following points were made with respect to the development of health claim messages:

• many industry people are experts in knowing how to design labels to appeal to consumers - most new food products are carefully tested before launch and this resource should be tapped into;
• there is also a large field of research on how consumers respond to printed messages, in particular in health-related areas:
  - research of this type should be incorporated into the development and trialling of any health claims
  - focus group testing would be necessary to develop the claims
  - it was felt that some consistency in the tone/presentation of health claims was essential and would aid consumer awareness
  - overseas research exists on consumer reaction to health claims but this may not be completely applicable to consumers in Australia/New Zealand
3.2 The folate pilot

A broad range of education and communication activities were undertaken as part of the folate health claim pilot. These activities were coordinated by ANZFA and undertaken in conjunction with a range of partners including community groups and non-government organisations, health professionals and professional associations, food retail companies, food manufacturers and producers, and State Government Health Departments (through the nutrition network SIGNAL).

A Working Group on Education and Communication met in early 1998 to develop an education and communication framework that would effectively support a folate health claim. The working group articulated four principles that underpin the framework:

- a health claim about folate needs to be placed within a total dietary context;
- there should be consistency in terminology within the educational materials when referring to the nutrient, the disease and the target group;
- the educational framework to support a health claim for folate should be sustainable; and
- women of the child bearing age will be the primary target group for intervention and health professionals should be the secondary target group.

The working group developed guidelines for the development of education and communication resources. They also developed an implementation strategy. The main education messages in the folate pilot focused on awareness and knowledge about the role of folate in the diet, food sources of folate, and the link between folate and neural tube defects.

The following education strategies accompanied the folate pilot: (ARTD Management and Research Consultants, 1999).

3.2.1 Development of materials by ANZFA

ANZFA developed a brochure, poster, fact sheet and tear-off-pad which were tested using focus groups. These materials target women of child-bearing age.

3.2.2 Development of partnerships with health and community organisations

ANZFA formed partnerships with a range of health and community organisations. In August 1998, representatives of these organisations met with ANZFA to review the range of activities they could undertake and discuss ways they could work together.

3.2.3 Health and community organisations disseminated the ANZFA education materials

- Copies of pamphlets, posters and fact sheets were distributed to consumers by the Australian Nutrition Foundation, Australian Spina Bifida and Hydrocephalus Association and 20 Family Planning Australia centres throughout Australia (except SA);
- A copy of the poster, a tear-off information pad and fact sheet were distributed to every general practitioner in Australia via the Royal Australian College of General Practitioners;
• Home economics professionals and all high schools in Australia received information on the campaign via the Home Economics Institute of Australia;
• Folate shelf-talkers and fact-sheets were displayed in Self Care Pharmacies (1500). This was organised through the Pharmaceutical Society of Australia (PSA). An additional 500 copies have been sold to other pharmacists. This material complements existing pharmacy folate promotional materials produced by the PSA in 1997; and,
• A copy of the fact sheet was also distributed to all its members by the Dietitians Association of Australia.

The Australian Spina Bifida and Hydrocephalus Association in partnership with ANZFA set up a 1300 telephone service to answer consumer enquiries about folate and neural tube defects. This telephone number was listed on the education pamphlet and poster. The Australian Nutrition Foundation and the New Zealand Nutrition Foundation also provided consumer information services and were listed on this material as places where consumers may call to get further information.

In addition to these strategies, a range of professional associations published articles in their newsletters and journals to inform their members about the pilot. These organisations included the Home Economics Institute of Australia, the Dietitians Association of Australia, Country Women’s Association, Australian College of Midwives, Australian Lactation Consultants Association, Maternity Alliance, Northcott Society, the Australian Nutrition Foundation, the Australian Spina Bifida and Hydrocephalus Association, and the Pharmacy Guild of Australia.

The public health nutrition network SIGNAL was used to inform government public health agencies about the pilot and accompanying education activities.

In New Zealand a number of activities were also undertaken. The folate brochure was modified for New Zealand contact addresses. The brochure was not officially distributed although 5 cartons were sent to the New Zealand CCS for distribution through their branches. Wider distribution was not made as it was decided that it best coincide with the release of product with the folate health claim on the market.

Linkages were made with a range of health and community organisations. The ANZFA fact sheet was modified for the New Zealand market and support in the form of logo endorsement was gained from a significant number of organisations.

Consumer information services on folate and neural tube defects were made available through an 0800 number with CCS and with the New Zealand Nutrition Foundation.

Articles were published in the newsletter of the New Zealand Dietetic Association and presentations on the folate health claim pilot were made at a number of national conferences.

3.2.4 Partnerships with the retail sector

Coles supermarkets nationally and Woolworths supermarkets in NSW, Queensland, SA, NT and the ACT, undertook in-store promotions during February and March 1999. Point-of-sale materials were displayed and educational materials were available for customers. ANZFA supplied the education materials with the supermarket chains funding the display and distribution process.
Shelf wobblers displaying a folate health claim were produced for approved fresh produce. In this way, these products could use the health claim as part of their advertising in participating supermarkets.

### 3.2.5 National Healthy Eating Logo

ANZFA developed a Folate Health Claims logo for use in conjunction with a folate health claim on approved food products and associated education and promotion materials developed by partner groups. The logo was intended to give credibility to folate health claims and associated materials. Approved products were not required to use the logo but did so on a voluntary basis.

### 3.2.6 Public relations strategy

ANZFA and other partner organisations used a number of public relations opportunities to gain media exposure for the education strategy. Media events coincided with key stages of the pilot such as the National Folate Awareness Day (27 August 1998) and the day health claims became legal in Australia (19 November 1998). When use of the folate/neural tube defect claim became legal in Australia it was officially launched by the Parliamentary Secretary to the Minister for Health and Family Services. A further Australian media event took place on 23 February 1999 in conjunction with the start of folate promotion by the retail sector. Media releases were distributed nationally over the period of the pilot.

### 3.2.7 Links with existing public health folate strategies

Nutrition education strategies, which focused on the promotion of folate to prevent neural tube defects, have been run by both government, non-government and industry organisations over the past decade. Where possible, ANZFA established links with the groups implementing folate strategies to ensure that educational material was consistent and that information networks were used.

### 3.2.8 Links with food industry (product-related) education activities

*An Interim Code of Practice for the communication of health benefits of food products* was developed and provided guidelines for organisations undertaking education and communication activities which ensured that appropriate messages were communicated to consumers. Food companies supported health claims they made about their products with ongoing promotional and educational material which described how health claims should be used in the context of a balanced diet and as a part of comprehensive health management and healthy lifestyle advice.

### 3.2.9 Communications effectiveness

Communication effectiveness was addressed as part of the folate health claim pilot. The folate health claim message, the ANZFA endorsed logo and the various pamphlets, shelf wobblers etc that were used in the folate pilot were tested using focus groups for appropriateness, clarity, effectiveness and interpretation. They were then adapted based upon the outcome of these focus groups.

The findings from the folate focus groups were (Van Duyn, 1998):
• In terms of wording, one nutrient term should be mandated. There was no consensus in Australia and New Zealand as to whether it should be folate or folic acid.
• Specificity for women of child bearing age on the front of a food package was seen as inappropriate narrowing of the market. However it was seen as necessary on the back or at the side of the pack.
• Either a positive or negative message can be conveyed for a folate health claim. There was no consensus between the two countries.
• A qualifier 'may' or 'can' is required. The health claim is misleading without a qualifier.
• The proportion of recommended daily intake per serving is desirable in the nutrition information panel (NIP).
• Consumers liked the statement "Food variety optimises health" but preferred the information graphically via a Food Pyramid.
• There was a strong preference for a creditable authority to verify the claim and strong preference for a linking of ANZFA with a symbol or graphic. Although consumers did not know about ANZFA they felt it could be a source of authority.
• Consumers preferred endorsement from friends whose opinions they valued and from their doctors.
• Consumers preferred a short claim on the front of the pack but it must be accompanied with the words "See back of pack" or "See side of pack" as information on the back or side of the pack was wanted by consumers.

3.3 Summary of issues raised from the process evaluation of the folate pilot

Although key informants broadly agreed that education and communication strategies were an important part of the management framework, they raised a number of issues to be considered if health claims are permitted more generally (ARTD Management and Research Consultants, 1999).

3.3.1 Need for public health education campaigns

Some informants from the public health sector strongly supported well-resourced public education campaigns for each health claim, in order to support the achievement of anticipated public health benefits. In addition, public education campaigns were perceived as being needed to contextualise a health claim as some public health informants felt that health claims have the potential to distort an individuals diet. Only a limited education message can be communicated on a food label.

In contrast, key informants from the food industry did not support mandatory public education campaigns for each health claim. While supportive of the Code of Practice guidelines, which encouraged food companies to produce education materials to provide additional nutritional information to their customers, the food industry was concerned about the costs and diversion of resources from the regulatory issues, which they perceived as the central focus of a health claims system.

Key informants from the food industry saw their role as providing product-related consumer information, which uses messages consistent with government public health priorities. In this way, if public health agencies chose to undertake a public education campaign that took advantage of a particular health claim, food companies would tailor their education materials to support the campaign messages.
3.3.2 Sustainability of public health education campaigns

Key informants from the public health sector indicated that if public health education campaigns are required for future permitted health claims, then considerable resources would be needed to ensure such campaigns deliver a sustainable impact on the target group.

Informants commented that resources for public education were likely to be fixed, with the consequence that multiple health claims would result in ‘tokenistic’ campaigns with limited impacts. It was felt that multiple campaigns for multiple health claims were unlikely to attract commitment from the SIGNAL network and its New Zealand and Australian public health nutrition agency members, without integration into the Eat Well Australia Strategy that is currently being developed.

3.3.3 ANZFA’s education role

Key informants from the public health sector indicated that the appropriate education role for ANZFA in a future health claims system, was to focus on consumer education about food labelling rather than public health education campaigns.

3.3.4 Need for product-related information by food companies

There was strong support across all sectors for food industry education activities associated with the use of a health claim. Food companies participating in the pilot indicated that it was appropriate that the Code of Practice for using health claims encourages companies to provide consumers of their products with access to additional information about the health claim within the context of a healthy diet.

3.4 Recommendations from the 2000 Expert Advisory Group on Education and Communication Strategies to Accompany Health Claims

A report of the Expert Advisory Group on Education and Communication Strategies to Accompany Health Claims is at Appendix 3 to this Attachment.

The group felt that there are a number of potential risks associate with health claims. These are:

- may encourage trade-offs: consumers buy a low fat biscuit but continue to have other high fat items in the diet e.g. ice-cream;
- may lead to diet distortions: consumers limit the variety in their diet as they believe they can get all they need from one product and/or the consumer believes can get all of the nutrients they need from processed foods and eliminate fruit and vegetables;
- may promote consumer anxiety;
- may place greater emphasis on diet than on other factors e.g. lifestyle, smoking; and
- may lead to micronutrient deficiencies: too much of one nutrient can create deficiency in another.

Whether or not a health claim has the capacity to distort an individual’s diet is also dependent on the following contributing factors:
• susceptibility
• severity;
• benefits;
• barriers;
• self-efficacy;
• stage of change individual is at; and
• cues to action.

The group considered that education could not just be limited to the design and distribution of pamphlets. There would be a need to link to existing education systems, such as:

• education programs in schools, training colleges and universities;
• continuing education programs of health professionals – nurses, doctors, dietitians;
• popular media – TV, internet;
• existing media programs;

The group considered that education must be tailored to both countries and there may need to be different messages/initiatives in New Zealand to Australia. It was also recognised that these education initiatives may not be very appropriate for the minority population in both Australia and New Zealand, that is Maori, Pacific Islanders (New Zealand) and Aboriginals and Torres Strait Islanders (Australia) and this would also require special consideration.

The group believed that consumer testing of the understanding of each health claim was essential. This would be an important part of preventing consumer harm; testing their understandings/misunderstandings and likely changes in consumer behaviour. They also felt that food companies had to be given some flexibility in the wording of their claims. Therefore they supported Option 3, mandating certain required elements of the claim, with focus group testing to determine the mandated elements.

This position may be able to be reviewed after consumer testing has been carried out on the first few claims, to see if there are common elements that mean principles could be developed from which an expert group could develop the mandated elements. The importance of a range of target groups and sufficient numbers for the consumer testing was emphasised. It would also need to be carried out in both Australia and New Zealand. A range of quantitative and qualitative methods could be used. Focus groups would need to be used for the development of educational materials.

3.4.1 A logo for food products carrying approved health claims.

In the folate pilot, an ANZFA endorsed logo was designed for products approved by ANZFA to carry the health claim. The group considered that a uniform logo should be designed for authorised health claims. The group was unanimous that it should be ANZFA who was the endorser. However, they did not feel ANZFA could just take out the word folate from the folate pilot logo and use this logo. It was felt that the word “endorsed” should not be on the logo, especially if there was not product-by-product approval. The logo would need to be tested in focus groups.
Focus group testing on the folate logo suggested that some education on who ANZFA is also necessary if an ANZFA endorsed logo was to be used (Rush Social Research Agency, 1998). The group supported this and commented this could be part of the wider education campaign for health claims and ANZFA’s priorities generally.

The group believed that there is a need to ensure that consumers understand health claims and they are not distorting diets. Focus groups should be carried out after health claims are widely available on the shelves to provide an indication of consumer interpretation. There may be a need to modify the mandated elements of the claims in light of this research. It may also be necessary to mandate the wording of the claim if there seems to be consumer confusion over the wording of the claims. This would need to be done before national surveys on consumer knowledge, attitudes and behaviour.

3.5 The role SIGNAL members see SIGNAL playing in Education and Communication Strategies to Accompany Health Claims

A report from the ANZFA workshop on health claims held with SIGNAL is at Appendix 5 to this Attachment.

3.5.1 Prerequisites and Responsibility

Most SIGNAL members felt that approval of health claims should be contingent on accompanying education. There was a range of views expressed on who should be paying for and responsible for educating consumers. This depended on the type of claim and the aspect, e.g. ANZFA is responsible for educating about health claims and labelling generally, government may pay for generic claims and industry for specific claims.

3.5.2 Management Strategy

There is a need to develop a set of principles for best practice education acknowledging that the public sector is interested in health promotion outcomes while the private sector is interested in marketing or profit outcomes.

SIGNAL could formulate the guidelines and oversee the development of education materials while industry funds and implements the education programs.

3.5.3 SIGNAL's role

Concern was expressed at the limitations of SIGNAL in terms of time and resources to take an active role.

Participants felt that SIGNAL needs to keep within its own priorities incorporating health claims education where appropriate and convenient, e.g. as part of Eat Well Australia and SIGNAL campaigns such as Fruit & Vegetables. SIGNAL indicated that it still needs to formulate its fall back minimum stand on what it would be prepared to do, regarding education.
3.6 International research on communications effectiveness

3.6.1 The United States

Health Claims have been allowed in the US since 1993. Currently there are 12 approved health claims. Two major studies have been carried out by the Centre for Food and Applied Nutrition, FDA (Levy, 1995; Levy, 1997). They found that:

- If health claims are to be used on products, claims should be stripped of as much details, verbiage, and qualifications as possible and turned into “reminders”. As “reminders”, they should reference a credible authority and refer the consumer to more complete nutrition information on the back of the product. As “reminders” they are effectively equivalent to nutrient content claims.
- Consumers viewed health claims on certain products (e.g. lasagne as opposed to yoghurt) with suspicion.
- Overall, health claims were no more compelling than nutrient claims.
- Short claims were generally more effective than long messages.
- Splitting messages between the front and back label made little difference.
- Health claims increased the likelihood that respondents would repeat or “playback” the key message points from the health claim when asked about product health benefits.
- Consumers were less likely to acquire other relevant health information from the product label as a consequence of seeing a health claim on the front of the package.
- Health claims also lead consumers to believe that the product was likely to have health effects that it did not have.

3.6.2 Canadian Research

Canada is presently considering adopting the generic health claims that are authorised in the US and developing a regulatory approach for a Canadian Health Claims system. Focus groups were conducted to test consumer understanding of health claims (National Institute of Nutrition, 1999). It was found that:

- Overall, 92% of respondents said they perceived health claims on foods as fairly useful or very useful.
- The focus groups preferred language that was positive and pro-active rather than negative. For example, words such as to “promote health” were preferred over “to prevent illness”.
- The US claims received a high approval rating for clarity and understanding.
- Canadians perceived a claim on a product with an endorsement from a health organisation as more credible.
- Canadians preferred consistent wording among claims with “limited flexibility” for manufacturers.
- The ideal message would include a short, eye catching statement on the front panel, supported by additional information on the side or back.
4. MONITORING

4.1 Recommendations from the 1997 working group

In 1997, a monitoring and evaluation working group met to estimate the costs of developing and implementing a monitoring and evaluation program for health claims. This required the agreement of a strategy for effectively assessing the public health and safety impact of a health claims system. The working group decided that in order to examine the impact of a regulatory change to permit health claims, the following information would need to be collected:

4.1.1 The sales and composition of products carrying health claims

It would be necessary to collect information on market changes in the types and numbers of foods with health claims. This process requires information on the following:

- the number of new and reformulated products developed to take advantage of an ability to make a health claim;
- the number of existing products with label changes to take advantage of an ability to make a health claim; and
- market penetration of foods containing a health claim.

