Part 2

Process evaluation of the management framework for the folate–neural tube defect health claims pilot

Final report

ARTD Management and Research Consultants

Consultancy Team:
Wendy Hodge
Michael Brooks
Kerry Hart

15 July 1999
1 Introduction

1.1 Folate–neural tube defect health claim pilot

Under Australian and New Zealand food regulations, health claims about foods on product labels and in associated advertising has been previously prohibited. Health claims are messages that make a direct link between eating a food or a component of that food and the reduced risk of disease. This prohibition is being reviewed by the Australia New Zealand Food Authority (ANZFA) under Proposal P153 to determine whether there is scope for properly substantiated health claims on food to deliver a public health benefit.

To obtain a clearer, more practical understanding of the regulatory, social and public health impact of health claims, ANZFA agreed in March 1998 to raise a proposal (P170) to conduct a pilot of a management framework for health claims. This pilot was to use a health claim about the benefits of folate (a B vitamin) in reducing the incidence of neural tube defects (NTDs), such as spina bifida, in babies.

It was agreed that the folate-NTD pilot would run until 13 February 2000 [and subsequently amended to 13 August 2002] and be conducted in both Australia and New Zealand. The pilot is managed by ANZFA in partnership with the Australian Food and Grocery Council (AFGC), the fresh food industry, individual food companies, the Commonwealth Department of Health and Aged Care, and health and community organisations.

The stated objective of the pilot is ‘to trial the management framework being proposed under P153 Health and Related Claims for health claims generally, using folate-NTD health claims in order to:

• enable ANZFA to refine the proposed management framework for health claims prior to finalising the full assessment report for Proposal 153;
• help to identify strengths and weaknesses in the framework; and
• promote public health through communication of the link between increased maternal folate consumption and a reduction in the incidence of neural tube defects.’

1.2 Proposed management framework for health claims

The proposed management framework for health claims under P153 describes the processes and systems that are perceived to be necessary for the appropriate, effective and efficient use of health claims. The proposed framework comprises five components:

• scientific assessment—systems for scientifically substantiating the health claim and setting qualifying and disqualifying criteria for food products that could use the claim;
• regulatory systems—regulatory and practical arrangements for approving products to carry health claims;
• surveillance and enforcement—systems to ensure compliance with the regulatory system;

* Subsequently amended to 13 August 2002.
1.3 Process evaluation

ANZFA engaged an independent consultancy firm, ARTD Pty Ltd, to conduct a process evaluation of the proposed management framework as it was implemented using the folate–NTD health claim.

The folate–NTD health claim pilot covers the period from March 1998, when ANZFA agreed to a proposal (P170) to conduct a pilot of a management framework for health claims, until February 2000. This covers the seven-month period for establishing the pilot and the 15-month operational phase of the pilot from 13 November 1998, when changes to the Food Standards Code were introduced, until their expiry on 13 February 2000. This evaluation covers the first six months of the operational phase of the pilot up until June 1999.

The terms of reference for the evaluation focus on assessing and making recommendations on how experience gained from conducting the pilot should guide further planning, development and decision making, if health claims were permitted more generally. The terms of reference are:

- to determine the overall effectiveness of the management framework trialled in the pilot for the folate–NTD health claim from the points of view of ANZFA and its stakeholders;
- to identify the strengths and limitations of each element of the management framework and to make recommendations on how the limitations might be overcome or minimised, and how the strengths might be built on if health claims were to be permitted more generally;
- to review the costs associated with the pilot and by which sectors they were borne, and to recommend the most cost-effective ways in which health claims could be managed in the future; and
- to assess the effectiveness of the management of the pilot across both Australia and New Zealand by ANZFA and its stakeholders and partners.

The focus on the evaluation is on ‘how to do health claims’ rather than either the impacts associated with the particular folate–NTD health claim used in the pilot or whether health claims should be allowed under the Food Standards Code.

The separate evaluation of outcomes, which examines the effects of the pilot, starts on page 71.

1.4 Methodology

The methodology for the evaluation was based around two rounds of consultations. During the first round of consultations, ARTD, in conjunction with ANZFA, prepared an initial discussion paper to provide background information on the evaluation and the management framework for the pilot. The paper was distributed to over 100 key informants.

Subsequently amended to 13 August 2002.
In March and April 1999 it was used as the basis for 60 interviews with key informants from government, industry and consumer, community and professional organisations. These interviews focused on informants’:

- involvement in the pilot to date;
- perceptions of the strengths and weaknesses of the management framework trialled in the pilot; and
- broader views about the appropriateness and effectiveness of the management framework.

During the second round of consultations in May 1999, ARTD prepared a second discussion paper that was also distributed to over 100 key informants. This discussion paper presented a scenario of a generic management framework based on the stakeholder feedback to date about the strengths, weaknesses and issues associated with managing health claims. This scenario was written to promote debate and elicit further evidence, based on the experiences of the pilot, about managing health claims. In particular, it focused on drawing out views on:

- how strengths in the current management framework might be built on, if health claims were to be permitted more generally;
- how limitations in the current management framework might be overcome or minimised if health claims were to be permitted more generally; and
- the most cost-effective ways in which health claims could be managed in the future.

The consultants are confident that the methodology provided a comprehensive basis for addressing the terms of reference, particularly given the range of informants contacted and the quality of feedback received as a result of the consultations.
2 Implementation of the pilot

This section provides an overview of the implementation of the pilot to date. It covers:
• the establishment and implementation of the pilot (Section 2.1);
• the costs associated with the pilot (Section 2.2);
• the overall management of the pilot (Section 2.3); and
• the context for interpreting the findings of the process evaluation (Section 2.4).

Individual components of the management framework are described in detail in subsequent sections.

2.1 Establishment and implementation of the pilot

Establishment of the pilot

The proposal (P170) to conduct a pilot of a management framework for health claims using a folate–NTD health claim pilot was considered by ANZFA as a matter of urgency following a formal direction from the then Parliamentary Secretary to the Minister for Health and Family Services. In line with this direction, the Full Assessment Report on P170 was prepared in April 1998, omitting the usual public consultation steps in order to make a recommendation to the Australia New Zealand Food Standards Council by May 1998.

The preparation of the assessment report on the pilot was overseen by a Steering Committee with guidance from four expert working groups, two communications consultants, a corporate legal adviser and a business adviser. The full assessment included:
• draft amendments to Standard A1(19) of the Food Standards Code to permit a folate–NTD health claim;
• an assessment of the scientific issues which need to be considered with respect to the ability of a folate–NTD health claim to be true, valid and not misleading;
• nutritional criteria for claimable foods;
• results from consumer testing in Australia and New Zealand on communication elements of the folate–NTD health claim;
• an education and communication strategy;
• a monitoring and evaluation strategy;
• a strategy for co-regulation including a draft code of practice describing the conditions of use of the health claim by industry; and
• a business plan and contract for food companies which express an interest in participating in the pilot.

Following approval by the Australia New Zealand Food Standards Council, ANZFA coordinated a range of activities between May 1998 and November 1998 to refine the components of the pilot and prepare for the implementation of the pilot. In particular, significant time and resources were required to negotiate the funding arrangements for the pilot.
The pilot was launched in Australia on November 13 1998 when Standard A1 (19) of the Food Standards Code was amended to permit the use of a folate-NTD health claim on approved foods until 13 February 2000. In New Zealand, the Medicines Act was also amended in December 1998 to permit the use of a folate health claim. There has been no public launch to date in New Zealand.

Use of the folate health claim in the pilot

To date, ANZFA has approved the use of the folate health claim on over 100 products, including 28 primary foods and 72 processed foods. These approvals were sought by 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 pattern of use of the folate health claim to date has varied significantly between Australia and New Zealand, and between food sectors and companies.

Limited uptake in New Zealand

With the exception of eggs, which gained individual approval for Australia and New Zealand, no New Zealand food company or association had sought approval to carry the folate health claim before May 1999. In part, this reflected the fact that trans-Tasman companies had obtained approval for products through their Australian parent. In May 1999, a New Zealand fruit juice manufacturer sought and gained approval for a product and a supermarket chain began seeking approval for house-brand grocery products to carry the health claim.

Interviews with key informants in New Zealand confirmed a low level of interest in the folate health claim pilot. In particular, the millers and bakers, and fresh vegetable and fruit sectors are not intending to participate in the pilot. The limited interest in the pilot and direct uptake of the folate health claim in New Zealand is linked to a number of factors:

• the timing of the pilot coincided with ongoing debate in New Zealand about the value and appropriateness of fortifying food with folate. The perception that some community and nutrition groups strongly opposed fortification resulted in food companies, notably the millers and bakers, being wary of involvement in the pilot.

• key informants in the food industry perceived that the decision to proceed with a folate health claim pilot was made without adequate consultation in New Zealand, and the time available to prepare for participation was inadequate. A number of key informants commented that the involvement of New Zealand in the pilot was piecemeal and ad hoc.