4.1.2 Consumer data

It would be necessary to collect information on consumer awareness and understanding of health claims on products. Consumer research should consider:

- demographic data on consumers' purchasing foods with a health claim;
- consumers' awareness and understanding of generic claims, i.e., the link between diet and health and disease;
- changes in consumers' food choice behaviour as a result of generic claims;
- consumers' awareness and understanding of specific claims, i.e., the link between consuming a specific product, diet and health and disease;
- changes in consumers' food choice behaviour as a result of specific claims;
- consumers' ability to gain useful information from food labels and to relate these to health claims; and
- identification of possible safety issues in vulnerable consumer groups.

4.1.3 Shifts in the food consumption and supply

To ascertain if health claims are having an effect on food composition and supply, it would be necessary to undertake the following analyses:

- changes in food composition over time within product categories, e.g., an increase in the dietary fibre content of breakfast cereals or a reduction in the sodium levels in breads; and
- changes in the food supply relating to the amounts of different foods available and consumed.

The working group provided recommendations as to where this information could be obtained:
4.1.4 Product data

- register of all products in the marketplace that use a generic or specific health claim;
- AC Nielsen Scantrack Service sales data. This provides volume sales information broken down by state only and is provided by retailers.

4.1.5 Consumer data

- focus groups to identify issues, concerns and potentially vulnerable groups;
- quantitative assessment of consumers' awareness, understanding and behaviour related to generic and specific health claims and food label information. Demographic details are also required. This is required initially as a benchmark and after a period of 2 - 3 years post regulation. Expert advice is required regarding appropriate questions, sample size and method of interview;
- use of data from national nutrition surveys to assess changes in food and nutrient intake;
- other existing or proposed survey work at a State/Commonwealth government level and by industry should be considered in relation to the monitoring of health claims;
- standard indicator questions to be developed for use in population-based health surveys conducted at State and local level and in surveys of special groups (e.g., vulnerable groups) which can be collated to contribute to the overall evaluation of the impact of health claims. The Working Group suggested that the Australian Institute of Health and Welfare (AIHW) could have an active role in this area. In New Zealand, Otago and Massey Universities may be appropriate partners.

4.1.6 Shifts in food composition and supply

- ABS Apparent Consumption data.

4.2 The folate pilot

In 1998, a working group met to discuss a monitoring and evaluation strategy for the proposed folate pilot. The working group recommended that information be collected with respect to the following:

- changes in population (target and non-target groups) awareness and knowledge of foods rich in folate, the link between folate (from foods and supplements) and neural tube defects (NTDs), and awareness of the folate/NTD health claim on food labels and in associated advertising;
- changes in behavioural intention to eat more folate-rich foods and/or take folate supplements in women of childbearing age; and
- changes in product availability, product sales and price - for foods naturally rich in folate and folate-fortified foods, and for key indicator non-folate containing foods.

The working group concluded that monitoring and evaluation of sociocultural aspects of the pilot needed to be sufficiently comprehensive to be able to determine potential positive and negative outcomes. The positive outcomes could include:
desirable changes in consumer awareness, knowledge, attitudes, and intended practices/behaviours with respect to food label usage and food purchasing patterns; and positive consumer perceptions of health claims.

Negative outcomes could include:

- misinterpretation of health claims or associated promotion or advertising;
- undesirable skewing of the diet of the target group;
- undesirable dietary changes by non-target groups; and
- the creation of anxiety in some consumers by the use of health claims and supporting promotion and education.

4.2.1 Methodology in the folate pilot

The following methodology for monitoring and evaluation was used in the folate pilot (ARTD Management and Research Consultants, 1999)

4.2.1.1 Product data.

Participating companies were required by the *Interim Code of Practice for the Communication of the Health Benefits of Food Products* to record data on claims made on food products and in promotional materials and advertising campaigns, and to this data was made available to ANZFA. Data was collected on:

- number of products carrying a folate/NTD health claim;
- number of products using nutrition messages or nutrient claims about folate, but not a folate/NTD health claim;
- wording and presentation of claims;
- number and scope of folate/NTD related health education materials, advertisements and other activities across all sectors;
- number of consumers using the consumer information services (community and industry) and the types of enquiries;
- extent of involvement of different stakeholder groups;
- extent of media exposure about folate health claims; and,
- cost of education campaign materials and their distribution.

ANZFA also coordinated the collection of a range of data about short-term changes in consumers’ knowledge, attitudes and behaviour as a result of the folate health claim including:

- awareness and knowledge of foods rich in folate, links between folate rich foods and neural tube defects and the folate health claim by both the target and non-target group population;
- behavioural intention to eat more folate rich foods and or consumption of folate rich foods by both the target group and the rest of the population; and,
- consumer perceptions and attitudes to health claims.

ANZFA collected this information by negotiating the inclusion of a series of questions on folate and attitudes to health claims in a number of nutrition and health surveys including:
CSIRO Dietary Survey. A self-completed written survey of a total of 10,000 people. In order to provide data on the folate claim pilot the CSIRO surveyed 5,000 people in September 1998 and another 5,000 in May/June 1999.

Australian Supermarket Institute Consumer Monitor Survey. A capital city survey which samples a total of 1,000 people and is administered by telephone. This was conducted in July 1998. This was not repeated in 1999 but ANZFA funded the collection of the same questions from a demographically similar sample in October/November 1999.

Tasmanian Eat Well Survey. This telephone survey of 800 people living in Tasmania was conducted in November 1998 and repeated in November of 1999.

South Australian Health Monitor. This is a telephone survey of at least 2000 people living in South Australia. Information was collected in April 1999 and again in November 1999.

Kelloggs has conducted market research to monitor the impact of their product promotion associated with the folate health. They conducted nationwide telephone surveys in July 1998 (in Australia), November 1998 (in Australia and New Zealand) and April 1999 (in Australia and New Zealand) of levels of awareness of folate amongst women between the ages of 18 and 45 years.

Otago University, New Zealand has conducted a baseline survey on folate status, knowledge and behaviour about folate among populations at risk of inadequate or excess consumption of folate containing foods; women of child-bearing age, adolescents and older people. There are no plans to repeat this survey at this stage.

In addition, monitoring data on short-term changes in the food supply were also be collected including:

- nutritional profile of products using the claim;
- changes in product availability, sales and prices for folate rich foods; and,
- changes in product composition with respect to folate (especially folate fortified products).

The food retail sector also provided pre and post health claim pilot sales data obtained through electronic tracking of sales.

4.2.2 Recommendations from the process evaluation report

The process evaluation report identified that monitoring and evaluation strategies are an integral part of a health claims system. It suggested that (ARTD Management and Research Consultants, 1999):

1. ANZFA should develop a program evaluation plan for the health claims program covering the implementation and overall impact of the regulated approval of health claims, with performance indicators for monitoring the implementation and overall impact of the health claims program and strategies for the collection of performance data;
2. ANZFA should also plan for periodic independent evaluations of the health claims program to allow comprehensive assessments of its implementation and impact, including the overall impact of health claims as a tool to educate consumers about nutrition;
3. To ensure accountability of a health claims program, ANZFA should produce and publish an annual report on the implementation and impact of the health claims program including relevant performance information and findings from periodic program evaluations;

4. There was a need to develop guidelines on monitoring and evaluation activities required for each individual health claim, in line with ANZFA’s health claims policy. The guidelines would specify the situations, if any, in which a monitoring and evaluation strategy was required for a particular health claim and the scope and focus of such a strategy; and

5. Monitoring and evaluation activities should link with the broader food and health monitoring systems across Australia and New Zealand.

4.2.3 Recommendations from the outcome evaluation report of the folate pilot

A number of issues came up in the outcome evaluation of the folate pilot that should be considered for the implications of monitoring health claims more generally:

1. There is a need to monitor uptake of the claim and ensure that the claim is being widely used on a range of products for a reasonable period of time before monitoring changes in consumer knowledge, attitudes and behaviours and any changes sales of the products carrying the claim.

2. It was difficult to attribute changes in consumer knowledge, attitudes and behaviour and product sales solely to a health claim, as there are so many other issues impacting on behaviour. This is particularly so if there are extensive education campaigns accompanying the introduction of the health claim or promotional campaigns of products by industry.

3. In relation to monitoring of changes in consumer knowledge, attitudes and behaviour, a number of different surveys were used to collect this data and therefore there were differences in the survey methods. This could potentially occur again in the future if ANZFA continues to use opportunistic data sources. The main differences between surveys were:

   • Sampling frames. Differences in age, rural-urban mix, socio-economic status etc.
   • Methods of data collection. For example, CATI verses mailed questionnaire.
   • Questionnaire format. Differences in phrasing of questions, question order and length of interview.
   • Timing of surveys.
   • Differences in format of data files. For example, data was provided either in Excel, SPSS, unit records or cross tabulations of outcomes by key socio-demographic variables.

   In future, gaining useful, unbiased information would be greatly facilitated by ensuring consistency in survey methods, where data is available from a number of surveys. Collaboration with States on the issue of consistency between these surveys is being undertaken as part of the Eat Well Australia Initiative.

4. For the folate pilot, retail scanning data was obtained based on scan data for processed foods. This data is collected and collated monthly, so it was possible to obtain sales data for the same months in 1998 and 1999 in order to adjust for seasonal variation in sales.
5. This data was given to ANZFA free of charge. With future claims, particularly if ANZFA is requiring a lot of data frequently, it may not be possible to get this data without payment. This data is very expensive to obtain.

6. For the folate pilot, fresh fruit and vegetable data was only available from a major supermarket chain, as at that time, there was no national scan system in place for fresh fruit and vegetables. There of course would be major alternative sources of purchase for this group. National scan data is now available for fresh fruit and vegetables, but once again, at considerable expense.

7. In future, monitoring data must be obtained from New Zealand as well as Australia.

4.3 Recommendations from the 2000 expert advisory group on monitoring and evaluation strategies to accompany health claims

A report of this group is given in Appendix 4 of this Attachment.

The group agreed that the type of monitoring that needs to occur would differ depending on the answer to the fundamental question posed in the process evaluation report: whether health claims were viewed as a regulatory mechanism within which food companies could make balanced, substantiated claims or whether health claims were seen as a public health intervention. In the case of regulatory mechanism, a minimum level of monitoring which related to health protection may suffice, but in the case of a public health intervention tool, the scope of monitoring would need to be more comprehensive.

The group considered the minimum amount of monitoring that should be undertaken to be the minimum that could be done to check that health claims were not causing harm, since the primary function of ANZFA in developing and varying food standards is the protection of public health and safety.

The group considered it essential that there are random audits to check that the product actually contains the minimum/maximum amount of the claimed nutrients. However, the group wanted it noted that there were logistic issues with this. For example, a reliable method for measuring folate in New Zealand has not been established and analysis is very expensive.

4.3.1 How the monitoring of individual claims should be carried out

The group were presented with the following options:

Option 1: National surveys designed to evaluate the impact of health claims on consumer knowledge, attitudes and behaviour.

The group felt this option was not feasible if the aim was to present consumer harm, due to its large cost. If the aim was public health improvement this would be the preferred option.

Option 2: Incorporation of questions on health claims into national surveys.

This would be the preferred option if the minimalist approach was taken, to prevent harm. The concern was raised that there is only limited capacity to add questions to national surveys and it was possible that all the space available for inclusion of questions on nutrition may be taken up by health claims which would not be desirable.
**Option 3:** Incorporation of questions on health claims into current state surveys and New Zealand.

This option was not discussed by the group.

**Option 4:** No nationally coordinated system for monitoring and evaluating health claims. Any monitoring to be carried out by food companies.

The group were unanimous we could not just leave the monitoring to industry.

**Option 5:** No system for monitoring health claims.

This option was opposed by the group.

### 4.3.2 General comments

It was pointed out that if there were a large number of claims, and questions in detail on each, there could be too many questions on claims in the survey and people could answer as they think they should rather than honestly. The group suggested that there would be a need to limit the questions asked and change the order in which the questions appeared in the survey. All claims would not be able to be monitored in every survey. It was suggested that the monitoring may not need to be ongoing – it may be possible to monitor consumer knowledge, attitudes and behaviour in relation to a specific claim only once. There would also need to be a group convened to decide on how extensive the monitoring should be for each claim. There would be a need for more in depth questions if the aim was to monitor public health improvement.

### 4.3.3 Industry data

In the folate pilot, a form was filled in by all food companies participating in the pilot to provide information about sales and composition of their product. This would only be useful in a health claims system as a whole if product-by-product approval was continued.

It was pointed out that in New Zealand there is a therapeutic database used to track fortification. It is a voluntary system where food companies notify of any changes to their products. Such a register could be extended to include health claims or a separate database set up. The problem with a voluntary register is ensuring all products are listed. Therefore, there would need to be some spot checking in supermarkets of that register. The group suggested a system of random post-market audits. As part of this, there would be a check that products carrying a health claim were listed, as well as a check on their nutrient composition and labelling.

### 4.3.4 The roles and responsibilities in monitoring the effectiveness of claims.

The group felt that monitoring could not be left to individual food companies. However food companies needed to contribute to the funding of monitoring health claims.
4.3.5 Monitoring the system as a whole

The group suggested that there needs to be an annual report on the impact of health claims, pulling together the monitoring on each claim. It was felt that an independent group should do this report. In a sense it will be an audit of what ANZFA has permitted, and therefore ANZFA should not undertake to do this. However, ANZFA could coordinate the data collection process and pass on this information to whoever was carrying out the monitoring process. It was suggested that if a database was set up in the first year it may decrease the work in consecutive years.

The group felt there was also a need to monitor the effect of the system as a whole. Particular questions to be answered are:

- whether health claims have contributed to the medicalisation of the food supply;
- the profile of medical verses public health type messages;
- the impact of the change in policy on public health and the integrity of the food regulation system. For example, allowing orange juice to be fortified with calcium, when the general recommendation was to eat low fat products for healthy bones; and
- whether allowing health claims leads to consumer confusion and anxiety and therefore created scepticism about public health initiatives?;
- whether people change their eating patterns in undesirable ways;
- whether health claims use up time and resources that should be devoted to other public health initiatives?;
- interpretative food regulatory system – the cost verses the overall benefit of health claim in dollars.

In order to look at these questions, baselines need to be established before health claims are permitted. There then needs to be a broad evaluation 5 years after claims are introduced.

4.3.6 What SIGNAL’s members see the role of SIGNAL to be in monitoring and evaluation strategies to accompany health claims

A report from the ANZFA workshop on health claims held with SIGNAL is at Attachment 5 of this Appendix.

SIGNAL could provide advice on management of the process and could oversee the exercise. This might mean representation on a management committee and opportunistic involvement.

4.4 The National Food and Nutrition Monitoring Unit

The Australian Food and Nutrition Monitoring Unit was established in late 1998 to develop and manage a nationally coordinated food and nutrition monitoring system for Australia. The project was commissioned by the Commonwealth Department of Health and Aged Care (DHAC) in 1998 and is an initiative of the Australian National Food and Nutrition Policy, launched in 1992.
The aim of the project is to promote the coordination of existing food and nutrition monitoring activities and to address major gaps and deficiencies in information needed for the development and evaluation of public health and nutrition policies and programs (National Food and Nutrition Monitoring and Surveillance Unit, 1999).

The immediate aims of the project are to:

- promote the coordination of existing food and nutrition monitoring activities;
- monitor and report on trends in public health nutrition;
- link nutritional status with other health outcomes;
- help develop and coordinate national data collections and databases related to nutrition;
- promote uniformity in statistical standards, methods and definitions;
- address major gaps and deficiencies in existing nutrition monitoring systems; and
- inform national public health nutrition policy.

Tasks to be undertaken as part of the project include:

- development of a detailed work program for implementing a national food and nutrition monitoring and surveillance system;
- consultation and collaboration with relevant agencies in the development and implementation of the work program, including relevant state and territory agencies, the food industry and national organisations such as the Australian Institute of Health and Welfare (AIHW), the Australian Bureau of Statistics and the Australian New Zealand Food Authority;
- facilitating regular liaison between relevant agencies; and
- establishing links with agencies responsible for collecting, collating and or maintaining related national data collections, such as those for diabetes, cardiovascular disease and physical activity, being undertaken by AIHW.

In addition, the following specific priority tasks are included in the work program:

- evaluating the effectiveness of voluntary fortification of selected foods with folate as a means of preventing neural tube defects (including spina bifida);
- developing nationally agreed statistical practices for measuring the prevalence and duration of breastfeeding in Australia;
- monitoring relevant aspects of the implementation of the National Public Health Nutrition Strategy;
- preparation of guidelines for using and comparing existing national dietary survey data;
- specification of standard questions and guidelines for measuring selected food habits in the Australian population; and
- conducting specific analyses, as requested by the Commonwealth Department of Health and Aged Care, of data from the 1995 National Nutrition Survey.
4.5 Monitoring strategies in the United States

- The Nutrition Labeling and Education Act (NLEA), passed by Congress in November 1990, led to the most far-reaching changes in food labelling since the Food, Drug and Cosmetic Act of 1934. The new regulations, governing the content and format of food labels on virtually all FDA-regulated products, went into effect in August of 1994. The NLEA has multiple objectives and will have multiple short and long term implications.