• inadequate funding was allocated within the available pilot budget for New Zealand-specific activities such as a pilot launch, which could have triggered greater industry interest and commitment. In a sense, the failure to have a New Zealand launch was somewhat of a ‘Catch 22’ situation: food companies were unwilling or uninterested in

* Subsequently amended to 13 August 2002.
participating and so a launch was not particularly viable, but a launch was perceived as important to generate company interest and commitment.

- New Zealand food companies were generally reluctant to contribute to the costs of the pilot. A number of the large food manufacturers in New Zealand indicated they were unable to contribute additional funding to the pilot because their Australian parent company had already provided funding. Other organisations indicated that they could not see any benefits from participation in the pilot.

While a number of products from trans-Tasman companies will be available in New Zealand retail outlets, the evidence to date suggests a limited uptake of the pilot in New Zealand.

**Fresh produce**

There is generally strong interest in the Australian fresh produce sector for the use of the folate health claim. To date, 28 primary foods have been approved to carry the claim, including 16 fresh produce products supported by five produce associations and 12 legume products distributed by a single food company.

The retail strategy of the education component used during March and April 1999 (see Section 6) involved supermarkets displaying shelf wobblers linking approved fresh produce to the folate health claim. In this way, all 16 fresh produce products used the health claim at some stage during the pilot, although it was generally for a relatively short time and key informants reported variability in the extent to which individual supermarkets chose to display the shelf wobblers.

In contrast, there is limited interest and no active use of the health claim by the fresh produce sector in New Zealand. The peak vegetable and fruit industry associations in New Zealand can see no benefit for growers as a result of participating in the pilot.

**Milling, baking and cereals**

Roughly one-third (35) of the approved products are milling and baking products and a further 27 approved products are cereals. None of the milling and baking products are using the folate health claim so far, whereas eight breakfast cereals currently have approved products with the folate health claim on the shelves—seven from one large food company and one from a smaller company.

Key informants from the companies currently using the health claim identified a potential marketing value in using the folate health claim. The large food company with seven products using the claim had previously made folate nutrient claims as part of a marketing campaign with a community organisation and said that involvement in the pilot was a logical extension of this marketing strategy. The products carrying the health claim are marketed at women in the folate pilot target group.

The other cereal manufacturer using the folate health claim specifically developed a new product to take advantage of the pilot. Their market research showed a need to functionalise their products and target specific groups. The folate health claim provided them with this opportunity.

Key informants from companies with approved products which have not used the health claim to date, indicated that, while broadly supporting the pilot, they see limited marketing
value in using a folate health claim. The health claim was seen as being applicable to a narrow market segment which was often not the target market for the approved products.

2.2 Costs associated with the pilot

The core ANZFA budget to manage the pilot was set at $560,000, with funds coming from both ANZFA and industry through voluntary contributions (Table 2.1). This is the budget against which financial reporting to partners will be made. However, additional funds and in-kind contributions from government and industry were spent on activities associated with the pilot, resulting in estimated costs of $1.1 million in total for the pilot (Table 2.1).

Table 2.1 Pilot funding sources and expenditure

<table>
<thead>
<tr>
<th>Cost category</th>
<th>ANZFA</th>
<th>Industry</th>
<th>Other government</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core funding</td>
<td>$200,000</td>
<td>$200,000</td>
<td>Australian Food and Grocery Council (AFGC)</td>
<td>$563,909</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>A$120,909¹</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Horticultural Research Development Corporation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>A$43,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>other food companies</td>
<td></td>
</tr>
<tr>
<td>Non-core funding</td>
<td>$106,000²</td>
<td></td>
<td>Australian Department of Health and Aged Care</td>
<td>$306,000</td>
</tr>
<tr>
<td>for specific</td>
<td></td>
<td></td>
<td>NZ$100,000³</td>
<td></td>
</tr>
<tr>
<td>activities</td>
<td></td>
<td></td>
<td>New Zealand Ministry of Health</td>
<td></td>
</tr>
<tr>
<td>Subtotal</td>
<td>$769,909</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-kind contributions</td>
<td>$50,000⁴</td>
<td>$100,000⁵</td>
<td>(AFGC—in kind)</td>
<td>$250,000</td>
</tr>
<tr>
<td>specific to pilot</td>
<td></td>
<td></td>
<td>(various food companies—education activities)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>A$1,019,909</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data source: ANZFA (as at the end of April 1999).

1 Does not include A$10,000 committed by the Horticultural Research Development Corporation payable at end of project or NZ$10,000 from food company committed but not yet received.

2 Contributed under a separate agreement between the Australian Department of Health and Aged Care and ANZFA to fund specific related activities. This amount is being accounted separately to core funding.

3 Contributed under a separate agreement between the New Zealand Ministry of Health and ANZFA. The NZ$100,000 is being used to undertake folate status research and print education material for distribution in New Zealand. This amount is being accounted separately to core funding.

4 In-kind contribution of ANZFA Executive Team support.

5 In-kind contribution of the AFGC in developing and convening Code of Practice Management Committee.

6 Estimated funding expended by food companies on education materials produced and distributed for the folate pilot. This amount is being accounted separately to core funding by individual food companies.
The total direct funding available for the pilot at the end of April 1999 totalled $756,909, of which the food industry and associated partners contributed 48% and government agencies contributed 52%. The food industry made voluntary contributions to support the pilot, with funding contributions of between $10,000 and $30,000 from member companies of the AFGC. Other food companies made similar contributions. Fresh produce organisations contributed between $3,000 and $15,000 with matching funding from the Horticultural Research Development Corporation.

Over 95% of food industry funding was sourced in Australia. In New Zealand, a number of the large food manufacturers indicated they were unable to contribute additional funding to the pilot because their Australian parent company had already provided funding. As the pilot was a joint Australia–New Zealand initiative, they perceived that country-specific funding was not required. In addition, as highlighted in Section 2.1.2, a number of sectors of the food industry in New Zealand were not interested in participating in the pilot, including the fresh produce sector and bakers and millers.

However, direct funding to date does not provide a complete picture of the costs associated with the pilot and by which sectors they were borne. Other costs detailed in Table 2.1 include:

- management support by the ANZFA Executive Team (estimated to be of the order of $50,000);
- development of the Code of Practice and operation of the Code of Practice Management Committee (estimated to include costs of the order of $100,000 borne by the AFGC and the food industry over the term of the pilot); and
- education materials produced and distributed by food companies for the pilot (estimated to include costs of the order of $100,000 borne by the food industry over the pilot). For example, one large food manufacturing company spent over $20,000 producing pamphlets and posters for the pilot.

A range of other indirect costs has not been counted because such costs are often associated with the range of normal commercial or organisational practice. Examples of these indirect costs include:

- food company costs associated with the marketing of products carrying a folate health claim. For example, one company estimated that cost to be of the order of $500,000 including development and running of television advertisements and monitoring surveys. However, such costs are likely to be borne as part of normal product development and market research, regardless of the folate pilot.
- other professional and community organisations involved as partners in the education strategy incurred a range of costs in distributing materials and promoting the folate pilot, however these roles are generally part of the core business of these organisations. For example, a professional association which provided the use of its logo on promotional materials indicated that they would normally charge $10,000 to $20,000, but provided the logo free of charge in the pilot as a way of supporting a public health priority.
- supermarkets incurred a range of costs in supporting the retail component of the public education campaign. However, the participating supermarkets indicated that such
support is a normal part of being a ‘good corporate citizen’ in supporting public health initiatives.

**Pilot expenditure to date**

Direct expenditure by ANZFA on the pilot budget has covered the five elements of the management framework, with the majority of expenditure to date on the education and communication component (Table 2.2).

A breakdown of expenditure between Australia and New Zealand was not available as many of the activities were jointly shared. However, key informants from New Zealand raised concerns that inadequate resources were allocated to New Zealand and additional resources for a launch and education and communication activities may have triggered greater industry interest in the pilot.

<table>
<thead>
<tr>
<th>Pilot expenditure</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific assessment</td>
<td>7%</td>
</tr>
<tr>
<td>Regulatory processes</td>
<td>17%</td>
</tr>
<tr>
<td>Surveillance and enforcement</td>
<td>7%</td>
</tr>
<tr>
<td>Education and communication</td>
<td>56%</td>
</tr>
<tr>
<td>Monitoring and evaluation</td>
<td>13%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

*Data source: ANZFA, based on estimates to the end of May 1999.*

1 Estimates are based on direct costs and breakdowns of pilot staff time.

**Future costs associated with health claims**

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. However, care is needed in using these data as the costs associated with the pilot are not necessarily indicative of the future costs of a health claims system. In particular:

- not all costs are recurrent. For example, some of the costs associated with the pilot, such as the development of the Code of Practice, are one-off costs associated with establishing the management framework;
- cost reductions could be achieved by streamlining some of the activities undertaken in the pilot. For example, not all key informants believed that a public education campaign was required as part of all future health claims; and
- additional costs could be incurred with future health claims, particularly in relation to scientific assessment. In the pilot, the case for substantiation had been largely developed as part of a previous National Health and Medical Research Council (NHMRC) report, and payments were not made to experts sitting on the adjudication panels.