- To monitor some of these impacts, the FDA is tracking consumer awareness, attitudes and reported behaviours (by means of nationally representative consumer surveys) and examining changes in the marketplace (by looking at sales trends for selected product categories and assessing compliance with NLEA regulations).

- Alan Levy and colleagues present a report on preliminary findings from analyses of (Levy, 1996) FDA’s consumer tracking system and overall market trends for selected fat-modified products. The consumer data are based on two national probability samples of telephone households that asked comparable questions about consumer food label use and attitudes in the context of diet and health awareness and concerns. One survey was conducted prior to NLEA implementation (March, 1994) and the second 18 months later (November 1995), over a year after full implementation.

- FDA has upgraded its market surveillance system to identify new product introductions and shifts in market share that may be related to nutrition characteristics of food products, using a commercially available longitudinal database of food product sales from a nationally representative sample of supermarkets.

- The combination of the consumer and market data, the “Food Label and Nutrition Tracking System” (FLANTS), provides data to identify some of the impacts of the new food label regulations that occurred in the period shortly after the regulations were implemented. Ongoing analyses of these data, for example, link to consumers’ awareness and concerns regarding dietary risk factors to their reported food label attitudes and practices, will provide additional insights into the role of the new food label in the broader context of nutrition education and the behaviour changes needed to achieve healthier diets and reduced diet-related morbidity and mortality.

4.5.1 Impact measures used in the US

- Given the diverse possible uses for the food label, there are several equally valid ways to measure impacts of the new regulations. Impacts can be categorized as related to the behaviour of manufacturers, consumers or markets. Possible measures which differ in terms of precision, sensitivity, feasibility and practical significance are described below, along with possible data sources.

  - Measures of manufacturer behaviour
  - Compliance with NLEA labelling requirements
  - Prevalence of use of voluntary types of label information (e.g. use of health claims or nutrient content claims)
  - Number and type of product reformulations
  - Data on compliance and label content are available in FDA’s Food Label and Package Surveillance (FLAPS) system. Marketing databases exist to track new product introductions. Information about product reformulations are not generally available.
• Measures of market behaviour
• Market share trends for nutrition-promoted product segments within a given product category (e.g. sales of low/reduced/fat free products for a given product category).
• Comparative sales trends for product categories with contrasting nutrition characteristics (e.g. potato chips versus pretzel sales).
• Data on food market trends are available from a number of proprietary market research databases used by the food industry.

• Measures of consumer behaviour
• Short term trends in consumer perceptions and practices related to food labels (e.g. reported frequency of use, reported purposes for using food labels, and confidence in label information).
• Trends in knowledge and beliefs related to dietary advice.
• Data on consumer perceptions and practices are available from numerous consumer surveys conducted by a variety of organisations including industry, public health, consumer and governmental groups.

4.5.2 Long term

• Population changes in overall diet quality.
• Reduced morbidity and mortality from diet-related diseases.
• Data on nutrition and health status of the general public are available from several Federal government-sponsored dietary intake surveys that are part of the National Nutrition Monitoring Unit and Related Research Program.

5. ENFORCEMENT

5.1 How it worked in the folate pilot

In line with the co-regulatory arrangements used in the pilot, surveillance and enforcement processes were intended to operate at two levels:

a) At the first level, a Code of Practice Management Committee was established as the primary vehicle for ensuring compliance with the regulatory system. The first meeting of the Code of Practice Management Committee was on 7 May 1999. The Committee was comprised of:

• Chairperson - a senior food industry executive appointed for the duration of the pilot by signatory organisations;
• Secretary - the Executive Director of the Australian Food Council or their nominee;
• Members - five nominees from member companies supporting industry organisations (with representation from Australia and New Zealand):
  - one nominee from the Australian Supermarket Institute
  - one nominee from ANZFA
  - one nominee from the ANZFA Advisory Committee
  - two nominees representing community interests.
The intended role of the Code of Practice Management Committee was to oversee regular surveillance audits of participating companies, as well as setting up a formal complaint handling procedure to address non-compliance or non-approved use of a claim. To date, there have been no formal complaints or alleged breaches referred to the Code of Practice Management Committee or legal actions initiated by government enforcement agencies about the folate/NTD claim. It was envisaged that any complaints (whether from other food companies or consumers) would be investigated by the Management Committee and mediated through direct negotiation with the company and/or complainant.

b) At the second level, surveillance and enforcement can be undertaken directly by government enforcement agencies. New Zealand and Australian state/territory government health agencies have responsibility for undertaking legal action to enforce compliance with the Food Standards Code. While these agencies could initiate independent enforcement activities during the pilot, it was intended that action in regard to the folate health claim would normally be undertaken following a referral from the Code of Practice Management Committee following unsuccessful mediation.

5.2 Issues arising from the process evaluation of the folate pilot

The process evaluation report raised a number of issues related to surveillance and enforcement processes that are important to consider if health claims and/or nutrition messages are permitted more generally. These included the need to:

- establish a Code of Practice Management Committee to ensure compliance with the Code of Practice for the Communication of the Health Benefits of Food Products. The Code of Practice Management Committee would provide the primary mechanism for surveillance and enforcement of the Code of Practice. The Committee would include members of the food industry, community and consumer organisations, ANZFA and New Zealand and Australian state/territory regulatory authorities. The surveillance and enforcement activities of the Committee could include:
  - promoting the role and function of the Committee to food companies, government enforcement agencies, public health agencies and consumer groups, including procedures for making complaints;
  - maintaining a log of alleged breaches and complaints with regard to the Code;
  - mediation and attempted resolution of alleged breaches and complaints (see below); and,
  - preparing regular public reports on compliance including the number of complaints received, action taken and outcomes of such action.

- develop and promote guidelines on how the Code of Practice Management Committee would mediate and attempt resolution of complaints and alleged breaches of the Code. The process evaluation report recommended that, in line with the processes used during the folate pilot, mediation and attempted resolution would involve:
  - a Complaints Officer (possibly in ANZFA) recording and tracking all complaints received;
  - the Complaints Officer requesting input from both the complainant and the company or organisation alleged to have breached the Code in writing within fourteen (14) days from the receipt of the request;
- the Management Committee attempting to resolve the complaint through mediation, if necessary involving the CEO of the company or organisation against which the complaint is made. If the complaint cannot be resolved within twenty eight (28) days through mediation, it would be reviewed by the Management Committee which would decide whether further action is required based on the information to hand and the degree of importance of the complaint;
- where breaches of the Code of Practice have been clearly established and negotiations have failed to resolve the issue, the Management Committee could write to the company or organisation seeking a written undertaking to discontinue practices determined to constitute a breach of the Code or seek a corrective statement as appropriate;
- where any company or organisation does not respond positively to the requests or recommendations of the Management Committee in a timely manner, the matter would be referred to government regulatory authorities; and,
- continued refusal by the offending company or organisation to undertake the required remedial action may lead to the Management Committee recommending the suspension or expulsion of the company from the relevant industry organisation.

- Further work on the guidelines is needed to clarify the interface between the Code of Practice and the responsibilities of New Zealand and Australian state/territory government agencies to enforce the *Food Standards Code*. In particular, there is a need to clarify:
  - responsibility and resources for undertaking regular surveillance audits to identify possible breaches of the Code;
  - processes for follow-up of potential breaches identified from a surveillance audit (where a complaint has not been made);
  - procedures for handling anonymous complaints;
  - the criteria to be used by the Management Committee for determining the “degree of importance of the complaint” when deciding whether further action is required on a complaint; and,
  - details of what constitutes a “timely” response to a request or recommendation of the Management Committee.

It was also noted that there is a need to examine the resource implications of New Zealand and Australian state/territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee for breaches that are unable to be resolved at the Code of Management Committee level.

In the context of the broader discussions taking place on the relative advantages and disadvantages of health claims, the terms of reference of the regulation and enforcement working group were to provide advice to ANZFA on:

1. the preferred option for a regulatory framework for a health claims system should health claims be permitted;
2. the preferred option for regulating ‘nutrition messages’ should they be distinguished from ‘health claims’ within the considerations of P153;
3. the enforcement of this/these regulatory system(s);
4. the role of a code of practice in a health claims system; and
5. steps that can be taken to ease the burden of enforcement, on current enforcement agencies, arising from any health claims system that may be introduced.

The membership of this group is outlined in Attachment 1 to this Appendix.

It needs to be noted that the group were asked to provide advice on the process of regulating and enforcing health claims on the assumption that health claims would exist. Members of the group have not passed their opinion on whether health claims should be permitted or not.

1. DEVELOPMENT OF A REGULATORY SYSTEM TO ACCOMPANY ANY HEALTH CLAIMS THAT MAY BE PERMITTED

1.1 Principles

The discussions of the group led to the emergence of a number of underlying principles for the regulation and enforcement of health claims. These are:

- health claims need to be clearly defined;
- adequate monitoring needs to be undertaken;
- local and imported foods need to be treated equitably;
- claims need to be strictly regulated; and
- co-regulation would be appropriate with a management committee the first port-of-call for complaints.

1.2 Definitions

For the purposes of the discussions of this expert group the following definitions were agreed upon:

- nutrient/nutrition claims be defined as claims referring to nutrient content/level;
- nutrition messages be defined as claims referring to nutrient function; and
• health claims be defined as claims which include the name of a disease.

1.3 A regulatory framework

It was considered that regulation and enforcement needed to be considered as two options vis a vis a 2-tiered or 3-tiered system, and that clear definitions of nutrient content claims, nutrition messages and health claims would underpin such options.

The regulatory framework preferred by the majority of the group was option 2. This was largely because there was the view that the end-point implications of nutrition messages and health claims may be very similar in a situation where consumers may infer similar disease-related outcomes from either type of message/claim.

Option 1

2-tiers:

1. nutrient content claims;
2. combined nutrition messages/health claims; and

Option 2

3-tiers:

1. nutrient content claims;
2. nutrition messages;
3. health claims.

The regulatory options for either the 2-tiered or 3-tiered system were proposed as follows. Note that the regulation of ‘nutrient claims’ as outlined in the tables below represents the status quo (i.e. as regulated within the context of nutritional claims according to the Food Standards Code and the New Zealand Food Regulations (NZFR)) and consideration of this was not within the brief of this working group. The item is included to complete the definitional context.
### OPTION 1- NUTRITION MESSAGE AND HEALTH CLAIMS REGULATED TOGETHER

<table>
<thead>
<tr>
<th>Nutrient content claims</th>
<th>Regulated as per current standing within the <em>Food Standards Code</em> and NZFR for ‘nutrition claims’, noting that relative claims for macronutrients are addressed by COPONC(^9) within Australia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition messages and health claims</td>
<td>Prohibition of both within the <em>Food Standards Code</em>. Exemptions to the prohibition in the form of a list of approved messages and claims. Use of a code of practice and guidelines to support the standard.</td>
</tr>
</tbody>
</table>

### OPTION 2 – NUTRITION MESSAGES AND HEALTH CLAIMS REGULATED SEPARATELY

<table>
<thead>
<tr>
<th>Nutrient content claims</th>
<th>Regulated as per current standing within the <em>Food Standards Code</em> and NZFR for ‘nutrition claims’, noting that relative claims for macronutrients are addressed by COPONC within Australia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition messages</td>
<td>Generally agreed that co-regulation is the most feasible option incorporating a code of practice, managed by an industry-based committee. The definition of nutrition messages may need to be provided in the <em>Food Standards Code</em> however, there would be no prohibition as such, nor a list of permitted exemptions. The code of practice would, along with other information, describe the elements of an appropriate message and provide guidelines on substantiation.</td>
</tr>
<tr>
<td>Health claims</td>
<td>Prohibition within the <em>Food Standards Code</em>. Exemptions to the prohibition in the form of a list of approved messages and claims. Use of a code of practice and guidelines to support the standard.</td>
</tr>
</tbody>
</table>

\(^9\) Code of Practice on Nutrient Claims
1.3.1 Fair Trading Laws

Throughout the discussions the over-riding involvement of Fair Trading laws were also noted insofar as they encompass false and misleading labelling. However, experience to date by the ACCC (Australian Competition and Consumer Commission) indicates that misleading and deceptive conduct in relation to food labelling in many cases becomes a national issue and is not confined to individual States or Territories. This may take the matter out of the jurisdiction of individual State/Territory Health and Fair Trading Departments and back to the realm of the ACCC but, in this situation the ACCC may not be in a position to allocate to food matters the level of priority expected or sought by organisations such as ANZFA.

From a New Zealand perspective it was noted that the Fair Trading Act is invoked quite frequently in New Zealand, often by companies with a complaint against another company, or by consumers. It is anticipated that breaches of a code on health claims would be brought to the attention of a management committee in a similar manner. Such a committee would then need sufficient ‘teeth’ to enable retributive action and failing appropriate response, a pathway of reporting to a regulatory agency. It is important to note that compliance with food regulations or any code of practice does not ensure compliance with nor a legitimate defence against Fair Trading Act.

1.4 Considerations relating to scientific substantiation

It was necessary to also take into account the considerations of the Expert Advisory Group on the Scientific Substantiation of Health Claims in order to arrive at an integrated approach to the management of health claims. This group had considered that while regulation for nutrition messages and health claims may differ [Nutrition messages could be subject to self or co-regulation (with supporting evidence available upon request) and health claims regulated by means of a definitive list of exemptions within the Food Standards Code], the same level of substantiation should be considered for both.

1.5 Co-regulation and codes of practice

It was noted that codes of practice such as COPONC are not covered by Australian Quarantine Inspection Service (AQIS) nor New Zealand legislation therefore, any claims regulated by codes of practice rather than the Food Standards Code would need to be considered\(^{10}\).

Further information was provided by the ACCC which, in its regulatory capacity, has considerable involvement with codes of practice. In their experience, voluntary codes of practice such as the one proposed are likely to be successful so long as industry coverage is almost universal i.e., 85 percent or better. It is important to promote and facilitate cooperation between the various organizations in implementing codes of practice.

\(^{10}\) Furthermore in New Zealand, the Fair Trading legislation has no provisions to authorise codes of practice and, codes of practice must comply with the provisions of the Commerce Act.
1.5.1 Specific versus generic claims

Specific vs. generic claims were considered in relation to whether a code of practice would work equally well with either. Specific claims were regarded as being those for which a company holds the intellectual property and stands to gain exclusive benefits. It was agreed that specific claims do not need to be treated differently to generic claims for either option.

1.6 Product by product approval

Product by product approval was also discussed however, the experience from the folate pilot was that this is very labour intensive. It was considered that if the qualifying criteria were spelt out adequately there should be no need for individual product approval and that also, this approach was not helpful if a very long list resulted. Although it was noted that for monitoring and evaluation purposes product by product approval may be required (to enable a tracking system), there was nevertheless no support for this approach. It was noted that a voluntary register could be established for monitoring purposes but may have some limitations, such as compliance.

2. ENFORCEMENT/MANAGEMENT OF A CO-REGULATORY SYSTEM

This part of the discussion focussed on option 2 i.e. where nutrition messages and health claims were considered separately.

A code of practice and associated management committee as a co-regulatory mechanism for health claims were considered. There was general discussion regarding the effectiveness and potential resourcing of such a committee in order that it may provide effective support for the prohibition and any exemptions contained within legislation. It was noted that the ARTD Process Evaluation Report of the Folate pilot also raised the question of whether advice to industry (e.g. on how to comply with codes/regulation) should also be a function of the management committee. It was uniformly agreed that such a committee should not perform some sort of ‘clearing house’ function, which left the question of who/which body could provide advice regarding compliance with the code/regulation?

It was suggested that the recommendations in the ARTD process evaluation report for the role and functioning of such a committee be referred to. In relation to these, it was agreed by the group that the point “continued refusal by the offending company or organization to undertake the required remedial action may lead to the Management Committee recommending the suspension or expulsion of the company from the relevant industry organization” (ARTD report page 31) was not particularly meaningful if companies were not in an organisation such as the Australian Food and Grocery Council (AFGC) or Grocery Manufacturers Association (GMA) in New Zealand. It was therefore suggested that this point not be included in the operational procedures of such a committee, should one be established.

In response to the question of ‘who would this [management] committee be answerable to?’, it was noted that the Interim Code of Practice Management Committee for the Folate pilot was a committee comprising members of the Food Code Management Committee (an independent committee resourced by the AFGC) with additional experts including an ANZFA representative. For the purposes of the folate pilot this committee was answerable to the folate pilot steering committee.
Overall, it was considered that the membership of the folate pilot committee looked appropriate, with the amendments that New Zealand would need to be included and that representation by senior food officers would be more appropriate than Australia New Zealand Food Advisory Council representation. The difficulties of resource implications were also noted. The states and territories noted their concerns that current resources were not being used to their best advantage and that there are fundamental issues in relation to application of enforcement processes that need to be addressed at a political level. It was noted that a management committee for a broader claims system would be far more resource intensive than the folate pilot.

The success of such a committee was considered to be directly proportional to the support at the state/territory level. It was suggested some issues could be handled similarly to food recalls i.e. national issues addressed by ANZFA and state/territory issues handled at the local level.

2.1 New Zealand

New Zealand and Australia will need to work together to develop combined code(s) of practice. Such codes have a role to play in relation to nutrition messages, health claims and can assist in simplifying the legislation.