In addition, a number of different strategies for reducing the costs associated with the management framework processes are identified in subsequent sections of the report (see Section 8.4).
2.3 Management of the pilot

Evidence suggests that the pilot has been professionally and effectively managed by ANZFA with the support of the pilot Steering Committee, within the constraints of the available budget and timeframe.

Management tasks included:

- negotiating with key partners to participate in the pilot;
- negotiating with the food industry and government agencies to provide one-off funding for the pilot;
- coordinating the development of key components of the management framework (for example public education campaign, pilot evaluation);
- coordinating major pilot events (for example the Australian pilot launch);
- providing ongoing information about the pilot to partners;
- providing support and assistance to food companies wishing to participate in the pilot; and
- managing the budget for the pilot.

Informants from all sectors acknowledge the professionalism of ANZFA staff and their partners in establishing and implementing the pilot to date, particularly given the sensitive issues which had to be negotiated in the early stages.

Informants, particularly from the food industry directly involved in the approval process, generally held very positive views about the support and practical assistance provided by ANZFA staff during the pilot. The informants said that ANZFA staff were accessible, helpful and thorough.

A small number of informants from the fresh produce sector perceived a lack of support from ANZFA in regard to finding ways to promote their produce using the logo. These informants acknowledged that this might have reflected resource constraints.

Since April 1999, a number of informants noted an apparent decline in the responsiveness and support available from ANZFA staff. This coincided with the departure of a number of project staff from ANZFA. One informant stated that continuity of staff and advice is important to industry when dealing with ANZFA about administering approvals of products and marketing messages.

Stakeholders from Australian State and Territory health agencies and a range of New Zealand agencies raised concerns about the extent of initial negotiations with partners. Key informants from Australian State and Territory health agencies thought they were not sufficiently involved in the initial negotiations about the pilot and received inadequate information to allow them to fully participate. This was linked to the short timeframe in which to establish the pilot because of the need to report on the folate pilot as a matter of urgency.

The short establishment time constrained the ability of ANZFA staff to fully engage potential partners in the health sector. ANZFA staff were unsuccessful in actively involving SIGNAL, the national nutrition network covering New Zealand and Australian State and Territory...
public health agencies, because of the short time available to negotiate with the SIGNAL network.

The short timeframe also meant that not all relevant industry groups received adequate information at the start of the pilot. In one case, a fresh produce industry association expressed strong reservations about the management of the pilot because of the failure to adequately promote the pilot to his organisation and members.

Key government informants from New Zealand said that establishing the folate pilot without consultation, using the matter of urgency provision, was seen as an imposition in New Zealand. This contributed to a negative reaction to the pilot and limited their opportunities to properly involve partners. These informants stated that an initiative across both countries needs to be sensitive to the different strategic environments in each country.

Concerns were raised across all sectors about the quality of ongoing communication and follow-up during the pilot. Key informants indicated that they were not kept adequately informed about the progress of the pilot and the information that was provided was often not ‘user-friendly’. Informants were interested in knowing how the pilot was going across the industry. Some informants also raised concerns about the short notice for some pilot events, particularly media events such as the retail strategy launch. Informants felt that they would have been better able to participate and benefit from the media events if they had received greater notice.

ANZFA staff acknowledge that the resource implications of maintaining effective communication with partners need to be examined for future activities related to health claims.

Key informants made few comments about the pilot Steering Committee and their role in the management of the pilot. The only concern raised during the evaluation was from a number of consumer and community organisations which questioned the adequacy of consumer representation on the Steering Committee.

2.4 Context for interpreting evaluation findings

Interpreting findings from the evaluation of a pilot project requires careful consideration of the context and special features of the pilot. In this case, generalisations from the folate health claim pilot to other health claims need to be made with caution because of the specific features of this pilot.

Key informants across all sectors expressed strong reservations about being able to generalise from the findings about the management framework based on the folate pilot. Informants from the public health sector stated that the framework should be tested using several health claims.

In particular, five factors were identified which need to be borne in mind when interpreting the evaluation findings in this report.

Controversy of the health claims issue

The prohibition on health claims has been a complex and sensitive issue for a number of years. There are many public health and consumer agencies that have expressed concerns
about the concept of health claims because they regard them as being both primarily
motivated by marketing objectives within the food industry and subject to misinterpretation
by people who are not experts in public health matters. Others argue that, by combining the
findings of medical researchers with the skills of food technologists, there is an opportunity
to improve the health of significant sectors of the community.

While informants were asked to focus on the process of the pilot, their perceptions of the
pilot were inevitably influenced by their views on whether health claims should be
prohibited or not.

**Straightforward nature of the folate health claim**

Informants perceived the folate health claim to be relatively straightforward and non-
controversial compared with other potential health claims, because of the link between a
single, discrete nutrient (folate) and a specific, relatively uncommon abnormality (NTD).
Informants from the public health sectors said that other health claims are likely to be more
complex and affect a broader target group, and warned that as a consequence the lessons
learnt from the pilot could have limited application to other health claims.

**Variable uptake of the folate health claims**

As highlighted in Section 2.1, the uptake of the folate health claim to date has varied
significantly between Australia and New Zealand as well as between food sectors and
companies. This limits practical experience from the pilot, particularly in relation to the
regulatory, surveillance and enforcement components of the management framework. This
has led some informants to question the value of the pilot, particularly in relation to the
outcome evaluation, where it is perceived that it will be difficult to establish any causation
between the pilot and outcomes such as changes in consumer knowledge or behaviour.

**Limited timeframe to establish the pilot**

The limited timeframe to establish the pilot (because of the need to report on the folate pilot
as a matter of urgency) led a number of key informants to question the extent to which the
management framework had been properly tested. Key informants from the food industry
indicated that part of the low uptake of the folate health claim to date related to the limited
time to plan and implement the use of a health claim. Food manufacturers need time to make
applications, work with marketers and use up old stock before reprinting labels.

Other informants highlighted the fact that the limited timeframe exacerbated the complexity
of negotiations regarding health claims, with a likely impact on how the management
framework was implemented.

**Limited timeframe for the evaluation**

This process evaluation covers the first half of the folate pilot. Experiences from the second
part will need to be considered when using the findings.

While these limitations are important to bear in mind when interpreting the findings, they
do not negate the value of the insights from the process evaluation. The following sections
provide detailed descriptions of each of the components in the management framework to highlight:

• what has happened in the pilot to date;
• stakeholder perceptions of these processes; and
• stakeholder perceptions of issues if health claims were permitted more generally.

For each component, there was adequate depth and consistency of evidence to allow the consultants to draw out the implications of these findings for the future management of health claims.
3 Scientific assessment

The first component of the management framework used in the pilot involved processes for scientifically substantiating the health claim and setting qualifying and disqualifying criteria for food products that could use the claim.

This section outlines how the scientific assessment processes were implemented in the pilot (Section 3.1), stakeholder perceptions of these processes (Section 3.2), scientific assessment issues if health claims were permitted more generally (Section 3.3), and the implications of these findings for the future management of health claims (Section 3.4).

3.1 How it worked in the pilot

Scientific substantiation

The scientific case for the folate health claim had been broadly established in the 1995 NHMRC report Folate Fortification which concluded that the use of folate dietary supplements can reduce the incidence of NTDs.

To adjudicate on this evidence, ANZFA convened an expert working group whose members were chosen for their expertise in epidemiology, nutritional science, NTDs, folate metabolism and public health. The task of this expert panel was to confirm a link between maternal intake of foods containing folate and decreased risk of NTDs in the newborn.

The expert working group reviewed the scientific literature that looked at the link between consumption of folate and the reduction of NTDs, dose–response relationships, bioavailability of the nutrient, evidence of other potential health benefits, evidence of adverse health outcomes and other possible known side effects. They also considered probable intake of the nutrient from all sources and the potential to deliver health benefits given the range of normal consumption.

Establishing the criteria for eligible foods

An expert working group was also set up to determine the appropriate nutrient criteria for products and primary foods to carry a folate health claim. The criteria were based on the principles that approved foods should:
Part 2 Process Evaluation

- 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;
- contribute to the recommended dietary intake (RDI) of the nutrient in the target group and be commonly consumed by the target group; and
- not usually be consumed in amounts that would mean a risk of over-consumption of the nutrient by any segment of the community.

In line with these principles, the working group determined that foods carrying the health claim must contain:

- at least 40 micrograms of folate (10% of the amount of folate recommended for women of child-bearing age).

Foods which are not primary foods as listed in Standard A9 of the Food Standards Code (for example fruit, vegetables, grains, legumes, meat, fish, milk) 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.

The working group also recommended that, where the ability of a food to meet the qualifying criteria of at least 40 micrograms folate per serving at the time of consumption depends on particular storage, handling or cooking requirements, the label on the package containing the food must include a statement of those requirements.

3.2 Stakeholder perceptions based on the pilot

Scientific substantiation

The majority of informants across all sectors were satisfied that the expert working group, in reviewing the available scientific evidence, had successfully achieved the outcome of a clear, defendable link between folate intake and the reduced incidence of NTDs.

However, many informants raised the point that the pilot did not fully test the process of substantiation because the scientific case for the folate health claim had previously been established in the 1995 NHMRC report on folate fortification.