3. COMPLIANCE SURVEILLANCE

As part of this discussion the following considerations were noted:

- the working group on scientific substantiation of health claims had suggested that post-market surveillance may be an effective means of managing nutrition messages; and
- compliance surveillance carries implications that the onus is on the company and can be effective, particularly if the onus of proof is reversed;
- a good and equitable surveillance system of both imported and locally produced goods would be needed in order that local products are not disadvantaged;
- within New Zealand national food surveillance and enforcement is under the jurisdictions of the Ministry of Health (food legislation) and Commerce Commission (fair trading legislation); and
- that within Australia, national food surveillance is an ANZFA and state/territory enforcement issue.

3.1 Onus of proof

It was considered preferable that the onus of proof for claims made should be on the claimant, rather than the enforcement agency being required to prove that the claim is untrue. Mechanisms of achieving this were discussed and further work would be required on how this could occur.

For the information of the group, the following legal advice was provided in relation to Australia. Section 94 of Annex B of the Australian inter-governamental agreement responding to the recommendations of the Report of the Food Regulation Review (i.e. the Blair Review) identifies that in relation to nutritional declarations, the onus of verification of nutritional information in advertisements or on or attached to foods is borne by the manufacturer.
Annex B sets out the non-core provisions of the draft Model Food Act and jurisdictions can choose which sections they wish to adopt from Annex B, with the result that such provisions may not be nationally consistent.

In other words, in instances of nutritional declarations, and where an Australian state or territory chooses to adopt the relevant provision(s) from Annex B, the onus of proof for a particular claim is borne by the claimant, rather than the enforcement agency being required to prove that the claim is untrue, as is currently the case.
REGULATION AND ENFORCEMENT OF HEALTH CLAIMS

Membership

Mr Peter Liehne (chair), ANZFA
Ms Ellen Kitson, Dept of Human Services, Victoria
Mr Ian Doughty, Health Department of Western Australia
Mr Dieter Jurgeneit, ACT Health Protection Service
Ms Sophe Williamson, AQIS
Mr John McMahon, NSW Health Dept
Mr Bill Porter, NSW Health Dept
Ms Rachel Thom, NZ Ministry of Health
Mr James Stephanos, Queensland Dept of Health
Ms Elizabeth McDonald, NZ Ministry of Commerce
Mr Tony Downer, AFGC
Mr Ziv Gavrilovich, ACCC
Ms Brenda Cutress, GMA

CORRESPONDING MEMBERS:
Mr Eric Johnson, Dept of Health and Human Services, Tasmania
Ms Tracy Ward, Territory Health Services, Northern Territory
Mr Brian Delroy, South Australian Health Commission, South Australia

ANZFA members:
Ms Sue Jefferson
Ms Jane Allen
Ms Alison Wallace
Mr John Fladun

The terms of reference of the scientific substantiation working group were to provide advice to ANZFA on:

- suitable model(s) for the scientific substantiation of any health claims that may be permitted in the future, including the quality and quantity of evidence required to support claims;
- suitable model(s) for managing the process of scientific substantiation, should health claims be permitted;
- the criteria that should be applied to the use of endorsements by organisations on food labels and in advertising, if these were to be permitted;
- the qualifying and disqualifying criteria that should apply to foods before they can carry a health claim or an endorsement; and
- issues related to the review of each health claim that may be permitted, as new scientific evidence becomes available in the future.

The membership of this group is outlined in Appendix 1.

It needs to be noted that the group was asked to provide advice on the process of substantiating health claims on the assumption that health claims would exist. Members of the group have not passed their opinion on whether health claims should be permitted or not.

1.0 Definitions

The group felt that the definition of a health claim was critical to the scientific substantiation process and subsequent regulatory processes. The following definitions were proposed by ANZFA and endorsed by the group:

Nutrition Content Claim:

A claim in relation to a food that describes or indicates the presence or absence of a nutrient, energy content or biologically active substance in that food.

Nutrition Function Claim:

A claim in relation to a food which describes the physiological role of a nutrient, energy content or biologically active substance in the food, in the growth, development, maintenance and other like functions of the human body.

Health Claim

A claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a-

(a) enhanced function claim
(b) reduction of disease risk claim; or
(c) claim that a food is a slimming food or has intrinsic weight-reducing properties;
**Enhanced Function Claim** means a claim about the specific beneficial effects of a food or food constituent of a food on the physiological or biological functions other than the role of the nutrient or biologically active substance in the normal growth, development, maintenance and other like functions of the human body.

**Reduction of Disease Risk Claim** means a claim in relation to a food that a relationship exists between consumption of a food or food constituent and the reduced risk of developing a disease or health related condition.

The group also recommended that a number of principles must accompany any nutrition message. That nutrition messages must:

- trigger a nutrition information panel;
- not be strung together to link to a disease;
- make no implication or suggestion of a health claim;
- be accompanied by a post-market audit; and that
- the product must contain a significant amount of the specific nutrient/s or biologically active substance.

### 2.0 What constitutes a health claim?

Discussions centred on whether a nutrition function claim such as “calcium builds strong bones” was the same as “calcium reduces the risk of osteoporosis”. It was suggested that it is difficult for the public to tell the difference between a nutrition function claim and a health claim. It was also noted that investing resources into the development of a rigorous model for substantiating health claims could be undermined if nutrition function claims continue to be allowed without some form of regulation and requirement for the substantiation of the messages.

The following table summarises the working group’s recommendations for the regulation of nutrition content claims, nutrition function claims and health claims:

<table>
<thead>
<tr>
<th>Message on label</th>
<th>Regulation</th>
<th>Other requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition content claim</td>
<td>Self-regulation</td>
<td>Code of practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nutrition information panel</td>
</tr>
<tr>
<td>Nutrition function claim</td>
<td>Self-regulation or co-regulation</td>
<td>Code of practice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Statement on dietary variety to support message</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nutrition information panel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Same level of evidence required as for health claims but</td>
</tr>
<tr>
<td></td>
<td></td>
<td>manufacturer holds the evidence and makes own assessment</td>
</tr>
<tr>
<td>Health claim</td>
<td>Co-regulation or full regulation</td>
<td>Evidence assessed independently before claim can be made</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ANZFA-endorsed logo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Statement on dietary variety to support message</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nutrition information panel</td>
</tr>
</tbody>
</table>
3.0 Evidence required to support the substantiation of health claims

This is detailed in Appendix 2 to this report.

4.0 Options for managing the assessment of claims

The expert working group suggested that the process of substantiation should be carried out by an expert committee. The committee should consist of a core group of experts with skills in the areas of public health, food and nutrition, research methodology, and operations of government. There would also be a need to invite individuals with expertise in the areas of interest of each individual claim to review specific claims. The committee would need to review all the available literature and decide whether the evidence was sufficient to allow the health claim using the procedure outlined in Appendix 2.

5.0 Adoption of the US claims in Australia and New Zealand

It was considered that the US health claims ‘per se’ should not be adopted for Australia and New Zealand without review. The reasons for this were:
- The majority of the US health claims were reviewed in the early 90’s – there have been further studies and advances in nutritional science since this time;
- The US has different emphases on importance of different dietary factors. For example, limiting intake of dietary cholesterol is considered important for decreasing total cholesterol and hence risk of CHD whereas, in Australia and New Zealand, limiting dietary fat is considered more important;
- There are differences in the food supply and in the characteristics of the two populations; and
- If Australia copies the American system in toto without its own review, ANZFA would have no basis for responding if there is a complaint.

It was therefore agreed that if the US health claims were to be considered for use in Australia, the claims should be reviewed in the light of new evidence and their applicability to the Australian and New Zealand populations.

6.0 Further consideration of the process that ANZFA might use to authorise health claims

The group recommended that ANZFA should develop a policy to the effect that the overall effect of a health claim should be supportive of the national dietary guidelines in both Australia and New Zealand and be consistent with national public health priorities. The group was concerned that changes to ANZFA’s Act whereby, applicants could pay to have their application reviewed as a priority rather than ‘wait their turn’, would unfairly advantage industry groups over public health groups. Members believed that there would be a substantial need for ANZFA to raise its own proposals to provide a balance to the types of claims being considered. They also recommended that ANZFA make a concerted effort to educate consumer and public health groups about the process for making an application to facilitate applications from these sectors who do not have a record of applications to ANZFA. Applications for health claims should also identify the target population for which the claim is intended and the relevance of the food chosen to the target population.
The group identified a number of generic health claims that it felt should be given priority over other health claims. These were:
Vegetables and fruit and cancer;
Vegetables and fruit and CHD;
Folate and NTDs;
Calcium and osteoporosis;
Saturated fat (Trans) and CHD;
Polyunsaturated fat and serum cholesterol;
Sodium and hypertension;
Wholegrain food and cancer; and
Wholegrain food and CHD.

7.0 Endorsements on labels

The working group recommended that endorsements on labels or any implied representation or trade name should be subject to the same substantiation criteria as all other health claims. In addition members endorsed ANZFA's recommendations as provided verbally at the third meeting, that an organisation should apply to ANZFA to have their qualifying/disqualifying criteria for endorsements listed in the Food Standards Code. Endorsements should be subject to the same application procedure as a health claim. Labels with an endorsement should also contain a statement that the company has paid to use this endorsement.

8.0 Revision of health claims

A recommendation was made that all health claims should carry a sunset clause such that claims would need to be reviewed every five years and that ANZFA should have the right to review any claims on the basis of new evidence at any time.

9.0 Eligibility criteria

A report of the sub-group on qualifying/disqualifying criteria is at Appendix 3 to this item.

10.0 Testing of a model to substantiate health claims

The group noted ANZFA’s considerations of the need to have an independent testing process for the guidelines developed by the group. The emphasis of the testing would be as much about the process of substantiating a claim as about the outcome of reviewing the literature.

The group was concerned that the time and resources available would not be sufficient to adequately test the proposed substantiation guidelines. Members also questioned whether the qualifying and disqualifying criteria would be tested as part of the process.

It was recommended that ANZFA consider testing the following claims:
Fruit and vegetables and cancer; or
Calcium and osteoporosis; or
Sodium and hypertension.

It was agreed that the subgroup that developed the qualifying criteria guidelines would also trial two cases against their proposed criteria.
Appendix 1

Scientific Substantiation of Health Claims

Membership

Dr Alex Proudfoot, ANZFA (chair)
Prof Colin Binns, School of Public Health, Curtin University of Technology
Prof Terry Campbell, Medical Unit, St Vincent’s Hospital
Dr Karen Cashel, Division of Science and Design, University of Canberra
Dr Fiona Cumming, Office of Complementary Medicine, Therapeutic Goods Administration
Dr Marion Healy, ANZFA
Ms Janine Lewis, ANZFA
Dr Sally Poppitt, Nutrition Unit, University of Auckland
Dr Murray Skeaff, Nutrition Department, University of Otago
Prof Stewart Truswell, Human Nutrition Unit, University of Sydney
Appendix 2

Guidelines for the scientific substantiation of health claims.

Summary

The purpose in setting criteria for the scientific substantiation of a health claim is to ensure that health claims describe relationships between diet and health that are proven to exist. The assessment of the validity of the relationship between a food or food constituent and its potential to influence the development or course of a disease is based on the consistency, strength, relevance and quality of evidence in support of such a relationship. It is recognised that a variety of experimental approaches may contribute to the substantiation of a proposed health claim. Because of the limitations of the various research methods that can be used to study substance/disease relationships, it is not possible to specify the type or number of studies needed to support a health claim. When substantial evidence from different types of studies gives consistent results, together with supportive evidence from experimental and other biological research, this may be judged to be convincing evidence of a causal relationship (World Cancer Research Fund, 1997). Safety issues also need to be considered as part of a scientific assessment of the claim. A final decision on whether the claim is substantiated must take into account policy guidelines relating to nutritional qualifying/disqualifying criteria.

Step 1: Identifying studies

The scientific evidence that underlies substantiation of a health claim may be drawn from the following types of data:

1. data on biological mechanisms: data derived from chemical, cellular, human experimental or animal models investigating plausible mechanisms of action of foods or food substances.
2. clinical and intervention data:
   - observational studies of populations or groups assessing associations between food substances and disease (case-control, cohort, correlational, cross-sectional); and
   - intervention trials involving human subjects.

The different types of studies provide evidence of different strength. The Australian National Health and Medical Research Council (NHMRC) has developed a framework for levels of evidence for developing clinical practice guidelines (NHMRC, 1998). This framework has been modified for use in these guidelines for the substantiation of health claims for the following reasons:

1. Data from randomised controlled trials (RCT) are available for diet and a risk factor for a disease (e.g. plasma cholesterol, blood pressure) but are less common for a pure nutrient and disease and rare for diet and disease. When diet is the intervention, confounding factors are possible in ways not encountered in drug trials. It is therefore questionable for nutrition whether a single randomised trial of food and disease (said to be level II) is better evidence than a set of large, well-designed cohort studies (said to be level III-2).
2. It is generally accepted among public health nutritionists that cohort studies are more reliable than case-control studies (World Cancer Research Fund, 1997; Willett, 1990; Mann, 1997). This principle is exemplified by the greater reliance placed on cohort (prospective) studies than on case-control studies in considering the relationships between diet and coronary heart disease and diet and cancer.

The system for grading evidence with respect to using it to substantiate health claims relating to foods is therefore:

Grade A: evidence obtained from a systematic review of all relevant randomised controlled trials.

Grade B: evidence obtained from properly designed randomised controlled trials or evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).

Grade C: evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies).

Grade D: case-control studies, or interrupted time series with a control group.

Grade E: evidence obtained from comparative studies with historical control, two or more single arms, or interrupted time series without a parallel control group.

Grade F: evidence obtained from case series, either post-test, or pre-test and post-test.

Grade G: other relevant information including reports of expert committees.

Step 2: Evaluating the quality of the evidence from studies

Providing an explicit and standardised appraisal of all relevant studies that have been identified is important. Overall, the features that are most important to address are those that involve selection and measurement bias, confounding factors and follow-up of participants (National Health and Medical Research Council, 2000).

In evaluating the studies to assess the potential validity of a food substance and disease relationship the following must be taken into account:

- **Strength and quality**

  Consideration must be given as to whether the study was relevant and the study design was appropriate for exploring the proposed relationship and if the results are of sufficient significance to minimise the occurrence of these same events by chance. Studies must meet conventional standards of quality. This includes sample size, outcome, dietary collection methods, matching of groups, relevant confounders, reporting odds ratios.

  The results from multiple studies with inadequate sample size to detect a difference with confidence may be combined, under certain circumstances, through structured analyses, such as meta-analyses, that provide confident estimates of an effect not observed from individual studies (Keystone, 1996).
• Biological plausibility
The evidence of a causal relationship is enhanced if there is a known or postulated biological mechanism by which the exposure might reasonably alter risk of developing the disease (Hennekens, 1987).

• Dose-response relationship
Whether the data demonstrate a plausible dose-response relationship that would support the hypothetical activity of the food substance (Keystone, 1996). The possibility of a threshold effect should also be considered.

• Bioavailability in food
The nutrient/active ingredient must be in a form that can be readily absorbed into the body as part of a normal diet, and which influences blood and tissue concentrations of the nutrient/active ingredient, sufficiently to exist a changed effect. Therefore, when assessing studies, the form of the nutrient/active ingredient needs to be considered in terms of its effects when present in food as opposed to being provided as a supplement.

• Safety Issues
The safety of authorising a health claim regarding a food or food substance needs to be addressed. In particular:
1. Is there any evidence of acute or chronic toxicity or other safety concerns relative to the consumption of this food or food substance?; and
2. Are there any negative health consequences of consuming this food or food substance or of the resulting diet? (Keystone, 1996)

• Target group
It is necessary to consider which groups in the population will be affected by the health claim. If the beneficial effect of the food or food substance only occurs in a specific sub-group of the population, it needs to be considered whether a health claim on food products would be useful to this subgroup, taking into account gender, ethnicity, physiological status, age, or whether there are other more effective ways in which these information can be conveyed to the subgroup.

• Ability to obtain the required dose from foods
Having ascertained that a specified amount of a food/active ingredient is needed in order to obtain the observed benefit, it must be considered whether this is an amount that can be reasonably obtained from food consumed in the context of a healthy diet.

Step 3: Evaluating the totality of the evidence

After relevant, good quality studies are identified and their strengths and weaknesses assessed, the totality of this evidence needs to be assessed. In addition, consideration must be given to the issue of publication bias and whether this will influence the totality of the evidence.
A scheme for categorising the totality of evidence for health claim substantiation is as follows (adapted from World Cancer Research Fund, 1997):
• “Convincing”: studies show consistent associations, with little or no evidence to the contrary. There should be a substantial number of acceptable studies, preferably including prospective designs and randomised controlled trials, conducted in different population groups, controlled for possible confounding factors. Any dose-response relationships should be supportive of a causal relationship. Associations should be biologically plausible. Laboratory evidence is usually supportive or strongly supportive.

• “Probable”: studies show associations that are either not so consistent, with a number and/or proportions of studies not supporting the association, or else the number or type of studies is not extensive enough to make a more definite judgement. Mechanistic and laboratory evidence are usually supportive or strongly supportive.

• “Possible”: studies are generally supportive, but are limited in quantity, quality or consistency. There may or may not be supportive mechanistic or laboratory evidence. Alternatively, there are few or no epidemiological data, but strongly supportive evidence from other disciplines.