A small number of informants from the public health sector raised some concerns about the rigour of the process underpinning the scientific substantiation. These concerns related to a perceived failure to discriminate between natural and artificial sources of folate.

One Australian State/ Territory Government opposed the pilot because of concerns that the scientific substantiation process had not addressed all the confounding issues.
Establishing the criteria for eligible foods

There was broad support among informants for the principles used by the expert working group to establish eligibility criteria. This support extended to the working group’s recommendations.

On the other hand, a public health informant felt that the eligibility criteria worked against the dietary guidelines as the criteria promoted folate intake from individual foods regardless of how likely the food is to be eaten in terms of quantity and frequency. It was pointed out that total folate consumption is determined not by individual foods but by consumption of a wide range of foods from four food groups—fruits, vegetables, cereal foods and milk products. It was claimed that ‘...commonly and frequently eaten foods that contribute less than 10% of the RDI per serve (for example unfortified bread and potato) are major food sources of folate’, yet these foods are not able to make a folate health claim. Other public health informants also felt that the message relating to the intake of 400 micrograms of folate for women of child-bearing age misleads health workers into misinterpreting it as the RDI for all adult women.

A number of informants from the food industry raised concerns about the nutritional validity of disqualifying foods with more than 10 g of added sugar. These concerns reflect a broader debate in relation to the Dietary Guidelines for Australians and the New Zealand Food and Nutrition Guidelines, and as such are not specific to the folate pilot.

Some public health and food industry informants questioned the need for disqualifying criteria in this pilot as folate is a single nutrient with a single outcome and therefore need not relate to the dietary guidelines.

Informants from the food industry raised the concern that decisions about the disqualifying criteria were made without adequate consultation. Decisions about folate nutrient criteria were made at a one-day workshop involving a range of stakeholders. However, there was insufficient time to fully discuss the disqualifying criteria. As a result it was agreed that ANZFA would draft the disqualifying criteria. Participants in this workshop were very positive about their involvement in the process, but a number expressed concern that after ANZFA’s drafting of the disqualifying criteria there was no opportunity to comment on the final decision.

ANZFA staff indicated that ideally there should have been a second round of consultations to discuss the disqualifying criteria, but this was not possible within the available timeframe.

3.3 Issues if health claims are permitted more generally

Informants raised a number of issues that they perceive to be important to consider if health claims are permitted more generally.

Use of expert panels

There was broad support for an expert panel to adjudicate on the scientific evidence presented for a particular claim. The main point raised by consumer and professional organisations was that the credibility of such panels would be judged by both the professional reputation and independence of its members, and the appropriateness of the
convenor of the panel. ANZFA or the NHMRC were seen as appropriate agencies to convene such expert panels.

**Administratively simple processes**

Informants from the food industry sought scientific assessment processes that were administratively simple and timely, in order to ensure that these processes did not generate a bottleneck or unnecessary costs in a health claims system. Of particular concern was the time it might take for expert panels to convene, meet and make decisions.

**Level of substantiation**

Informants from the food industry and public health sectors indicated that the level of substantiation needed for future health claims is likely to vary from claim to claim, depending on the availability of credible evidence and consumers’ and public health professionals’ perceptions of the issues associated with the health claim.

Food industry informants strongly indicated that where substantiation had previously been established by a credible scientific or regulatory body (such as the NHMRC or the United States Food and Drug Administration (USFDA)), the process of substantiation should focus on checking the applicability of the evidence to the particular health claim and the Australian scene. For example, there are a number of generic health claims already substantiated by the USFDA.

Informants from all sectors broadly agreed that whatever the process, there was a need to ensure that it supported public confidence in a health claims system. Food companies in New Zealand indicated that it was essential to consider consumers’ perceptions of the substantiation processes in designing any future system. It was recognised that this might entail higher costs to ensure consumer confidence in the integrity of the system.

**Basis of eligibility criteria for approved foods**

Notwithstanding the broad support across all sectors for the principle that health claims should be ‘presented in the context of a balanced and healthy life style’, informants from industry were concerned about an eligibility criterion which included the idea that health claims have to support the Dietary Guidelines. They regarded this criterion as ‘somewhat simplistic’ and imposing a ‘rigid framework’ that may not be appropriate during the process of substantiation. They also raised the issue that some health claims may target narrow populations, and therefore not relate to the Dietary Guidelines.

One food industry informant, while supporting the criterion that foods contribute to RDIs of the target group and be commonly consumed, pointed out that some foods for which increased consumption is desirable are not commonly consumed and that these foods could be excluded from carrying health claims under this criteria. The informant suggested that the criteria be changed to ‘desirable to be consumed’. On the other hand, public health informants pointed out that foods that are infrequently eaten and which are small contributors to the diet are able to make health claims and this could distort broader nutrition education messages.
Difficulty in establishing causation

Epidemiologists from the public health sector highlighted the difficulties in establishing a causal pathway between intake of foods and changes in risk of disease. In the case of folate, there was evidence from trials that showed that the prevalence of NTDs changed when intake changed. These experts indicated that the evidence for other nutrients and diseases is likely to be less clear and that it may be more difficult to substantiate the link between food intake (the risk factor) and altering the risk of disease.

Public health input into the assessment process

Key informants from the public health sector highlighted the importance of public health input into the scientific assessment process to ensure adequate consideration of the efficacy of the health claims in preventing disease through the food system, and population groups who would benefit.

Guidelines for substantiation

Key informants from the food industry and public health sectors identified a gap in managing scientific assessment—the absence of well-defined guidelines that specify ANZFA’s requirements and standards for scientific substantiation. That is, what evidence would be required to make a case for a health claim. Such guidelines could specify what studies are needed, types of data required and presentation formats.

Informants also felt that the new guidelines should recognise differences in substantiating generic and specific health claims. For proprietary foods, for example, all the scientific evidence may be commercial-in-confidence with limited publicly available data.

Key informants from the public health sector commented that in developing guidelines to substantiate future health claims, ANZFA should draw on other government substantiation systems (for example therapeutic goods) and international experience.

Preparing a case for scientific substantiation

There was broad agreement that preparing a case for scientific substantiation of a particular health claim would normally be the responsibility of the applicant who sought a benefit from the claim. The applicant could be a public health agency such as a health department or ministry, if the health claim was intended to support a particular public health priority, or a food company wanting to use a specific health claim where it would be the sole beneficiary.

In practice, the benefits of health claims are likely to fall on a continuum and so responsibility for preparing the case for scientific substantiation may need to be negotiated between the interested parties.

Feedback from the evaluation indicates that such negotiations are unlikely to be straightforward. Food companies argued that there are no exclusive benefits for companies associated with general health claims. Government public health agencies indicated that in practice they were unlikely to be applicants as they currently did not view the use of health claims as a priority intervention strategy.
Others highlighted the potential cost barriers for smaller companies and the fresh produce sector, where insufficient resources are available for preparing a case for scientific substantiation.

**Costs of scientific assessment**

During the pilot, the costs of the scientific assessment processes were borne by ANZFA. If health claims were permitted more generally, the costs of scientific assessment processes could vary greatly depending on the health claim. Key informants from the public health sector and industry indicated that the work and resources to prepare a case for future health claims is likely to be far greater than for the folate claim. This reflected the fact that the scientific issues had been largely resolved in the 1995 NHMRC report.

While key informants across sectors were in broad agreement that the costs of establishing scientific substantiation should be borne by the beneficiaries of the health claim, there were divergent opinions as to who these beneficiaries were. For example, the food industry argued that the government was the beneficiary of general health claims as there were no exclusive benefits for companies. Others argued that food companies can use health claims for commercial benefit and so should be expected to contribute to the costs of scientific assessment processes.

There was less disagreement where key informants indicated that if a single food company was the sole beneficiary of a health claim (for example a health claim made in relation to a proprietary food) then it could be expected to meet the costs of establishing the case for scientific substantiation and convening an expert panel to adjudicate on the scientific evidence.

### 3.4 Implications for scientific assessment processes

On the basis of informant feedback on the scientific assessment processes used in the pilot (Section 3.2) and future issues (Section 3.3), the consultants made a number of recommendations which need to be considered to ensure cost-effective scientific assessment processes, if health claims were to be permitted more generally.

**Guidelines**

Guidelines on requirements and standards for scientific substantiation should be developed. These would include:

- a statement of the principles underpinning scientific substantiation (such as consideration of dose-response relationships, bio-availability of the nutrient, evidence of potential health benefits, evidence of adverse health outcomes and other possible known side effects);
- specifications of requirements of a scientific case such as the types of studies needed and presentation formats;
- any different requirements for general and specific health claims; and
- procedures for the adjudication process such as the timetable and expected length of time of adjudication as well as appeal mechanisms;
Use of expert panels

Expert panels should be set up, to adjudicate on scientific evidence. The expert panels could be convened by ANZFA or outsourced to a research body such as the NHMRC. A primary consideration in the membership of the expert panel is maintaining public confidence in the integrity of the process through the selection of credible, independent experts. The panel should include appropriate public health nutrition expertise.

The membership of such panels and the resources required would vary depending on the availability of credible evidence and consumers’ and public health professionals’ perceptions of the issues associated with the health claim.

Reducing costs

The costs associated with a scientific assessment process could be reduced by:

- placing the onus on the health claim applicant to prepare the case for scientific substantiation using the most efficient means at their disposal;
- using the same panel to adjudicate on multiple health claims where appropriate. For example, it may be possible to convene a single expert panel to review the applicability to Australia and New Zealand of health claims already substantiated by the USFDA; and
- using the same panel for adjudication and establishment of the criteria for eligible foods where feasible. Although such a process would require expansion of the membership of the panel to ensure that the full range of necessary expertise was available, there could be administrative savings associated with a one-step process.

Establishing the criteria for eligible foods

Guidelines for establishing the criteria for eligible foods should be developed. In line with the guidelines used in the pilot, they would state that approved foods should:

- support the aims of the Australian National Food and Nutrition Policy, New Zealand National Plan for Action, the Dietary Guidelines for Australians and the New Zealand Food and Nutrition Guidelines;
- contribute to the RDIs 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.

In addition, the guidelines would specify standard disqualifying criteria which should accompany health claims to ensure consistency with the Dietary Guidelines for Australians and the New Zealand Food and Nutrition Guidelines. Such standard disqualifying criteria would have been developed after a detailed consultation process undertaken by ANZFA and include, for example, maximum allowable levels of fat, saturated fat, sodium and sugar in one serving. These disqualifying criteria would be used in all health claims, except where the expert panel assessed that the health claim was justifiable on public health grounds without connection to the dietary guidelines, for example where the claim only related to a single nutrient with a single disease outcome.
4 Regulatory system

The second component of the management framework involves regulatory and practical arrangements for approving products to carry health claims.

This section outlines how the regulatory processes were implemented in the pilot (Section 4.1), stakeholder perceptions of these processes (Section 4.2), regulatory issues if health claims were permitted more generally (Section 4.3) and the implications of these findings for the future management of health claims (Section 4.4).

4.1 How it worked in the pilot

Co-regulatory system

Labelling food products (including claims made about products) in Australia is regulated nationally through the Food Standards Code. Standard A1(19) of the Code specifically addresses the use of health and related claims on food products. Although a joint Code for Australia and New Zealand is still being developed, the Australian Food Standards Code is recognised by the New Zealand Government as an alternative to its current Food Regulations. Health claims are also subject to the New Zealand Medicines Act 1981.

In Australia, the Food Standards are adopted by each State or Territory and become law in each State. The surveillance and enforcement of food regulations is the function of State and local government officers. In New Zealand, surveillance and enforcement is the responsibility of the New Zealand Ministry of Health (Section 5).

Under the proposed management framework for health claims, the Food Standards Code is being supported by an 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 (Section 5), make up the co-regulatory system.

<table>
<thead>
<tr>
<th>Regulations</th>
<th>Food approval system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Standards Code; NZ and Australian State Food Regulations; Trade Practices Act (Aust); NZ Medicines Act; NZ Fair Trading Act</td>
<td>Contracts between ANZFA and food companies; pre-market approval</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code of Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim Code of Practice for the Communication of the Health Benefits of Food Products; Code of Practice Management Committee</td>
</tr>
</tbody>
</table>
Public consultation

The ANZFA Act requires ANZFA to consult with the public about proposed changes to the Food Standards Code. In this case, ANZFA was unable to undertake the usual consultation process as it was directed by the then Parliamentary Secretary to the Minister for Health and Family Services to consider the folate pilot as a matter of urgency and to make a recommendation to the Australia New Zealand Food Standards Council by May 1998.

However, public consultation is being undertaken on an ongoing basis in relation to the list of products approved to carry a folate-NTD health claim as part of the pilot.

Amendment to the Food Standards Code

In the folate health claims pilot, Standard A.1(19) of the Food Standards Code was amended in November 1998 to permit the use of one claim, a folate-NTD health claim on approved foods. The amendment is time-limited and will cease on 13 February 2001.

The amendment:
• provides for a list of products which are approved to carry a folate-NTD health claim in the table subclause (e) of Standard A.1(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 for the use of folate-NTD 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, 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.

Pre-market approval for individual products

During the folate health claims 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 for the Communication of the Health Benefits of Food Products and complete an application form. Companies are encouraged to contribute financially to the pilot, although contributions are made on a voluntary basis.

As part of the regulatory arrangements, companies enter into a contract with ANZFA which entitles them to use the ANZFA folate health claims logo and encourages them to produce

* Subsequently amended to 13 August 2002.
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. Following the approval of the first round of products in October 1998 and the second round in December 1998, it was anticipated that the assessment and approval process would take place every three months.

Food companies are able to develop their own wording and format for the folate health claims, within the constraints of the Food Standards Code and the Interim Code of Practice for the Communication of the Health Benefits of Food Products. Model folate health claim statements have been drafted to guide the format, contents and tenor of health claims made on food products or in advertisements. The model statements are included in the Interim Code of Practice.

Interim Code of Practice for the Communication of the Health Benefits of Food Products

The Interim Code of Practice for the Communication of the Health Benefits of Food Products is intended to supplement the Food Standards Code.

For the folate health claims 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 that 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.

4.2 Stakeholder perceptions based on the pilot

Co-regulatory system

There was broad support across all sectors for the co-regulatory system of legally binding rules specified in the Foods Standards Code, supported by an industry code of practice which provides additional information and guidelines on the use of health claims in the pilot.

Public consultation

Informants from consumer groups, public health agencies and professional associations were concerned about the lack of public consultation in relation to P170, the proposal to conduct a folate–NTD health claim pilot. While these groups were generally aware that P170 was considered as a matter of urgency, they felt that fundamental issues about the relative
priority of a folate health claim had not been adequately debated. This was particularly the case in New Zealand where informants felt the pilot had been ‘dumped’ on them.

Food industry informants expressed similar reservations about the lack of consultation with industry about the choice of the health claim used in the pilot.

Several agencies with interests related to therapeutic goods complained that there was no mechanism in the pilot for raising concerns on issues such as differences between the claims allowed on pill packets and those allowed on foods.

During the pilot, public consultations were undertaken in relation to individual product approvals through newspaper advertisements and calls for comment. While most informants were supportive of this process, a small number thought the timeframe for providing feedback to ANZFA was too short—in one case it was claimed to be only five days.

**Amendment to the Food Standards Code**

There was broad support across all sectors for the amendments made to the Food Standards Code for the folate pilot, in particular the requirement that health claims be used in conjunction with nutrient labelling and a nutrient panel. Informants also generally supported the flexibility given to food companies to develop their own wording for the health claim.

Changes to the legal arrangements were more complex in New Zealand because the New Zealand Medicines Act had to be amended first to allow health claims on food.

Opinions were divided as to the desirability of listing approved products in amendments to the Food Standards Code. Those in favour highlighted the clarity achieved by gazetting eligible products as lists in the Code, whereas others indicated that this is against the move to streamline food standards. A number of key informants suggested that a compromise may be to list approved products in a Register referred to in the Food Standards Code.

ANZFA staff reported that some food companies had difficulty understanding the technical and legal aspects of the standards, particularly the distinction between nutrient and health claims.

**Pre-market approval for individual products**

Food companies who had products approved agreed that the pre-market process is effective and administratively efficient.

These food companies were generally satisfied with the application process which involved food companies providing:

- evidence of the nutritional composition of a recommended serving of the food or food product (to confirm that the food meets the qualifying nutritional criteria);
- a statutory declaration that the product meets all other requirements of the Food Standards Code; and
- a statutory declaration that the applicant will abide by the requirements and intent of the Interim Code of Practice.
One food company commented that it was not clear whether companies were obliged to submit finished packaging and promotional material as part of the application process. They preferred that this not be the case for future health claims and wanted the issue clarified.

ANZFA indicated that such information was not required—applicants only needed to submit evidence that the mandatory elements of the health claim, as outlined in the food standards, were covered.

Informants from other sectors commented that the pre-market approval was particularly important to engender public confidence in the regulatory process.

ANZFA staff indicated that they provided considerable support to applicants, particularly from smaller companies, to ensure compliance with the Food Standards Code and Code of Practice. Support involved not only advice in relation to the nutrient content of products but the wording of the proposed health claim. This support was seen as cutting the ‘red tape’ for companies and effectively reducing reliance on post-market surveillance to ensure compliance.

A number of food companies commented that such support was very valuable.

A small number of informants were concerned about the rigour of the food approval process, in particular the lack of data on folate levels in Australian and New Zealand foods. These informants pointed out that because Australian foods have not been systematically analysed for folate, ANZFA relied on United Kingdom and United States food composition tables for their information. For some foods there are significant variations between the two countries’ data. One legume processor was not prepared to use the ANZFA approval as independent tests showed that some of the company’s approved products did not meet the folate criteria.

Informants were also concerned about the lack of information on the volatility of folate levels in some foods.