• “Insufficient”: there are only a few studies, which are generally consistent, but really do no more than hint at a possible relationship. Often, more well-designed research is needed.

It is unlikely that a health claim would be approved on the basis of less than “convincing” scientific evidence.

Step 4: Eligibility criteria

Finally, having taken into account all the above factors and decided that the totality of the evidence supports authorising a health claim, certain qualifying/disqualifying criteria need to be developed that a product has to meet before it can be authorised to carry a health claim. These criteria need to be based on:

- the scientific evidence determining the amount of the nutrient necessary to potentially deliver the claimed reduction in disease risk;
- the variety of food sources that would also deliver the nutrient of interest; and
- the public health context.

GLOSSARY

Pre-test post-test study
A study design where a group is studied before and after an intervention. Interpretation of the result is problematic as it is difficult to separate the effect of the intervention from the effect of other factors (National Health and Medical Research Council, 2000).

Bias
Bias is a systematic deviation of a measurement from the ‘true’ value leading to either an over- or underestimation of the treatment effect. Bias can originate from many different sources, such as allocation of patients, measurement, interpretation, publication and review of data (National Health and Medical Research Council, 2000).
Bioavailability
The ability of the nutrient/active substance to be absorbed into the body and to influence blood and tissue levels of the nutrient/active substance (Elwood, 1992).

Biological Plausibility
The observed association has a known or postulated biological mechanism by which the exposure might reasonably alter the risk of developing the disease (Hennekens, 1987).

Blinding
Blinding or masking is the process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatments subjects are assigned. It is undertaken in order to minimise bias occurring in patient response and outcome measurement. In single-blind studies only the subjects are blind to their allocations, whilst in double-blind studies both observers and subjects are ignorant of the treatment allocations (National Health and Medical Research Council, 2000).

Case-control study
Patients with a certain outcome or disease and an appropriate group of controls without the outcome or disease are selected (usually with careful consideration of appropriate choice of controls, matching etc) and then information is obtained on whether the subjects have been exposed to the factor under investigation (National Health and Medical Research Council, 2000).

Case series
The intervention has been used in a series of patients (may or may not be consecutive series) and the results reported. There is no separate control group for comparison (National Health and Medical Research Council, 2000).

Cohort study
Participants are classified on the basis of the presence or absence of exposure to a particular factor and then followed for a specified period of time to determine the development of disease in each exposure group (American Journal of Clinical Nutrition, 1999)

Comparative study
A study including a comparison or control group (National Health and Medical Research Council, 2000).

Concurrent controls
Controls receive the alternative intervention and undergo assessment concurrently with the group receiving treatment. Allocation to the intervention or control is not random (National Health and Medical Research Council, 2000).
**Correlational study**
Also called ecological study, where the rate of disease is compared across different populations (US Food and Drug Administration, 1999).

**Cross-sectional study**
Also called prevalence study, where both exposure and outcomes are measured at the same time (National Health and Medical Research Council, 2000).

**Dose-response**
A gradient of response associated with the degree of exposure (Hennekens, 1987).

**Level of evidence**
Study designs are often grouped into a hierarchy according to their validity, or degree to which they are not susceptible to bias. The hierarchy indicates which studies should be given most weight in an evaluation (National Health and Medical Research Council, 2000).

**Meta-analysis**
Results from several studies, identified in a systematic review, are combined and summarised quantitatively (National Health and Medical Research Council, 2000).

**Non-randomised cross-over design**
Patients are measured before and after introduction or withdrawal of the intervention and order of introduction and withdrawal is not randomised (National Health and Medical Research Council, 2000).

**Observational studies**
Also known as epidemiological studies. These are usually undertaken by investigators who are not involved in the clinical care of the patients being studied and who are not using the treatment under investigation in this group of patients (National Health and Medical Research Council, 2000).

**Randomised controlled trial**
An experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism. Participants have an equal chance of being allocated to an intervention or control group and therefore allocation bias is eliminated (National Health and Medical Research Council, 2000).

**Randomised cross-over trial**
Patients are measured before and after exposure to different treatments (or placebo) which are administered in a random order (and usually blinded) (National Health and Medical Research Council, 2000).

**References:**


The role of epidemiology in determining when evidence is sufficient to support nutrition recommendations. American Journal of Clinical Nutrition 1999:69 (suppl): 1297S-1367S.

US Food and Drug Administration. Interpretation of significant scientific agreement in the review of health claims. Food Advisory Committee Meeting, June 24-25, 1999.


Flow Chart - sequence of events in assessing the evidence for a Health claim

**Primary Evidence**
- Observational
- Intervenional

**Level of Evidence?**
- C
- D
- E
- F

**Supporting Evidence**
- Yes

**Biologically Plausible?**
- Yes
- No

**Dose response**
- Yes
- No

**Threshold effect?**
- Yes
- No

**Dose response**
- Yes
- No

**Bioavailable in food?**
- Yes
- No

**Relationship Established?**
- Yes
- No

**Strength of Relationship?**
- Yes
- No

**Convincing**
- Yes
- No

**Probable**
- Yes
- No

**Possible**
- Yes
- No

**Insufficient**
- Yes

**Safety, Dose Feasible, Target group?**
- Yes
- No

**Make Claim**
- No Claim
Appendix 3
The Nutritional Criteria sub-group on qualifying/disqualifying criteria that should apply to products carrying a health claim

This group was established as a sub-group of the Scientific Substantiation Expert Advisory Group charged with the task of:

- advising ANZFA on the generic qualifying and disqualifying nutrient content criteria that should apply to foods before they can carry a health claim or an endorsement.

This sub-group was formed because there was insufficient time during the meetings of the Scientific Substantiation Expert Advisory Group to give the qualifying/disqualifying criteria that should apply to products carrying a health claim due consideration. The membership of this sub-group is at attachment 1.

1. The Principles around the eligibility criteria for foods bearing a health claim

The process evaluation of the folate pilot showed that there was broad support for the principles used to establish eligibility criteria. On further consideration by the Nutritional Criteria sub-group, it was decided to adopt these principles for health claims more generally, with appropriate amendments.

1 Foods included must make an appropriate contribution\(\text{11}\) to the dietary intake of the nutrient that is the subject of the claim.

2 Foods included should also support the dietary guidelines in both Australia and New Zealand, with the link acknowledged through accompanying education program(s).

3 Consideration to be given to excluding foods that may in any way be harmful to the target group(s).

Where appropriate:

4 There should be compatibility with Standard A9, of the Australian *Food Standards Code* with regard to established minimum reference amounts for “source” (10% RDI/serve) and “good source” (25% RDI/serve) of vitamin and minerals.

5 There should be encouragement of changes in the food supply, such as increased use by manufacturers of nutrient fortification permissions.

6 Account should be taken of the criteria laid down in the Code of Practice on Nutrient Claims.

7 Account should also be made of the relevant Codex regulations.

2. General Qualifying/disqualifying criteria

The Nutritional Criteria sub-group considered that the qualifying/disqualifying criteria for total fat, saturated fat and sodium and the rationale for their use and levels as suggested by the folate pilot were appropriate for health claims generally. Therefore, they proposed that these qualifying/ disqualifying criteria apply to all health claims. These criteria are:

\(\text{11}\) This means that: in the case of positive nutrients, a significant contribution of the nutrient in question should be made by the food e.g. folate, or; in the case of negative nutrients, the food itself should not provide undue amounts of the nutrient in question e.g. fat.
<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Criterion</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>total fat</td>
<td>&lt; 14g/serve</td>
<td>20% of recommended fat intake (based on 30% 8400 KJ energy intake)</td>
</tr>
<tr>
<td>saturated fat</td>
<td>&lt; 5g/serve</td>
<td>one third of total fat, based on Australian and New Zealand recommendations.</td>
</tr>
<tr>
<td>sodium</td>
<td>&lt; 500mg/serve</td>
<td>20% upper limit of RDI range for adult</td>
</tr>
</tbody>
</table>

All three criteria should be satisfied for a food to be eligible to carry a health claim. As in the folate pilot, manufacturers are able to set the serve size for their products.

The basis for deciding on these nutrients was that:
- Total fat and saturated fat are nutrients of public health significance.
- Because of the public health concern about high intakes of sodium and the fact Australia and New Zealand have a RDI for sodium and a dietary guideline on salt, it was considered appropriate to set an upper limit for sodium.

In the folate pilot, primary foods were exempt from the general qualifying/disqualifying criteria. However, this exemption will not apply to this proposed system. This means that meats with a fat content of 14g/serve or more are no longer eligible for qualification to bear a health claim because they do not comply with the generic criteria. Nuts will be able to meet the total fat criteria if they use a 20 gram serve size (a commonly used serve size for nuts).

**Nutrient density**

The Nutritional Criteria sub-group decided that in order for a food to be eligible to carry a claim, the food must also contain at least 10% of the RDI/serve for a nutrient for which there is an RDI in Australia or New Zealand (except Sodium and Potassium). This is to ensure that foods carrying a health claim are of moderate nutrient density. In the folate pilot, in order to be eligible to carry a claim, the food had to contain less than 10g of added sugar per serve. This criteria worked well for positive nutrients (where the claim is for being high in a nutrient) but will not work for low fat or low sodium claims, or foods with a small serve size. For example, a jelly bean can use a 10 gram serve size, of which 9 grams is sugars and meet the added sugars criteria, as well as the other qualifying/disqualifying criteria, for say a low fat claim. However, if they used a 20 gram serve size, they would not meet the added sugars criteria. If the 10% RDI criteria was applied, they would not be able to make a low fat claim. Therefore, the % RDI criteria more adequately reflects the intent, that is: not to allow health claims on foods of low nutrient density.

**3. Generally prohibited foods**

The group believed that the following principles should apply for the additional exclusion of foods from bearing a health claim.
• The food bearing the health claim should:
  o be appropriate for the target group; and
  o not, by composition nor promotion, cause a risk to the health of the target group, for example, alcoholic beverages; and
  o not deter consumption of a wide variety of foods, consistent with the philosophy behind the dietary guidelines e.g. complete special dietary foods.

4. Establishment of claim-specific minimum entry criteria

The group believed that claim specific minimum entry criteria would need to be established by the scientific substantiation expert committee in relation to each claim, based on:
• scientific evidence that determined the amount of nutrient necessary to potentially deliver the claimed reduction in disease risk; and
• the variety of food sources that would also deliver the nutrient of interest.
Attachment 1

Nutritional Criteria Sub-group

Membership

Ms Janine Lewis, Principal Nutritionist, ANZFA

Dr Fiona Cumming, Office of Complementary Medicine, Therapeutic Good Administration

Dr Karen Cashel, Department of Applied Sciences, University of Canberra

Ms Jane Allen, ANZFA

Ms Sue Jeffreson, ANZFA

Ms Alison Wallace, ANZFA

The terms of reference of the education and communication working group were to provide advice to ANZFA on the following, should health claims be permitted:

- the preferred option for education strategies to accompany health claims;
- the extent of education that should accompany a health claims system;
- the roles and responsibilities of different organisations in educating consumers about health claims; and
- strategies for establishing and monitoring the communication effectiveness of health claims.

The membership of this group is outlined in Attachment 1 to this Appendix.

It needs to be noted that the group were asked to provide advice on the education and communication strategies to accompany health claims on the assumption that health claims would exist. Members of the group have not passed their opinion on whether health claims should be permitted or not.

1. THE DEVELOPMENT OF AN EDUCATION STRATEGY TO ACCOMPANY ANY HEALTH CLAIMS SYSTEM THAT MAY BE PERMITTED

The group considered one of the recommendations in the report of the process evaluation on the folate pilot as being fundamental to the discussion of this issue, that is, whether health claims are viewed as purely a regulatory mechanism to permit industry to make balanced, substantiated claims or a public health intervention tool. The amount and type of education required to support claims will differ depending on the answer to this question.

The group were opposed to diverting public health resources into health claims, thereby allowing them to potentially overshadow other public health priorities. However, it was suggested that health claims could be used as another tool to support current and future public health initiatives. In addition, there needs to be a partnership between the public sector and industry.

The group considered that education could not solely be left to industry because: Industry has already indicated that they are not prepared to fund education on generic claims. They believe this should be a government responsibility. They do however believe that they should carry out education on specific health claims.

There is a difference between education campaigns and advertising. Industry invests a lot in the latter but not the former.

Industry know how to sell individual products but this is not the same as promoting the role of individual products in the context of the total diet.
2. **EDUCATION INITIATIVES AND METHODS OF DELIVERY OF MESSAGES ABOUT HEALTH CLAIMS**

Stages in promoting health messages:

Consumer reads health claim + information on label

↓

Consumer recalls information

↓

Consumer understands information correctly *

↓

Consumer is motivated to intend to change

↓

Consumer buys product

↓

Food habits change

↓

Nutrient intake changes

↓

Biochemical markers give evidence of change

↓

Health outcomes

* Alternatively, the consumer could misunderstand the information, leading to consumer anxiety, longer shopping, stress, diet distortion, trade-offs.

2.1 **The potential risks associated with health claims are that they:**

- may encourage trade-offs: consumer buys a low fat biscuit but continue to have other high fat items in the diet e.g. ice-cream;
- may lead to diet distortions: consumers limit the variety in their diet as they believe they can get all they need from one product and/or the consumer believes can get all of the nutrients they need from processed foods and eliminate fruits and vegetables;
- may promote consumer anxiety;
- may place greater emphasis on diet than on other factors e.g. lifestyle, smoking; and
- may lead to micronutrient imbalances: too much of one nutrient can create deficiency in another.

Whether or not a health claim has the capacity to distort an individual’s diet is also dependent on the following contributing factors:
• susceptibility
• severity;
• benefits;
• barriers;
• self-efficacy;
• stage of change individual is at; and
• cues to action.

2.2 How education should be done:

The group considered that education could not just be in the form of pamphlets. There would be a need to tap into existing education systems, such as:

• curriculum of schools;
• training colleges;
• education of health professionals – nurses, doctors, dietitians;
• popular media – TV, internet;
• existing media programs;

There is a need to use creativity in exploring options for education. It was suggested for example that teaching videos could be developed in conjunction with the New Zealand Institute of Food Science and Technology and the Australian Institute of Food Science and Technology.

The group considered that education must be tailored to both countries and there may need to be different messages/initiatives in New Zealand to Australia. It was also recognised that these education initiatives may not be very appropriate for the minority populations in both Australia and New Zealand, that is Maori and Pacific people (New Zealand) and Aboriginal and Torres Strait Islander peoples (Australia) and this would also require special consideration.

Option 1
The minimalist approach – i.e. health claims as a regulatory mechanism to allow industry to make balanced, substantiated claims.

The group believed that this approach should be limited to strategies to prevent health claims doing any harm, in accordance with the primary objective of ANZFA, that is, the protection of public health and safety.

In order to prevent harm as outlined above, the group recommended that there needs to be education on:

• general information on what health claims are and what they mean (include list of approved claims, update as reprinting of pamphlets is needed, government promotion of dietary guidelines and healthy eating guides to provide context). However, education should not solely focus on health claims. The focus should be to how to read food labels, of which health claims are a part;
• how to use the information but not distort diets;
• the importance of dietary variety; and
• industry to undertake their own education on each claim e.g. heart disease and cancer.
Option 2
The maximum approach – i.e. health claims as a public health intervention.

This approach would involve all the education strategies outlined under the minimalist approach as well as incorporation of the claims, where appropriate, into the current public health initiatives of government and non-government organisations. It was felt that current and future public health initiatives would be able to incorporate most of the generic health claims (because they would most likely be those that support dietary guidelines, as happened in the US). For example, the Strategic Inter-governmental Nutrition Alliance (SIGNAL) is starting a promotion of fruits and vegetables, so a health claim on fruits and vegetables and cancer, for example, could be incorporated into this initiative; or cancer may also be of interest to non-government organisations with a cancer or heart focus.

The aim of this approach is that education is not solely on health claims, but that it is part of broader education on the role between diet and disease as a whole. The group suggested that a checklist be developed that outlined what activities could be undertaken as part of incorporating health claims education into an effective education campaign. They suggested that it be developed from the recommendations of the 1997 working group’s recommendations for running a campaign for dietary change. However, they suggested that these recommendations needed to be expanded and updated.

The extent of the activities in this option could differ depending on the resources available for educating consumers on health claims. The group did not want specific education campaigns solely focussing on each of the health claims. If greater resources were available, they felt it was better to put these resources into more active promotion of existing priorities and activities rather than separate education campaigns.

3. THE DEVELOPMENT OF A COMMUNICATION STRATEGY TO ACCOMPANY ANY HEALTH CLAIMS SYSTEM THAT MAY BE PERMITTED

3.1 Communication strategies to accompany health claims

The following options were presented to the group:

- Option 1: Mandate the words of health claims. Use focus group for each health claim to determine the most effective claim.
- Option 2: Mandate the words of health claims, with no prior consumer testing.
- Option 3: Mandate certain required elements of the claims. Allow food companies to develop their own wording that incorporates these required elements (this was the system used in the folate pilot).
- Option 4: Food companies develop their own wording – no mandated elements.