Government food safety officers and consumer groups were concerned about the transparency of the food approval system used in the pilot. They felt that because the system was linked to voluntary payments by food companies, this raised questions about the possible preferential treatment of companies. One State government officer also felt that they would have difficulty prosecuting a company without product approval who was using the health claim if similar products have been approved for other companies.

**Interim Code of Practice for the Communication of the Health Benefits of Food Products**

There was broad support from the food industry for the Interim Code of Practice in that it provided helpful and straightforward guidance on using a folate health claim. Feedback from other sectors on the code of practice related to surveillance and enforcement (Section 5).

4.3 Issues if health claims are permitted more generally

Key informants broadly agree that a co-regulatory approach based on amendments to the Food Standards Code supported by a Code of Practice provides an appropriate regulatory framework for health claims.
Key informants raised a number of issues related to the regulatory arrangements. They indicated that it was important to consider these issues if health claims are permitted more generally.

**Need for public consultation**

A number of key informants, particularly from the public health sector, raised the issue of distinguishing between scientific substantiation of a health claim and the efficacy of regulating to allow a health claim. The public consultation process was perceived as providing the link between scientific substantiation and regulation.

Consumers’ and other stakeholders’ views about a health claim provide a basis for determining whether the benefits associated with a scientifically valid health claim outweigh possible costs (for example risk of distortion of diet, controversy associated with the health claim).

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.

A number of key informants identified the need for an ANZFA health claims policy that articulated the basis on which the relative benefits of health claims could be assessed. Such a policy was seen as necessary to guide decisions following the public consultation process.

**Need for a pre-market approval process**

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.

**Dealing with specific health claims**

Informants indicated that the approach to regulating specific health claims, where a particular company had an exclusive benefit, would be different from 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.
Costs associated with the regulatory process

During the pilot, the costs of managing amendments to the Food Standards Code and the individual product approval process were borne by ANZFA. The major costs associated with the Code of Practice were borne by industry, in particular the costs to the AFGC of drafting the Code.

If health claims were permitted more generally, the costs associated with any pre-market approval process would vary depending on the level of support provided by ANZFA to applicants. To reduce costs, key informants from the food industry suggested a simple food approval system that limited ANZFA’s role to accepting or rejecting applications, rather than providing advice and support to applicants. In effect, this would place the onus on applicants to seek independent regulatory and technical advice before submitting their application for pre-market approval.

Key informants who supported retention of the individual product approval system raised a number of other issues related to cost. First, a pre-market approval process was seen as a proactive investment to avoid the high cost of post-market surveillance. Second, it was felt that any payment system associated with pre-market approval needed to be transparent to avoid the perception of a conflict of interest for ANZFA.

The majority of key informants accepted that, subject to satisfactory progress, the pre-market approval process for general health claims could be phased out over time as food companies became more familiar with the regulatory requirements.

4.4 Implications for regulatory processes

On the basis of key informant feedback on the regulatory processes used in the pilot (Section 4.2) and future issues (Section 4.3), the consultants identified a number of matters which need to be considered to ensure cost-effective regulatory processes, if health claims were to be permitted more generally.

Need for public consultation

There is a need for an appropriately resourced public consultation process associated with a health claim proposal to amend the Food Standards Code, as required by Section 22 of the Australia New Zealand Food Authority Act 1991. Funding for the consultation process would form part of an overall ANZFA Health Claims Program budget.

Health claims policy

ANZFA should develop, in consultation with stakeholders, a health claims policy that would articulate the basis on which the relative benefits of health claims could be assessed. Such a policy would be used to guide decisions following the public consultation process.

Amendments to the Food Standards Code

Simple amendments to the Food Standards Code for each health claim which is to be permitted would cover:
• the nutritional criteria that must be met by a food or food product in order to be eligible to make the claim; and
• the mandatory elements which must be covered in the claim, including a statement that it is important to maintain a varied diet.

Approved foods could be listed in a Register referred to in the Food Standards Code.

**Pre-market approval process**

There is a need for an administratively simply pre-market approval process, based on individual product’s applications from companies. The applications would contain:

• evidence of the nutritional composition of a recommended serving of the food (to confirm that the food meets the qualifying nutritional criteria);
• the proposed health claim wording (to confirm that the mandatory elements are covered in the claim);
• a statutory declaration that the product meets all other requirements of the Food Standards Code; and
• a statutory declaration that the applicant will abide by the requirements and intent of the Code of Practice (see below).

Guidelines should be developed for the pre-market approval process for products wanting to make approved specific health claims.

There is a need to reduce the costs associated with a pre-market approval process, 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 accepting or rejecting 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.

**Code of Practice**

The Food Standards Code should 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:

• the principles and practices governing the use of health claims in general, including pre-market approval process, general restrictions on health claims such as not quantifying the risk reduction, and marketing and advertising practices; and
• attachments 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.
5 Surveillance and enforcement

The third component of the management framework used in the pilot involved systems to ensure compliance with the regulatory system. This section outlines how the surveillance and enforcement processes were implemented in the pilot (Section 5.1), stakeholder perceptions of these processes (Section 5.2), surveillance and enforcement issues if health claims were permitted more generally (Section 5.3), and the implications of these findings for the future management of health claims (Section 5.4).

5.1 How it worked in the pilot

In line with the co-regulatory arrangements used in the pilot, surveillance and enforcement processes were intended to operate at two levels. 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 comprised:

- 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; and
  - two nominees representing community interests.

Although the Code of Practice Management Committee has been involved in only preliminary activities during this evaluation, it is intended that the Committee would oversee regular surveillance audits of participating companies as well as setting up a formal complaint-handling procedure to examine non-compliance or non-approved use of a claim. Any complaints (whether from other food companies or consumers) will be investigated by the Management Committee and mediated through direct negotiation with the company and/or complainant. It was agreed at the first meeting of the Committee that the Complaints Officer would operate out of ANZFA.

At the second level, surveillance and enforcement can be undertaken directly by government enforcement agencies. New Zealand and Australian State and Territory government health agencies have responsibilities for undertaking legal action to enforce compliance with the Food Standards Code. Although these agencies could initiate independent enforcement activities during the pilot, it is intended that action on health claims would normally be undertaken following a referral from the Code of Practice Management Committee following unsuccessful mediation.
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.

5.2 Stakeholder perceptions based on the pilot

There was little feedback from key informants about the surveillance and enforcement processes used in the pilot because of the limited range of activities, although some significant evidence was cited.

Key informants from the food industry pointed to the fact that the pilot had not resulted in a ‘flood of illegal health claims’, which indicated that food companies understood the regulations operating in the pilot and were deterred from making illegal claims by the surveillance and enforcement processes. ANZFA staff confirmed that isolated examples of illegal health claims remained at pre-pilot low levels.

Other informants cited examples of illegal health claims, even though they did not relate to the folate health claim, as indirect evidence that surveillance and enforcement of the existing Standard A1(19) code is inadequate. Consequently, they believed that surveillance and enforcement of the amendments to allow a health claim must also be inadequate. Informants from the therapeutic goods industry stated that some food manufacturers are currently flouting the general prohibition on health claims, and compared this unfavourably to the surveillance and enforcement mechanisms in place for therapeutic goods.

Some key informants from the consumer and public health sector believed that there had been illegal folate health claims made during the pilot. A number of these informants cited an article ‘Folate Health Claims: Food Firms Flout Conditions’ in the February 1999 edition of Consumer Food News. This article listed seven products that were allegedly making illegal folate health claims. ANZFA staff confirmed that in all instances these products were using legal nutrient claims rather than health claims and as such there was no breach of the Food Standards Code.

5.3 Issues if health claims are permitted more generally

Informants raised a number of issues related to surveillance and enforcement processes which they indicated were important to consider if health claims are permitted more generally.

Need for appropriately resourced surveillance and enforcement

Key informants from the Australian consumer and public health sectors wanted surveillance and enforcement processes strengthened, if health claims are permitted more generally. They characterised the pilot surveillance and enforcement system as industry self-regulation in the absence of adequate funding for government enforcement. Some public health informants thought that co-regulation was equivalent to self-regulation and opposed the retention of the Code of Practice on the grounds that it allows industry to run the show.

Other informants supported co-regulation and suggested changes to strengthen the system. For example, informants thought that there may be difficulties changing the Code of Practice
if it was not working. One informant suggested that a mechanism to review the Code of Practice be developed.

Interestingly, consumer and public health groups in New Zealand were more confident than their Australian counterparts that the Code of Practice Management Committee was an appropriate mechanism for surveillance and enforcement.

Other sectors expressed broad support for the Code of Practice Management Committee as the principal vehicle for surveillance and enforcement processes. Key informants from government agencies responsible for undertaking legal action to enforce compliance expressed support for the Code of Practice, both because of its potential to address problems internally and because of the practical limitations of enforcing health claims when compared with higher priority regulatory issues such as food safety.

Informants from all sectors indicated that potential confusion about the co-regulatory approach could be addressed by improved promotion of the role and function of the Code of Practice Management Committee and promotion of the guidelines for mediation and attempted resolution of alleged breaches and complaints.

**Greater involvement of government enforcement agencies**

A number of informants commented that New Zealand and Australian State and Territory government health agencies responsible for legally enforcing the Food Standards Code should have greater involvement in planning and designing future surveillance and enforcement processes. One way of expanding the role is, for example, through membership of the Code of Practice Management Committee. This reflects their concern that the resource implications for government enforcement agencies have not been fully considered in planning the pilot. Informants said that current government-funded surveillance and enforcement systems are overloaded and that they have neither the resources to take on an extra role nor the resources for prosecuting large companies.

**Delineation of responsibilities of the Code of Practice Management Committee and government enforcement agencies**

Informants, including members of the Code of Practice Management Committee, highlighted the need to clearly delineate the responsibilities of the Code of Practice Management Committee and New Zealand and Australian State and Territory government enforcement agencies.

There was a broad consensus that the Code of Practice Management Committee's responsibilities related solely to monitoring and enforcing compliance with the Code of Practice, whereas government enforcement agencies maintained responsibilities for enforcing the Food Standards Code.

However, informants indicated that there was limited experience from the pilot for managing the interface between the Code of Practice and enforcement of the Food Standards Code. The key issue was that, where any company or organisation does not comply with the recommendations of the Management Committee in regard to a breach of the Code of Practice, there needs to be clear procedures, including standard documentation and timeframes, for referring the matter to the relevant government regulatory authorities.
Further clarification was sought on the processes for handling anonymous complaints, the criteria for determining the degree of importance of particular complaints and details of what constitutes a ‘timely’ response to a request or recommendation of the Management Committee.

**Active surveillance of compliance with the Code of Practice and the Food Standards Code**

Key informants from the public health sector highlighted the need for active surveillance of compliance with the Code of Practice and Food Standards Code. They raised concerns about the adequacy of a complaints-based system of surveillance and wanted independent audits of products in the marketplace to identify potential breaches. A number of these informants indicated that the Code of Practice should clearly state the processes that would be used to follow-up breaches identified by a surveillance audit.

**Costs associated with the regulatory process**

During the pilot, the direct costs of surveillance and enforcement processes to date have been shared by ANZFA and the food industry, with New Zealand and Australian State and Territory enforcement agencies contributing indirectly to the costs of surveillance, at low levels.

Key informants from the food industry highlighted the importance of building on existing surveillance and enforcement structures in order to reduce costs. In particular, they supported the amalgamation of the Nutrient Code of Practice Committee with any Health Claims Management Committee to avoid duplication of workload and administration.

The costs associated with active surveillance of compliance with the Code of Practice and Food Standards Code will need to be considered in future decisions about the resources required for a health claims system.

### 5.4 Implications for surveillance and enforcement processes

On the basis of feedback on the surveillance and enforcement processes used in the pilot (Section 5.2) and future issues (Section 5.3), the consultants identified a number of matters which need to be considered to ensure cost-effective surveillance and enforcement processes, if health claims were to be permitted more generally. These included the need to:

**Ensuring compliance with the Code of Practice**

A Code of Practice Management Committee should be established to ensure compliance with the Code of Practice for the Communication of the Health Benefits of Food Products (see Section 4.4). 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 and Territory regulatory authorities.
The surveillance and enforcement activities of the Committee could include:

- promoting the role and function of the Committee, including procedures for making complaints, to food companies, government enforcement agencies, public health agencies and consumer groups;
- maintaining a log of alleged breaches and complaints with regard to the Code;
- mediating and attempting to resolve 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.

Guidelines for mediating complaints

There is a need to develop and promote guidelines on how the Code of Practice Management Committee would mediate and attempt to resolve complaints and alleged breaches of the Code. In line with the processes used during the folate pilot, mediation and attempted resolution would involve:

- a Complaints Officer in ANZFA recording and tracking all complaints received;
- a Complaints Officer requesting input from both the complainant and the company or organisation alleged to have breached the Code in writing within 14 days from the receipt of the request;
- the Management Committee attempting to resolve the complaint through mediation, if necessary involving the chief executive of the company or organisation against which the complaint is made. If the complaint cannot be resolved within 28 days through mediation, it will be reviewed by the Management Committee which will 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 may write to the company or organisation seeking a written undertaking to stop the practices that breach 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 will 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 and Territory government agencies to enforce the Food Standards Code. In particular, there is a need to clarify:

- the responsibility and resources for undertaking regular surveillance audits to identify possible breaches of the Code;
- the processes for following up potential breaches identified from a surveillance audit (where a complaint has not been made);
• the 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.

Resource implications

There is a need to examine the resource implications for New Zealand and Australian State and Territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee for unresolvable breaches.
6 Education and communication

The fourth component of the management framework used in the pilot involved education and communication strategies to promote and support the health claims.

This section outlines how the education and communication strategies were implemented in the pilot (Section 6.1), stakeholder perceptions of these strategies (Section 6.2), education issues if health claims were permitted more generally (Section 6.3), and the implications of these findings for the future management of health claims (Section 6.4).

6.1 How it worked in the pilot

A broad range of education and communication activities has been undertaken as part of the folate health claims pilot.

These activities have been 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
- nutrition messages about the specific effects of folate need to be delivered to women of child-bearing age and health professionals and community groups in contact with women of child-bearing age.

The main education messages focussed on awareness and knowledge about the role of folate in the diet, food sources of folate, and the link between folate and NTDs.

The main education and communication activities are listed below.

Materials developed 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.

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.
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 in all Australian States except South Australia;
- a copy of the poster, a tear-off information pad and fact sheet were distributed to every general practitioner in Australia by the Royal Australian College of General Practitioners;
- home economics professionals and all high schools in Australia received information on the campaign through the Home Economics Institute of Australia;
- folate shelf-talkers and fact-sheets were displayed in 1500 Self Care Pharmacies, organised through the Pharmaceutical Society of Australia. An additional 500 copies have been sold to other pharmacists. This material complements existing pharmacy folate promotional materials produced by the Pharmaceutical Society in 1997; and
- a copy of the fact sheet was also distributed to every member by the Dietitians Association of Australia.

The Australian Spina Bifida and Hydrocephalus Association, in partnership with ANZFA, also set up a 1300-number telephone service to answer consumer inquiries about folate and NTDs. This telephone number is listed on the education pamphlet and poster. The Australian Nutrition Foundation and the New Zealand Nutrition Foundation also provide consumer information services and are 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, there has been no public education to date, but education materials which are suitable for the New Zealand context are currently being published and are planned to be distributed through health professional organisations.

**Partnerships with the retail sector**

Coles supermarkets nationally and Woolworths supermarkets in New South Wales, Queensland, South Australia, the Northern Territory and the Australian Capital Territory 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 educational 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.

In addition, Woolworths supermarkets' national magazine Australian Good Taste featured the folate health claims pilot in the March 1999 edition, including editorial and other stories. A copy of the folate brochure was included as an insert in copies of Australian Good Taste distributed in New South Wales, Queensland, South Australia, the Northern Territory and the Australian Capital Territory.

**National Healthy Eating Logo**

ANZFA developed a Folate Health Claims logo for use with a folate health claim on approved food products and associated education and promotion materials developed by partner groups. The logo is intended to give credibility to folate health claims and associated materials. Approved products are not required to use the logo but may do so on a voluntary basis.

So far, only one of the products currently in the market with a folate health claim has used the logo, although a New Zealand supermarket chain plans to use the logo with its ‘house brand’ products.

**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 have coincided with principal 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–NTD claim became legal in Australia it was officially launched by the Parliamentary Secretary to the Minister for Health and Family Services. Another Australian media event took place on 23 February 1999, with the start of folate promotion by the retail sector. There have been no media events in New Zealand.

Media releases have been distributed Australia-wide over the period of the pilot.

**Links with existing public health folate strategies**

Nutrition education strategies that focus on the promotion of folate to prevent NTDs have been run by government, non-government and industry organisations over the past decade. Some of these strategies are still being implemented. As part of the pilot, the food industry is also undertaking a range of promotional activities to support the folate health claim pilot.

Large government consumer education strategies have previously been implemented in Western Australia, South Australia and, recently, in Victoria. A folate awareness strategy has also been initiated by the Northcott Society and Kellogg nationally.

Where possible, ANZFA has established links with the groups implementing folate strategies to ensure that educational material is consistent and that information networks are used.
Links with food industry (product-related) education activities

The Code of Practice provides guidelines for organisations undertaking education and communication activities. These guidelines aim to ensure that appropriate messages are communicated to consumers. Food companies are supporting their health claims with promotional and educational materials that describe 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. This is consistent with, and provides a necessary extension to, support for the public education material being disseminated by government and non-government agencies.

6.2 Stakeholder perceptions based on the pilot

Public health education campaign

Key informants said the education material produced by ANZFA for the pilot was both professional and broadly appropriate for delivering nutrition messages about the specific benefits of folate for women of child-bearing age to health professionals and community groups in contact with these women. Key informants from New Zealand said that the material needed to be better tailored to fit their local context and they would have liked additional input into the design. However, it was acknowledged that this has been hampered by the lower level of interest in the pilot in New Zealand.