The group believed that consumer testing of the understanding of each health claim was essential. This would be an important part of preventing consumer harm; testing their understandings/misunderstandings and likely changes in consumer behaviour. They also felt that food companies had to be given some flexibility in the wording of their claims. Therefore they supported option 3, mandating certain required elements of the claim, with the added proviso that there was focus group testing to determine the efficacy of the mandated elements.
It was considered that consumer testing of each claim would be very expensive. However, the group were adamant that at this point in time we did not have the research/knowledge necessary to be able to mandate certain elements without consumer testing on each claim. It was suggested that this position could be reviewed after consumer testing had been undertaken on the first few claims, to see if there were common elements that meant principles could be developed from which an expert group could develop the mandated elements.

The importance of a range of target groups and sufficient numbers for the consumer testing was emphasised. It would also need to be carried out in both Australia and New Zealand. A range of quantitative and qualitative methods could be used. Focus groups would need to be used for the development of educational materials.

3.1.1 *A logo for food products carrying approved health claims.*

The testing undertaken as part of the development of a logo for the folate pilot found that consumers liked the idea of a product carrying an endorsement from a credible authority. Therefore, an ANZFA endorsed logo was designed for products approved by ANZFA to carry the health claim.

The group considered that a uniform logo should be designed for authorised health claims. The group was unanimous that it should be ANZFA who was the endorser. They wanted ANZFA since it was a food authority and does not have the word “health” in the name. However, they did not feel ANZFA could just take out the word folate from the folate pilot logo and use this logo. It was felt that the word endorsed should not be on the logo, especially if there was not product-by-product approval. The logo would need to be tested in focus groups.

Focus group testing on the folate logo suggested that some education around who ANZFA was is also necessary if an ANZFA logo was to be used. The group supported this and commented this should be could be part of the wider education campaign for health claims and ANZFA’s priorities generally.

3.2 *Strategies for establishing and monitoring the communication effectiveness of health claims*

The group believed that there is a need to ensure that consumers are understanding health claims and they are not distorting diets. Focus groups should be carried out after health claims are widely available on the shelves to provide an indication of consumer interpretation. There may be a need to modify the mandated elements of the claims in light of this research. It may also be necessary to mandate the wording of the claim if there seems to be consumer confusion over the wording of the claims. This would need to be done before national surveys on consumer knowledge, attitudes and behaviour.
ANZFA Expert Advisory Group on Education and Communication Strategies to Accompany Health Claims

Membership

Ms Sue Jeffreson, ANZFA (Chair)
Ms Catherine Deeps, SIGNAL and Department of Health and Aged Care
Ms Claire Harrison, Australian Nutrition Foundation
Ms Cathy Campbell, Health Department of Western Australia
Mrs Winsome Parnell, Nutrition Department, University of Otago
Dr Karen Webb, Department of Public Health and Community Medicine, Department of Biochemistry (Human Nutrition), University of Sydney
Ms Jenny Yee, Public Health Nutritionist
Checklist – activities to be undertaken as part of incorporating health claims into an effective education campaign

**Phase 1**
Increasing people’s awareness and knowledge of health claims as being credible and a useful tool for making informed food choices when used in association with dietary guideline messages.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>System (whose responsibility?)</th>
<th>Individual claim (whose responsibility?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Official Government Ministerial launch of the health claims system outlining the importance of health claims in association with national dietary guidance messages and increase its awareness among consumers of its value as a believable food labelling communication tool.</td>
<td>Yes (ANZFA)</td>
<td>No</td>
</tr>
<tr>
<td>Media coverage, involving television advertising, women’s magazines and the daily press, appropriately targeted towards target audiences.</td>
<td>Yes (ANZFA)</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Radio, including in-store radio, and television coverage to promote health claims as being believable messages, and individual claims.</td>
<td>Yes (Supermarkets, industry, ANZFA, partnerships with health and community organisations)</td>
<td>Yes (Supermarkets, industry, partnerships with health and community organisations)</td>
</tr>
<tr>
<td>Widely distribute print material, such as brochures, point-of-sale education materials (e.g. posters, recipes, banners), an eating guide (e.g. providing tips about how to include various foods in a healthy diet using both health claims and the food selection guide), articles in magazines.</td>
<td>Yes (Supermarkets, industry, ANZFA, partnerships with health and community organisations)</td>
<td>Yes (Supermarkets, industry, partnerships with health and community organisations)</td>
</tr>
<tr>
<td>1-800 phone line for consumer queries and support.</td>
<td>No</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Distribution of an A4 size poster depicting health claim examples to all school age children, and also to all general practitioners, and supermarkets.</td>
<td>Yes (Information on health claims developed by ANZFA, distributed by relevant groups)</td>
<td>Yes (Information on each claim developed by industry)</td>
</tr>
</tbody>
</table>
Phase 2: Motivating people to use information on food labels, including health claims and the nutrition information panel, to help make informed food choices which would result in a healthy diet.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>System (whose responsibility?)</th>
<th>Individual claims (whose responsibility?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development of motivational messages for use on print materials, point-of-sale materials, and in electronic media.</td>
<td>No</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Incorporation of motivational messages into a 1-800 phone line for consumer queries and support.</td>
<td>No</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Building of motivational messages into teacher training practices in schools, e.g. in-service training of teachers to help them to work out how to further incorporate nutrition messages into existing national and local classroom curricula.</td>
<td>No</td>
<td>Yes (Industry + relevant community and health organisations)</td>
</tr>
<tr>
<td>Key personnel from nutrition education organisations would be assisted through in-service training to integrate motivational activities into their educational agendas.</td>
<td>No</td>
<td>Yes (Industry + relevant community and health organisations)</td>
</tr>
</tbody>
</table>
Phase 3: Helping people to develop skills which would facilitate dietary change.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>System (whose responsibility?)</th>
<th>Individual Claims (whose responsibility?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-store promotions of health claims</td>
<td>Yes (ANZFA)</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>In-store food preparation demonstrations, directed towards showing appropriate selection and preparation of foods based on dietary guidance principles.</td>
<td>No</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Development of slide sets/scripts/videos for health professionals to use in consumer presentations about health claims and their implications around each state.</td>
<td>Yes (relevant community and health organisations in conjunction with ANZFA)</td>
<td>No</td>
</tr>
<tr>
<td>Development of slide sets/scripts/videos for teachers to help children develop skills in food labelling.</td>
<td>Yes (Relevant community and health organisations in conjunction with ANZFA. Could be sponsored by industry)</td>
<td>Yes (Industry + relevant community and health organisations)</td>
</tr>
<tr>
<td>Write and publish articles for inclusion in professional “broadsheets” and newsletters - e.g. Medical Observer, DAA, Public Health newsletters.</td>
<td>Yes (ANZFA to coordinate)</td>
<td>Yes (Industry)</td>
</tr>
<tr>
<td>Target primary health care settings, e.g. general practitioners, family planning clinics, antenatal clinics, and community health services. Strategies could include: - Brochure distribution - “Short” assessment and advice package describing key aspects of dietary behaviour, and providing examples of how to apply these principles to the task of informing and motivating consumers to effectively use health claims information to make informed food choices.</td>
<td>No</td>
<td>Yes (Industry + relevant community and health organisations)</td>
</tr>
</tbody>
</table>
Appendix 4 - Report from the Expert Advisory Group on Monitoring and Evaluation Strategies to Accompany Health Claims

The terms of reference of the monitoring and evaluation working group were to provide advice to ANZFA on:

1. the extent of monitoring and evaluation that should accompany a health claims system, should health claims be permitted;
2. the preferred option for monitoring and evaluation of consumer knowledge, attitudes and behaviour in relation to health claims, should health claims be permitted;
3. roles and responsibilities of public and private sector agencies in monitoring activities;
4. how frequently monitoring and evaluation tasks would need to be undertaken; and
5. strategies for the periodic review of all health claims in the light of changing nutrition and knowledge; and
6. guidelines for monitoring changes in the public health nutrition infrastructure.

The membership of this group is outlined in Attachment 1 of this Appendix.

It needs to be noted that the group were asked to provide advice on the monitoring and evaluation strategies to accompany health claims on the assumption that health claims would exist. Members of the group have not passed their opinion on whether health claims should be permitted or not.

1. MONITORING OF INDIVIDUAL CLAIMS

The group agreed that the type of monitoring that needs to occur would differ depending on the answer to the fundamental question posed in the process evaluation report: whether health claims were viewed as a regulatory mechanism within which food companies could make balanced, substantiated claims or whether health claims were seen as a public health intervention. In the case of regulatory mechanism, a minimum level of monitoring which related to health protection may suffice, but in the case of a public health intervention tool, the scope of monitoring would need to be more comprehensive.

There was a general discussion about whether health claims could actually have an explicit public health benefit. It was the view of some members of the group that they would not.

The group considered the minimum amount of monitoring that should be undertaken to be the minimum that could be done to check that health claims were not causing harm, since the primary function of ANZFA in developing and varying food standards is the protection of public health and safety.

In terms of the scope of monitoring that should occur to assess the public health impact of claims, the group decided to approach this problem by describing the stages of change that would occur once a claim was approved. As presented, the pyramid provides a framework for discussing stages of change for both regulatory and public health purposes.
The group considered that issues of significance may occur all along the continuum and there is a need to monitor these in order to prevent harm occurring. It was considered that the way in which to define a minimum and maximum monitoring approach was to define a minimum and maximum set of questions/issues to be monitored for each element of the spectrum. This is given in Attachment 2 to this Appendix.

The group considered it essential that there are random audits to check that the product actually contains the minimum/maximum amount of the claimed nutrients. However, the group wanted it noted that there were logistic issues with this. For example, a reliable method for measuring folate in foods in New Zealand has not been established and analysis is very expensive.

They also felt it was essential that consumer testing occurred at the time that the health claim statements were developed. The consumer testing needs to occur before the health claim wording is finalised so that it is written in such a way that is meaningful to consumers.

1.2 How the monitoring of individual claims should be carried out

1.2.1 Options for monitoring and evaluating the consumer impact of health claims

The group were presented with the following options:

Option 1: National surveys designed to evaluate the impact of health claims on consumer knowledge, attitudes and behaviour.

The group felt this option was not feasible if the aim was to prevent consumer harm, due to its large cost. If the aim was public health improvement this would be the preferred option.

Option 2: Incorporation of questions on health claims into national surveys.

This would be the preferred option if the minimalist approach was taken, to prevent harm. The concern was raised that there is only limited capacity to add questions to national surveys and it was possible that all the space available for inclusion of questions on nutrition may be taken up by health claims which would not be desirable.

Option 3: Incorporation of questions on health claims into current state surveys and New Zealand.

This option was not discussed by the group.

Option 4: No nationally coordinated system for monitoring and evaluating health claims. Any monitoring to be carried out by food companies.

The group were unanimous we could not just leave the monitoring to industry.

Option 5: No system for monitoring health claims.

This option was opposed by the group.
1.3  **General comments**

The comment was made that industry should contribute to the costs of monitoring, because industry is the primary beneficiary. It was noted in the process evaluation report that industry were happy to pay for the monitoring of specific claims where they had an exclusive market benefit, but they would not pay for the monitoring of generic claims. Industry consider that generic claims support dietary guidelines and are therefore the responsibility of government to monitor.

It was pointed out that if there were a large number of claims, and questions in detail on each, there could be too many questions on claims in a survey and people could answer as they think they should rather than honestly. The group suggested that there would be a need to limit the questions asked and change the order in which the questions appeared in a survey. All claims would not be able to be monitored in every survey. It was suggested that the monitoring may not need to be ongoing – it may be possible to monitor consumer knowledge, attitudes and behaviour in relation to a specific claim only once. There would also need to be a group convened to decide on how extensive the monitoring would be for each claim. There would be a need for more in depth questions if the aim was to monitor public health improvement.

The group noted that if the survey method was a random telephone survey, many of the Pacific Island population in New Zealand did not have a telephone. In addition, research had found that many Pacific Island people did not make a connection between diet and health.

1.3.1  **Industry data**

In the folate pilot, a form was filled in by all food companies participating in the pilot to provide information about sales and composition of their product. This would only be useful in a health claims system as a whole if product-by-product approval was continued.

It was pointed out that in New Zealand there is a therapeutic database used to track fortification. It is a system where food companies are asked to notify of any changes to their products. Such a register could be extended to include health claims, or a separate database set up. The problem with a voluntary register is ensuring all products are listed. Therefore, there would need to be some spot checking in supermarkets of the completeness of that register. The group suggested a system of random post-market audits. As part of this, there would be a check that products carrying a health claim were listed, as well as a check on the veracity of their nutrient composition and labelling.

1.3.2  **The roles and responsibilities in monitoring the effectiveness of claims.**

The group felt that monitoring could not be left to individual food companies. However food companies needed to contribute to the funding of monitoring health claims.

2.  **MONITORING THE SYSTEM AS A WHOLE**

The group suggested that there needs to be an annual report on the impact of health claims, pulling together the monitoring on each claim. It was felt that an independent group should do this report. In a sense it will be an audit of what ANZFA has permitted, and therefore ANZFA should not undertake to do this.
However, ANZFA could coordinate the data collection process and pass on this information to whoever was carrying out the monitoring process. It was suggested that if a database was set up in the first year it may decrease the work in consecutive years.

It was noted that the Australian Food and Nutrition Monitoring Unit at the University of Queensland were well equipped to take on the role of monitoring health claims. The Department of Health and Aged Care currently support a wide range of public health monitoring activities through the Australian Food and Nutrition Monitoring Unit and Australian Institute of Health and Welfare and therefore should be consulted. Ms Watts noted that the Ministry of Health has responsibility for monitoring in New Zealand, and already carries out some general nutrition and health status monitoring and this information could be used in the monitoring of health claims, where appropriate. The problem was noted that if different groups collated the results in different countries, it might be hard to get consistency in the collation and reporting.

Some members felt that a strategy needs to be developed to monitor the effect of the system as a whole. Particular questions to be answered are:

- whether health claims have contributed to the medicalisation of the food supply;
- the profile of medical versus public health type messages;
- the impact of the change in policy on public health and the integrity of the food regulation system. For example, allowing orange juice to be fortified with calcium, when the general recommendation was to eat low fat dairy products for healthy bones;
- whether allowing health claims leads to consumer confusion and anxiety and therefore created scepticism about public health initiatives?;
- whether people change their eating patterns as a result of health claims in undesirable ways;
- whether health claims use up time and resources that should be devoted to other public health initiatives?; and
- interpretative food regulatory system – the cost versus the overall benefit of health claim in dollars.

In order to look at these questions, baselines need to be established before health claims are permitted. There then needs to be a broad evaluation 5 years after claims are introduced.

2.1 Whether there is a need for the periodic review of all health claims in the light of changing nutrition and knowledge

It was pointed out the substantiation working group had considered this issue and suggested that a sunset clause apply that claims be reviewed in the light of new evidence every 4-5 years. The group were concerned it would decrease consumer confidence if claims that were approved that were later withdrawn. Ms Jefferson pointed out that it was really only a safeguard, that a health claim would not be approved if there was not a substantial body of evidence to support it.
ANZFA Expert Advisory Group on Monitoring and Evaluation Strategies to Accompany Health Claims

Membership

Ms Sue Jeffreson, ANZFA (Chair)

Dr Katrine Baghust, Department of Human Nutrition, CSIRO

Ms Jacinta Dugbaza, Primary Prevention Unit, Department of Health and Aged Care

Mr Mark Lawrence, School of Health Sciences, Deakin University

Dr Geoff Marks, Nutrition Program, University of Queensland

Mrs Winsome Parnell, Nutrition Department, Otago University

Dr Karen Webb, Department of Public Health and Community Medicine, Department of Biochemistry (Human Nutrition), University of Sydney

Ms Carolyn Watts, Ministry of Health, New Zealand
Appendix 5 - Health Claims meeting with SIGNAL

15 FEBRUARY 2000

Background

SIGNAL members were provided with background reading prior to the workshop (Attachment 1) and were asked to consider a range of questions focusing on education of consumers and monitoring of health claims and their use.

ANZFA contracted Maree Davidson to help facilitate the workshop. The demands of juggling an overcrowded SIGNAL agenda resulted in the workshop running for less than five hours rather than the six hours planned for. The workshop agenda was modified accordingly.

Purposes

In acknowledging the key roles played in public health nutrition by SIGNAL and its members, ANZFA was keen to gain input about health claims at both a general and specific level. More particularly ANZFA was looking for feedback on:

- the conditions under which SIGNAL might support the introduction of health claims
- the role SIGNAL might play in relation to health claims
- practical suggestions around education of consumers and monitoring of health claims

Program

There were three components of the workshop. The first part comprised a general discussion around health claims and required SIGNAL members to address the following:

- Relevance of health claims to SIGNAL and its public health nutrition agenda.
- The introduction of health claims primarily as a regulatory mechanism or as a public health measure.
- Beneficiaries of the introduction of health claims. Is it community, government or industry?
- Canvassing the advantages and disadvantages of health claims from a public health perspective.
- Identification of opportunities and risks related to public health nutrition.
- Consideration of how health claims can be built into the public health nutrition system and other public sector activities.
- Conditions under which SIGNAL would support the introduction of health claims, e.g. would industry funding make a difference?
- Discussion of an appropriate framework to manage health claims (referring to the framework developed for the folate pilot).

The second part of the program dealt with prerequisites for approval, responsibility and options for education around health claims. A small-group exercise requested that participants consider and report back on the following:
- What constitutes education and communication around health claims, including how extensive it needs to be and how it needs to be managed? A list of suggestions was included based on experience from the folate pilot, overseas experience and input from previous ANZFA working groups.
- Who is best placed or should be conducting this?
- Revisit the options put forward by the ANZFA health claims education group for educating consumers. Which option does your group prefer? What needs to be set in place to make it a reality?
- What could or should SIGNAL’s role be in education and communication related to health claims?

The third session focused on monitoring and evaluation. As with the education discussion participants were asked to focus their attention on what needs to be done, who needs to be doing it, how it should be managed and the role SIGNAL feels it should or could play. Also tabled for discussion but not reached because of lack of time was the issue of the process or procedure for evaluation of claims in light of new scientific evidence.

**Summary of Report of Discussion**

**Part 1 - General Discussion**

1. **SIGNAL’s Interest in the Introduction of Health claims.**

   It was noted that although SIGNAL was providing opinions on how best to educate consumers and monitor claims, this should not be taken as a sign of SIGNAL’s support or otherwise for health claims.

   Opinion within the group varied across jurisdictions and personal opinion however there was agreement that SIGNAL is interested in health claims. As a group charged with responsibility nationally for public health nutrition, SIGNAL must have a demonstrated interest.

   Unless SIGNAL is proactive it is likely to find itself in the position of having to respond to a situation rather than actively deciding whether or not it wants health claims. Industry and political pressure indicates that health claims may be introduced. SIGNAL’s discussion proceeded on this basis.

2. **Health claims - A Public Health Intervention Tool or a Regulatory Mechanism?**

   SIGNAL members felt that the potential for health claims as a public health intervention is limited. In fact, rather than provide opportunities for promoting healthy eating choices, there is probably more potential for health claims to do harm in the event that consumers are not informed and educated, e.g. they may be tempted to reduce their choices by selecting only products carrying health claims labels. Also confusion may arise about the relative nutritional value of the product. The introduction of health claims therefore needs to be seen in terms of a public health intervention at the very minimum to reduce potential harm.

   The possibility was raised of SIGNAL or other public health nutrition groups making application for claims in line with The Dietary Guidelines and public health nutrition priorities, e.g. fruit and vegetables. A further suggestion was made to include a checklist as part of the application process.
This checklist would inquire both about the significance of the disease stated in the claim in the Australian / New Zealand context and the potential of the use of the claim for public health benefit. The objectives of the ANZFA Act relating to the protection of the public health and safety, the provision or adequate information relating to food to enable consumers to make informed choices, & the prevention of misleading or deceptive conduct were considered to be a good starting point.

3. **Canvassing the Issue**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Risks</th>
<th>Opportunities for Public Health Nutrition</th>
</tr>
</thead>
<tbody>
<tr>
<td>If claims were in the context of comprehensive promotion strategy they could support health initiatives</td>
<td>Could promote a move away from variety of foods</td>
<td>Confusion of roles and responsibilities within states and territories, e.g. between nutrition units and enforcement units</td>
<td>May increase political support for nutrition more broadly</td>
</tr>
<tr>
<td>There is potential to promote good public health nutrition</td>
<td>Could promote inequity, e.g. a situation where health claim products are more expensive.</td>
<td>Expenditure of resources that may make no real difference</td>
<td>May provide a focus for education of health care workers and consumers</td>
</tr>
<tr>
<td>Existence or tightening the health claims regulations may result in a reduction in transgressions</td>
<td>It could lead to industry bias, e.g. easier to put a label on packaged foods</td>
<td>Enforcement by states is not uniform.</td>
<td>May provide an opportunity to educate about other aspects of nutrition using health claims as a springboard</td>
</tr>
<tr>
<td>It may be possible to leverage other sources of funding, e.g. industry</td>
<td>Substantial cost to government for implementation and management</td>
<td>Prohibition has helped the (TAS) government/industry relationships. The relationship has been forged in the absence of health claims. Their introduction may jeopardise these links</td>
<td>Can point consumers in right direction., i.e. primed to look for products that reflect healthy nutrition choices</td>
</tr>
<tr>
<td>May create opportunity as a branding tool for primary produce</td>
<td>May not be able to ensure all claims relate to foods the public health nutrition community wants to promote</td>
<td>Potential modification of products in line with public health nutrition priorities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Could devalue nutrition claims</td>
<td></td>
<td>Possible to incorporate claims about fruit and veg into current plans and to promote these more broadly</td>
</tr>
<tr>
<td></td>
<td>May raise anxiety about the link between food and disease - leading to consumer confusion regarding food and health</td>
<td></td>
<td>Could increase or shift focus of monitoring and evaluation activity</td>
</tr>
<tr>
<td></td>
<td>May lead to diversion of resources and expertise away from other important activities</td>
<td></td>
<td>Could lead to more positive collaboration with industry and between NGOs and industry</td>
</tr>
</tbody>
</table>
The exercise to canvas the health claims issue from a public health nutrition perspective led SIGNAL members to discuss recommending to ANZFA a set of generic claims. This could include claims relating to fruit and vegetables and grains. Claims could be prioritised according to public health nutrition priorities. It was felt that government could be in a position to pay for the costs associated with these high priority claims. Should SIGNAL propose a health claim then the requirements of any management framework, such as substantiation, would need to be satisfied. SIGNAL members suggested the introduction of two or three claims each year. An industry funded mechanism could then be considered for introducing specific health claims.

4. **Framework for Health claims**

The framework developed for the folate pilot was discussed. There was support for the elements of the framework particularly if the checklist suggested earlier (in fact congruent with ANZFA's objectives) was applied as part of the substantiation stage and if each element can be undertaken properly, i.e. adequate resources are available.

Participants expressed the need for the monitoring and evaluation section to be extended to include a review process.

**Part 2 - Education**

1. **Prerequisites and Responsibility**

Most SIGNAL members felt that approval of health claims should be contingent on accompanying education. There was a range of views expressed on who should be paying for and responsible for educating consumers. This depended on the type of claim and the aspect, e.g. ANZFA is responsible for educating about health claims and labelling generally, government may pay for generic claims and industry for specific claims.

2. **Management Strategy**

In its report back, one group suggested that SIGNAL establish a standing sub-committee which would include others with expertise. This sub committee would take a significant role in determining the type of educational activities that should occur for each claim.

There is a need to develop a set of principles for best practice education acknowledging that the public sector is interested in health promotion outcomes while the private sector is interested in marketing or profit outcomes.

SIGNAL could formulate the guidelines and oversee the development of education materials while industry funds and implements the education programs.
3. **Content and Extent of Education**

The two groups tackled this question in different ways. Group 1 was specific about the content which should cover:

- population group
- dosage (serve size)
- health benefits
- possible risks
- context of a balanced diet

Group 2 felt that the type and extent of education would depend on the health claim and also on the current state of awareness amongst consumers of the health claim being made, i.e. if it is well known there may be less need to educate.

Group 2 expressed the need for a minimum step prior to approval to demonstrate that the claim will do no harm. More specifically they wanted to test consumer understanding in a way similar to an impact evaluation. This arose from discussion around the need for education to ‘prevent harm’ as well as to promote public health messages. Discussions confirmed the view that education is required to tell consumers about health claims and how to interpret these (an ANZFA responsibility).

4. **Options for Educating Consumers from a SIGNAL Perspective**

Three options were presented for groups to discuss

Option 1 A nationally coordinated education strategy, specifically for each health claim along with specific education campaigns for food companies.

Option 2 Incorporate the national education campaign for health claims into current public education initiatives, along with specific education initiatives by food companies.

Option 3 No education campaign to inform consumers about health claims. The onus will be on food companies to carry out appropriate educational campaigns

Variations on Option 2 were preferred by both groups. Alternate suggestions from SIGNAL were:

a) Establish a management structure, that included a standing sub-committee of SIGNAL as reported.

It was acknowledged that this would require significant funds.

b) SIGNAL carries on with its own priorities. In the case that health claims education fits into SIGNAL and jurisdiction priorities, then it would be incorporated as part of a mix of appropriate activities.
ANZFA is to educate on label changes.

ANZFA is to ensure industry undertake education programs with consumers. Specific requirements for health claims applicants should include consumer testing and ongoing monitoring.

5. **Responsibility**

Concern was expressed at the limitations of SIGNAL in terms of time and resources to take an active role.

Participants felt that SIGNAL needs to keep within its own priorities incorporating health claims education where appropriate and convenient, e.g. as part of Eat Well Australia and SIGNAL campaigns such as Fruit & Vegetables. SIGNAL indicated that it still needs to formulate its fall back minimum stand on what it would be prepared to do, regarding education.

**Monitoring**

1. **What Needs to be Monitored?**

There was agreement from the large group that all three areas outlined need to be monitored, i.e.

1. The sales and composition of products carrying health claims
2. Consumer knowledge, attitudes and behaviour
3. Shifts in food consumption and supply

Discussion around monitoring indicated that the following needed to be taken into consideration:

- information as to the number and type of products carrying the claim
- pre-testing the potential of health claims with consumers
- identification of who is consuming health claim labelled products
- monitoring of positive to negative shifts in composition and supply issue

2. **Staging of Monitoring**

Two aspects of staging were discussed. The first is the need to have sales and composition data around products carrying health claims. Also needed is an understanding of consumer knowledge, attitude and behaviour before being able to identify shifts in food consumption and supply. It was noted from the experience of the folate pilot that not enough happened in 1) to justify 2) and 3) of the areas outline above.

The second aspect is the need for staged criteria. It may be wise to begin with process evaluation of sales and consumption of products carrying health claims and then to consider:

- health outcomes in the longer term
- biochemical indicators pre and post introduction and association between indicator and the health claim
3. How to Monitor

SIGNAL recommended a National Nutrition Survey every five years in both countries, perhaps managed by AIHW or an independent body. This would need to be funded.

SIGNAL members considered five options for monitoring health claims.

Option 1: A national survey designed to evaluate the impact of health claims on consumer knowledge, attitudes and behavior

Option 2: Incorporation of questions on health claims into a national survey. (NB: there is currently no regular national survey)

Option 3: Incorporate questions on health claims in current state surveys

Option 4: No nationally coordinated system for evaluating health claims. Any monitoring to be carried out by food companies.

Option 5: No system for monitoring health claims.

Of these options SIGNAL supported Option 2 - Incorporation of questions on health claims into a national surveys; and Option 3 - Incorporation of questions on health outcomes in current state survey. However the former is only possible with substantial funding. The latter is a possibility if consistency could be achieved in sampling, time of year etc. SIGNAL is working on this as part of Eat Well Australia.

4. Role of SIGNAL

SIGNAL could provide advice on management of the process and could oversee the exercise. This might mean representation on a management committee and opportunistic involvement.

Summary

- SIGNAL is interested in health claims from a public health perspective - as much in order to prevent harm as to promote health (as an intervention health claims can only make a small contribution).
- Resourcing the introduction and implementation of health claims is a major issue. Establishing and managing the framework and processes appropriately is contingent on adequate resources.
- SIGNAL may well be best to keep strictly to its own public health agenda, picking up relevant health claims as they occur and incorporating activity around them into SIGNAL’s (and jurisdictions) agenda.
- SIGNAL could apply to register the first health claim for fruit and vegetables.
- SIGNAL is well positioned to take an advisory and overseeing role in education and monitoring to protect and promote the public health interest
The United States

In 1990 the United States government introduced the Nutrition Labelling and Education Act (1990) (NLEA), which was an effort by public policy makers to improve communication to consumers regarding the effects of dietary choices on their health. The NLEA proposed extensive changes to food labelling, including mandatory nutrition labelling for most foods, standardised serving sizes, and uniform use of health claims.

The US Food and Drug Administration (FDA) issued the final regulations implementing the NLEA in 1993 with the majority of regulations, including those concerning health claims, becoming effective on 8 May 1993. Those regulations pertaining to nutrition labelling and nutrient content came into effect one year later.

The health claims that were authorised under the NLEA are statements that describe a relationship between a food substance and a disease or other health-related condition. The law mandates that a health claim be authorised in the labelling of FDA-regulated products only if "based on the totality of evidence significant scientific agreement" exists about the validity of the relationship described in the claim.

During the development of the NLEA the US Congress directed the FDA to initiate and evaluate the scientific support for 10 specific food substance-disease relationships. These relationships were:

1. fat and cancer
2. fibre and cancer
3. fat and heart disease
4. fibre and heart disease
5. sodium and hypertension
6. calcium and osteoporosis
7. antioxidant vitamins and cancer
8. folic acid and neural tube defects
9. zinc and immune function in elderly individuals
10. omega-3 fatty acids and heart disease (Farley, 1993).

Ultimately, only the first seven relationships were authorised by the FDA for health claims. The zinc-immune function and omega-3 fatty acids-heart disease relationships were not authorised for health claims due to lack of reliable data supporting such relationships in the scientific literature (Farley, 1993). The folate-NTD claim was subsequently authorised in 1996 in addition to a claim about dietary sugar alcohol and dental caries claims. In 1997, a claim relating the soluble fibre in whole oats to a reduced risk of heart disease was authorised. This was revised in 1998 to include soluble fibre from psyllium seed husks. FDA has also recently authorised claims on the relationship between soy protein and heart disease and wholegrain and heart disease and cancer.
Soon after the passage of the NLEA questions arose about the FDA's implementation of the Act, particularly with respect to health and nutrient content claims among other issues. In 1993 the Keystone Centre was asked to convene a Dialogue among stakeholders so that these issues could be discussed and recommendations for future action made. The Keystone Centre is a non profit public policy, science and education organisation. Its primary mission is to resolve conflicts and facilitate mutual understanding and education among diverse parties. The final report of this Dialogue, which involved 65 individuals and continued for 2 years, was published in 1996 (Keystone Centre, 1996).

The goals of the Dialogue were to identify and propose recommendations for public policy that in the context of a healthful diet:

- promote the consumption of currently available foods that advance health;
- promote the development of foods that advance health; and
- better enable consumers to make informed food choices.

The findings and recommendations of this report, along with other relevant research about health claims, provides the basis for Australia and New Zealand to explore the aspects of health claims and their implementation that have worked in the US, and those that have not, from the perspectives of the general community and of the food industry.

In 1997, the Food and Drug Modernization Act (FDAMA) was introduced which allowed food labelling of health claims for food products and nutrient content claims based on an authoritative statement that is publicly available and from a recognised scientific body. This statement has to be an official position; it does not include statements of employees made in an individual capacity. The statement has to be based on a deliberative review and identify a nutrient level to which the claim refers. This had the potential to allow more health claims and decrease the lengthy process of substantiating the health claims when a petition is raised. However, since the FDAMA, there has been approval of only three more diet-disease relationships - soluble fibre and CHD and soy protein and CHD and wholegrain and CHD and cancer.

Regulation

Any interested person may petition the FDA to issue a regulation regarding a health claim. Within 100 days the FDA will notify the petitioner by letter that the petition has been either been filed for comprehensive review or denied. Within 90 days of the date of filing, FDA will by letter of notification to the petitioner deny the petition or inform the petitioner that a proposed regulation to provide for the proposed use of the health claim will be published in the Federal Register. The public then has the opportunity to comment on the proposal. The FDA reviews the comments that are made and makes a ruling as to whether or not the health claim should be permitted. When the FDA determines on the basis of its review of the evidence on a nutrient-disease relationship that a health claim should be authorised, the agency will propose a specific regulation permitting a claim in subpart E of 21 CFR part 101. In the authorising regulation, FDA will set out the requirements to ensure that any claim made under it will fully reflect the scientific facts justifying the claim. These requirements will not only describe the nutrient-disease relationship but will define other relevant factors, such as non-dietary elements (e.g. the need for exercise) and relevant nutrient interactions (e.g. calcium and phosphorus levels in a food).
The regulation will carefully identify the elements that must be included in a claim to assure its validity. In addition, the agency will illustrate the claim that is permitted through an example of an appropriate claim. Firms are not required to use the model claim but are free to develop their own claim within the terms of the regulation (examples of types of claims that are permitted in the US and the required terms and model claims are in appendix 1 pages 19-24). In addition, there are certain qualifying /disqualifying criteria that a food must meet before it may carry the claim (the criteria that must be met for all claims is on page 24 of appendix 1, and the specific food criteria for each claim is on pages 19-24). There is no product-by-product approval required in the US.

**Substantiation**

The following information relates to the specific requirements as outlined by the FDA, that must be met by any interested person making a petition to the FDA to issue a regulation regarding a health claim:

>A summary of scientific data must be provided outlining the basis upon which authorising a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognised scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

"The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such a group and shall include scientific data showing how the claim is likely to assist in meeting such needs."

FDA requests that issues addressed in the summary of scientific data include answers to questions such as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?
2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?
3. Are there certain populations that must receive special consideration?
4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

The FDA also states that the summary should include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption.

It is asked that if the claim is intended for a significant sub-population within the general US population, the analysis should address the dietary practices of such groups, and should include data sufficient to demonstrate that the dietary analysis is representative of such groups.
It is also requested that if appropriate, the petition shall explain the prevalence of the disease or health-related condition in the US population and the relevance of the claim in the context of the total daily diet.

In addition to a summary of scientific data, the FDA also require:

- analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the health claim;
- one or more model health claims that represent label statements that may be used on a food label or in labelling for a food to characterise the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data; and
- copies of any computer literature, articles cited in the literature, any other information relied upon to support the health claim or concerning adverse consequences to any segment of the population, and any other information pertaining to the US population.

Once the FDA receives a petition, a review of the data is undertaken to determine if it will be filed for comprehensive review or denied. If the petition undergoes comprehensive review, the FDA determines if the petition will be denied or published as a proposed rule. If a proposed rule is published, the FDA receives comments about the rule and, based on the comments received, decides whether to authorise a final claim.

In 1997, the Food and Drug Modernization Act (FDAMA) was introduced which allowed food labelling of health claims for food products and nutrient content claims based on an authoritative statement that is publicly available and from a recognized scientific body. This statement has to be an official position; it does not include statements of employees made in an individual capacity. The statement has to be based on a deliberative review and identify a nutrient level to which the claim refers. This had the potential to allow more health claims and decrease the lengthy process of substantiating the health claims when a petition is raised. However, since this act there has only been approval of two more diet-disease relationships – soluble fibre and risk of CHD and soy protein and CHD.

In response to a recent decision of the Court of Appeals for the District of Columbia in the case of Pearson vs. Shalala, the FDA has been asked to prepare a document that gives more guidance as to what constitutes significant scientific agreement. This has lead to the FDA Food Advisory Committee providing a comprehensive report on how the scientific review of data for health claims is carried out and the interpretation of the significant scientific agreement standard.

Canada

Health Canada issued a policy paper Nutraceuticals, Functional Foods and Health Claims on Foods (November 1998), in which it was recommended that structure/function and risk reduction claims be permitted for foods. Two types of health claims are envisaged. The first is a diet-related or generic claim which may be made for any food meeting certain compositional criteria. The second is a product specific claim which relates to the action or effect of the food itself.

In implementing the health claims policy for foods, the Food Directorate of Health Canada is taking a three-part approach:
• To adopt the US generic health claims in the Canadian context; In order to do this, they are reassessing the US generic health claims that were authorised by the FDA to ensure they are consistent with current science and that stakeholders agree they are appropriate in the current context.

• To develop standards of evidence and a guidance document on data requirements for supporting the validity of new health claims for foods. An expert advisory panel of 23 individuals has been set up to advise Health Canada on developing standards of evidence for supporting new health claims. A discussion paper on standards of evidence is being prepared for public comment. A guidance document on data requirements will be published at the completion of the consultation process.

• To develop an appropriate regulatory framework to allow for new generic and product-specific risk reduction and structure/function health claims for foods.

Substantiation

At present, ANZFA has not seen what Health Canada are proposing in terms of their scientific substantiation model. A draft is expected to be released for public consultation in June 2000.

Sweden

Health claims in Sweden are self-regulated by the food industry. The food industry’s self-regulated program consists of rules which govern the use of health claims in the labelling and marketing of food stuffs based on the principle that only health claims founded on generally accepted and well-documented connections between diet and health may be used.

Health claims must be consistent with official Swedish dietary and nutrition recommendations and must be based on scientific facts generally accepted in Sweden. However, health claims based on the fact that a certain product has a specific effect should not be made.

An example of an approved health claim is:
Saturated fatty acids increase the level of cholesterol in the blood. The product X contains low levels of saturated fat and total fat.
Therefore, in effect, these are equivalent to nutrition messages in Australia and New Zealand.

An example of a non-approved health claim is:
Eating X will improve your blood cholesterol level.

Japan

In Japan health claims in the broad sense of the term may only be used with one type of food: Foods for Specified Health Uses (FOSHU). The Japanese Ministry of Health and Welfare issued a decree in July 1991, under the Nutritional Improvement Law, to approve "Foods for specified health use" in response to perceived abuses of the previous non-mandatory food control. The approval includes permission to make certain claims in the food label relating to the benefits to health which consuming the food or drink can be expected to produce. There are also requirements to print warnings regarding intake of some of these foods (for example, a warning on foods containing oligosaccharide that excess intake causes a loosening of the bowels).
Substantiation

In order for a product to be approved as FOSHU, companies need to go through an application process that typically takes about 1 year to complete. Applications must include scientific documentation demonstrating the medicinal or nutritional basis for a health claim, the basis for the recommended dose of the functional ingredient, information demonstrating the safety of the ingredient, information on physical and chemical characteristics, relevant test methods, and a compositional analysis. However, the FOSHU system remains voluntary. Companies can market so-called "health foods" without obtaining FOSHU approval as long as they refrain from making express claims that the product can reduce the risk of a disease or health-related condition.

From 1991 to 1998 only 126 products received FOSHU approval. However approximately 1000 other functional foods have been introduced into the Japanese market-place as health foods. The majority of approved health claims referred to improved gastrointestinal function or were related to preventing dental caries. One claim was for the low allergenicity of a rice product, another food was claimed to be suitable for people with chronic renal disease and another was for the iron content of a soft drink and its role in anaemia. Several claims were related to the cholesterol lowering properties of soy protein. Most of the foods carrying FOSHU claims were soft drinks, candies and sugar.

In Spring of 1998, in order to increase participation in the FOSHU approval system, the government recently made several significant changes to the application procedure. First, the amount of scientific documentation that manufacturers must submit has been reduced. Second, the requirement that all submitted documentation had been reviewed by outside scientific experts has been eliminated. The requirement now is that studies be published in a scientific journal. Third, the manufacturer may carry out their own analytical tests instead of having them done by the National Health and Nutrition Laboratory. Fourth, there is now no expiration date on FOSHU approvals (it was 4 years). The effects of these changes on the number of approvals are unknown as yet.

The Netherlands

The Code of Practice for assessing the scientific evidence for health claims on food and drink products was drawn up on the initiative of the Netherlands Nutrition Centre. The Code gives manufacturers, importers and distributors of food and drink products a means to test the grounds for health claims on food and drink products. Adherence to the Code is voluntary.

Substantiation

The scientific evidence for a health benefit is assessed by an independent panel of experts at the request of the party using or intending to use the health claim for the marketing of a product. The party using or intending to use a health claim is charged an assessment fee. The scientific evidence for a health benefit is assessed using the following criteria:

- The quality of the evidence - the evidence must be based on relevant scientific data on human subjects. The evidence must apply to a product or product group. Evidence proving the effectiveness of an ingredient or substance only will not be accepted;
• Relevance to the target population. The data must concern normal use by the target population and the product must carry a health benefit relevant to the target population; and
• The health benefit must not clash with dietary guidelines.

The panel assesses an application to make a health claim within three months of the application being received. The panel always attempts to reach a unanimous decision. On failing to do so, the panel bases its decision on a majority vote. Those panel members whose agreement did not agree with the majority view, may explain their decision in the final report.

South Africa

South Africa is currently deciding whether or not to adopt the United States FDA approved health claims.

The United Kingdom

The Food Safety Act of 1990 prohibits claims that "a food has the property of preventing, treating or curing a human disease or any such reference to such a property". Health claims which relate to the bodily effects of the food or its components, such as "can aid digestion" are generally permitted in the UK, provided they are true and do not mislead the consumer.

In 1996, the Food Advisory Committee (FAC) of the Ministry of Agriculture, Food and Fisheries (MAFF) circulated draft guidelines on health claims for foods. The guidelines were however put on hold pending the 1997 elections and never finalised. In 1997, the Food and Drink Federation and the National Food Alliance and Local Authorities Coordinating Body on Food and Trading Standards established the Joint Health Claims Initiative (JHCI). A final publication of a voluntary Code of Practice on Health Claims on Food with respect to both labelling and advertising is expected soon. The purpose of the joint code is to provide guidance on permissible claims for foods providing health benefits so that the claims do not constitute prohibited medicinal claims. The proposed code also provides guidelines on the level of evidence needed to substantiate health claims. It would permit claims "based on a systematic review of all the available scientific evidence relating to the validity of the health claim including published scientific literature". It should be noted that the prohibition still remains on foods claiming to prevent, treat or cure diseases.

Substantiation

Under the proposed code, a Code Administration Body would be established to provide pre-market advice to companies wanting to make health claims, and companies would be strongly advised to seek such advice before making a health claim. An Expert Authority would also be established to assess the scientific evidence companies submit in support of innovative claims. It would determine, prior to launch, whether a claim was substantiated or not. The problem is that the code is just a "voluntary agreement" so companies are not obliged to use this pre-market approval mechanism.
The Codex Situation

The proposed draft recommendations for health claims are at step three of the procedure. Codex Alimentarius has proposed two broad categories of claims: nutrition claims and health claims.

Nutrition Claims \textit{(Describes a nutritional property)}:

1) \textbf{Nutrient Content Claim}
A nutrition claim that describes the level of a nutrient contained in a food.

Health Claims \textit{(Describes a relationship between food/nutrient and health or disease)}:
Includes the following three categories (proposed)

1) \textbf{Nutrient Function Claim}
A nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body.

Examples of nutrient function claims include:
“calcium aids in the development of strong bones and teeth”
“contains folic acid: folic acid contributes to the normal growth of the fetus”.

2) \textbf{Enhanced function claim}

These claims concern specific beneficial effects of nutrients and non-nutrients on physiological and psychological functions or biological activities beyond their established role in growth, development and other normal function of the body.

3) \textbf{Reduction of disease risk claim}

These are claims about the reduction of disease risk related to the consumption of a food or a food component. Such a component might help reduce the risk of a special disease or condition because of specific nutrients or non-nutrients contained within it.

\textit{Codex Alimentarius} propose that health claims should be permitted provided the following conditions are met:

I. Health claims must be based on relevant scientific substantiation proportional to the type of claim being made. Any health claim must be recognised as acceptable by the competent authorities of the country where the product is sold. Only health claims that support national health policy and goals should be allowed.

II. The claim must be truthful and not misleading.

III. The claim about a food or food constituent should be stated within the context of a normal diet.

IV. The amount of food to be consumed to obtain the claimed benefit should be appropriate in the context of a normal diet.

V. If the claimed benefit is attributable to a constituent in the food, the food in question should be:
(i) a significant source of the constituent in the case where increased consumption is recommended; or
(ii) “low” in or “reduced” in, or “free” of the constituent in the case where reduced consumption is recommended.

VI. In the case of nutrient function claims or enhanced function claims, the claim does not make reference to any pathology.

VII. The claim does not make reference to an effect on the prevention, treatment or cure of a disease.

VIII. Only those nutrients for which a Nutrient Reference Value has been established in the Codex Guidelines on Nutrition Labelling or those nutrients which are mentioned in officially recognised dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.

IX. Health claims should have a clear framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.

X. Health claims should be enforceable: if the claimed effect is attributed to a constituent of the food, methods must be available to assess the presence of the constituent in the amount claimed.

XI. Health claims should be monitored and evaluated at regular intervals.

The following information should appear on the label or labelling of the food:

A. a statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim;
B. information on the target group, if appropriate;
C. information on how to use the food to obtain the claimed benefit;
D. advice to vulnerable groups on how to use the food, if appropriate;
E. maximum safe intake of the food where necessary.
**Comparison of current A1(19), proposal in A399 and proposal in P153**

<table>
<thead>
<tr>
<th>Current A1(19)</th>
<th>Proposed in A399</th>
<th>Comments on A399</th>
<th>Proposed in P153</th>
</tr>
</thead>
<tbody>
<tr>
<td>The wording of the clause relates to ‘food’ only.</td>
<td><strong>Clause 19(a)</strong> This clause applies to particular foods and classes of food.</td>
<td>The main comment regarding this subclause was in relation to the foods it covered. It was suggested that it was necessary to have a definition of ‘particular foods’ and ‘classes of foods’.</td>
<td></td>
</tr>
<tr>
<td>Current A1(19)</td>
<td>Proposed in A399</td>
<td>Comments on A399</td>
<td>Proposed in P153</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------</td>
<td>------------------</td>
<td>------------------</td>
</tr>
</tbody>
</table>
| The four subclauses of A1(19) vary in the extent to which they cover these issues. Subclause (c) most specifically covers some of these issues (prohibits ‘any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person’). | Clause 19(aa) For the purposes of this clause, ‘claim’ means any statement, representation, design or information which is not prescribed by this Code, and includes an express or implied claim. | A large proportion of submitters that opposed A399 did not agree with the proposed change. It was considered to widen the scope of A1(19) and will have the unintended consequence of prohibiting widely used legal claims that are nutrient claims or nutrition messages. The use of the word ‘implied’ was considered to cause difficulties in health promotion organisations working with food industry partners to disseminate food and health messages to the public. | ANZFA has attempted to overcome this by providing definitions of a health claim, a nutrition function claim and a nutrition content claim and giving an example of each. The drafting now reads: a health claim is prohibited unless otherwise specified in this code where a health claim means a claim that a relationship exists between a food or a constituent of that food and a disease or health related condition and includes a-

(a) enhanced function claim; and  
(b) reduction of risk claim  

but excludes a nutrition function claim and nutrition content claim. 

There was concern that the use of the words ‘statement, representation or design’ would restrict the use of drawings and figures. The proposed new standard has been drafting to allow endorsements, provided ANZFA has approved the criteria related to the organisation’s endorsement. |
<table>
<thead>
<tr>
<th>Current A1(19)</th>
<th>Proposed in A399</th>
<th>Comments on A399</th>
<th>Proposed in P153</th>
</tr>
</thead>
</table>
| (a) ... any label on or attached to a package containing or any advertisement of food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import. | **Clause 19(b)**
Save where otherwise expressly prescribed by this Code, any label on or attached to a package containing food or any advertisement for food must not include a claim, or a claim described by words of similar effect –
(i) for therapeutic or prophylactic action; or
(ii) that could be interpreted as advice of a medical nature from any person | A general concern raised in relation to Clause 19(b) was that the problem created by altering the definition of ‘claim’ in 19(aa) becomes apparent as 19(b)(i) “prohibits any claim (with extended meaning) for therapeutic or prophylactic action”. | A definition of prophylactic and therapeutic has now been added to the proposed new standard. |
<p>| (c) ... any label on or attached to a package containing or any advertisement of food shall not contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person |                                                                                                                                                                                                                                                               |                                                                                                  |                                                                                                  |</p>
<table>
<thead>
<tr>
<th>Current A1(19)</th>
<th>Proposed in A399</th>
<th>Comments on A399</th>
<th>Proposed in P153</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) … any label on or attached to a package containing or any advertisement of food shall not include the word ‘health’ or any word or words of similar import as part of or in conjunction with the name of the food</td>
<td><strong>Clause 19(c)</strong>  &lt;br&gt; Any label on or attached to a package of food or any advertisement for food must not include the word ‘health’ or any word of similar effect as part of or in conjunction with  &lt;br&gt; (i) the name of any food;  &lt;br&gt; (ii) any generic or specific description of food; or  &lt;br&gt; (iii) the trade name or trade mark of any food</td>
<td>While some submitters supported the prohibition of the word ‘health’ a large number of submitters objected to the proposed restriction. Submitters objected in particular to 19(c) (ii) as it was considered that this will effectively rule out any statements that are currently made about foods which are nutritional messages rather than health claims, for example ‘fruit and vegetables are essential for a healthy diet’. Submitters also strongly objected to 19(c)(iii), primarily due to the costs involved in implementing changes to these items in terms of trade names and trade marks. It was also questioned whether the proposed change will offer any increased benefit to public health and safety and it was argued that the Trade Practices Act is able to regulate ‘health’ used as part of a trade name or trademark if it is considered false or deceptive.</td>
<td>The proposed new standard now contains the following clause:  &lt;br&gt; A claim in relation to food must not include the word ‘health’ or any word of similar effect as part of or in conjunction with –  &lt;br&gt; (a) the name of the food;  &lt;br&gt; (b) any generic or specific description of the food; or  &lt;br&gt; (c) the trade name or trade mark of any food;  &lt;br&gt; unless the food meets the following criteria per serve:  &lt;br&gt; • no more than 3 g of fat, of which no more than 1.5 g is saturated;  &lt;br&gt; • no more than 500 mg of sodium; and  &lt;br&gt; • no less than 10% of a Recommended Dietary Intake of a nutrient other than sodium or potassium.</td>
</tr>
<tr>
<td>Current A1(19)</td>
<td>Proposed in A399</td>
<td>Comments on A399</td>
<td>Proposed in P153</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------</td>
<td>------------------</td>
<td>------------------</td>
</tr>
</tbody>
</table>
| (d) ... label on or attached to a package containing or any advertisement of food shall not contain the name of or any reference to any disease or physiological condition | **Clause 19(d)**
Save where otherwise expressly prescribed by this Code, the label on or attached to a package of food or any advertisement for food must not expressly or by implication contain the name of or reference to any disease or physiological condition, disorder, ailment, syndrome, symptom, sign or defect. | Some concern was expressed that there will be confusion over the definition of ‘physiological condition’.
A number of submitters claimed that the proposed changes to 19(d) also extend Clause A1(19) unnecessarily. For example, the phrase ‘helps keeps you regular’ on a high fibre food would be prohibited as it is an implied reference to the disorder of constipation. | A definition of this is available in dictionaries and therefore has not been included in the Standard.
The intention has been clarified by the addition of the definitions for therapeutic and prophylactic action as described above. |