Partners in the campaign from industry, health and community organisations and professional associations were positive about their involvement and indicated a willingness to be involved with ANZFA in future education campaigns if they were relevant to their interests. A number of the partners indicated that they would have liked more regular feedback from ANZFA about the progress of the campaign.

Key informants from the public health sector were broadly supportive of the individual education activities, but questioned whether the campaign was capable of delivering a sustainable impact on the target group. They commented that the campaign did not involve key groups such as State health promotion professionals and that the channels used to disseminate the materials were unlikely to lead to effective communication of the messages. Although evidence on the actual impact of the campaign will not be available until the outcome evaluation report is completed, public health sector informants felt that the campaign was not sufficiently coordinated at the regional or local level.

Informants who raised such concerns conceded that additional resources and time would have been needed to achieve the desired level of coordination. For example, ANZFA staff stated that they were unsuccessful in actively involving the national public health nutrition network SIGNAL because of the lack of time to negotiate how the campaign could fit within the SIGNAL’s strategic priorities and current activities.

There was also a mixed reaction to the retail strategy of the education campaign. Key informants from the fresh produce sector were initially very enthusiastic about the potential for the folate education campaign to promote their products in supermarkets. However, they were disappointed in the implementation and impact of the activities in supermarkets, namely, the relatively short time period in which product-specific information was used in
supermarkets (for example shelf wobblers linking approved fresh produce to the folate health claim) and the variability in the extent to which individual supermarkets chose to display the material.

**Food industry (product-related) education activities**

Individual food companies indicated they had produced and distributed a range of folate education materials either directly or indirectly related to the pilot, using product advisory services and product-related information materials. Food company nutrition education activities were extensive and said to reach a wide audience. Informants from the food companies also pointed out that many consumers actively seek information on products and nutrition from their organisations.

There was broad support from all sectors for the food industry’s contribution to pilot education activities.

6.3 **Issues if health claims are permitted more generally**

Although informants broadly agree that education and communication strategies are an important part of the management framework, they raised a number of issues to be considered if health claims are permitted more generally.

**Public health education campaigns**

There were divergent views from informants on the need for public education campaigns associated with each health claim.

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 campaign were perceived as being necessary to set a health claim in context, as some public health informants felt that health claims have the potential to distort an individual’s 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. Although the food industry supported the Code of Practice guidelines which encouraged food companies to produce educational materials on nutrition for their customers, it was concerned about the costs and diversion of resources from the regulatory issues which it 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 that used messages consistent with government public health priorities. In this way, if public health agencies choose to undertake a public education campaign that takes advantage of a particular health claim, food companies would tailor their education materials to support the campaign messages.

The feedback from informants ultimately focused on the policy issues of the relative importance of the public health and regulatory focus of a health claims system. For those who see the rationale of health claims as a public health intervention, it is logical to expect a well-resourced public education campaign. For those who see the health claims system as
primarily a regulatory system to allow food companies to make balanced substantiated claims, there is no need for strict linkage to public health campaigns. Inevitably, these discussions must also consider who pays for public education campaigns. The experience of the pilot is that such campaigns can account for over half the total costs (Section 2.2). Hence, the question of funding must be answered in any decision about requiring public education campaigns.

**Sustaining 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 will 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 token 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, unless they were integrated into its National Public Health Nutrition Strategy which is currently being developed.

**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.

ANZFA staff indicated that their coordination role in the folate campaign was not indicative of a future role in public education.

**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 inform consumers about the health claim within the context of a healthy diet.

**6.4 Implications for education and communication processes**

On the basis of key informant feedback on the education and communication processes used in the pilot (Section 6.2) and future issues (Section 6.3), the consultants identified a number of matters that need to be considered to ensure cost-effective education and communication processes, if health claims were to be permitted more generally.

**Guidelines for public health campaigns**

There is a need to develop guidelines on the requirements of public health campaigns used in conjunction with health claims, in line with ANZFA’s health claims policy (see Section 4.4) and taking into account the findings of the outcome evaluation regarding the reach and impact of the folate public education campaign.
The guidelines would specify the situations, if any, in which public health campaigns would be required and the scope of such campaigns.

The key policy issue to consider is the relative importance of the public health and regulatory focus of a health claims system. If health claims are perceived as a public health intervention, then it is logical to expect a well-resourced public education campaign. If the health claims system is primarily a regulatory system to allow food companies to make balanced substantiated claims, then there may be no need for strict linkage to public health campaigns.

It is also necessary to develop linkages between ANZFA’s guidelines on public health campaigns and the National Public Health Nutrition Strategy, which is currently being developed by the SIGNAL network.

**Guidelines in the Code of Practice**

The Code of Practice, which includes guidelines for education activities undertaken by food companies and associations, should be promoted. Such education activities are an important part of the health claims system in that they ensure consumers of products that carry a health claim can access additional information about the health claim within the context of a healthy diet.

**Consumer education about food labelling**

The costs associated with consumer education about food labelling should be budgeted for as part of any ANZFA health claims program budget. Such consumer education could include information about changes to the Food Standards Code, how to read food labels and interpreting health claim messages in general. For example, if health claims already substantiated by the USFDA were allowed as a group of new health claims, ANZFA could undertake a campaign to alert the public to the changes to food standards and the correct approach to interpreting claims.
7 Monitoring and evaluation

7.1 Processes used in the pilot

A broad range of monitoring and evaluation activities has been undertaken or is planned as part of the folate health claims pilot.

These activities were developed by ANZFA in conjunction with a specialist monitoring and evaluation working group which included nutrition and public health experts. The group met in early 1998 to develop a broad monitoring and evaluation strategy for the pilot and again in August 1998 to refine the data-collection strategy. The strategy focused on process and short-term outcomes.

Monitoring—process outcomes

In order to track the extent that the folate health claim has been taken up and implemented, ANZFA has coordinated the collection of a range of data through their food approval system, and from participating companies. The companies were required by the Code of Practice to record data on claims made on food products and in promotional materials and advertising campaigns, and to make the data available at regular intervals over the period of the pilot. Data were collected on the:

• 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 inquiries;
• extent of involvement of different stakeholder groups;
• extent of media exposure about folate health claims; and
• cost of education campaign materials and their distribution.

Monitoring—short-term outcomes

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 NTDs, 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
• consumers’ perceptions and attitudes to health claims.
Part 2 Process Evaluation

ANZFA collected this information by purchasing the right to place 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 will re-survey 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; and
- Tasmanian Eat Well Survey. This telephone survey of 800 people living in Tasmania was conducted in November 1998.

Companies which conduct market research to monitor the impact of their product promotion associated with the folate health claim agreed to provide these data to ANZFA to help in monitoring short-term impacts. For example, a major food company 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 among women aged between 18 and 45 years.

In addition, monitoring data on short-term changes in the food supply were 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 has undertaken to provide sales data obtained through electronically tracking sales both before and after the health claim pilot.

**Monitoring—intermediate outcomes**

Intermediate outcomes encompass the extent to which the health claim contributes to changes in the dietary intake of the nutrient among people in the target population.

New Zealand researchers from Otago University studied changes in dietary intake using blood folate measures and by reported food intake of folate-rich foods in three populations: women of child-bearing age, adolescents, and older people. Only baseline data were available in the timeframe of the health claim evaluation.

**Monitoring—long-term outcomes**

Long-term outcomes encompass the extent to which the health claim contributes to a reduced risk of the particular diseases or conditions.

In the longer term, it is anticipated that changes in NTD incidence will be tracked through already established National and State Birth Defects Registers. Such data will not be available within the timeframe of the evaluation.
Evaluation

The range of outcomes-monitoring data has been collated and analysed by ANZFA. The evaluation report on the outcomes of the folate health claims pilot begins on page 71.

Terms of reference for the outcome evaluation are on page 76.

7.2 Stakeholder perceptions based on the pilot

Monitoring processes

There was broad support from key informants across all sectors for monitoring and evaluation activities to be included in a management framework for health claims. Such activities were seen as having the potential to provide a better understanding of the impact of health claims.

Within the budget of $150,000 which was available for monitoring and evaluation activities in the folate pilot, key informants were generally satisfied that ANZFA had planned to collect an appropriate range of process and short-term outcome data, taking advantage of opportunistic data collection using existing nutrition and health surveys.

An organisation that conducts research for the fresh produce sector was concerned about the scope and extent of the planned data collection. They are particularly interested in data that track the impact of the pilot on the consumption of fruit and vegetables and were unsure if sufficient information is being collected to measure this.

Other stakeholders indicated that they were not yet able to assess the appropriateness and effectiveness of the monitoring activities, because to date there was limited information on the quality and scope of data produced.

Evaluation processes

A range of concerns was raised about the process for evaluating the outcomes of the health claims pilot.

Public health nutritionists emphasised that given the limited number of products using the health claim on food products to date, it would be difficult to establish causality between short-term changes in consumer knowledge, attitude and behaviour and the use of the folate health claim. In addition, they indicated that it may be difficult to distinguish between the contribution of the health claim from the range of other folate awareness-raising activities.

More broadly, it was pointed out that the pilot would shed no light on the question of whether allowing the folate health claim on foods would contribute to a positive public health outcome. This was acknowledged by ANZFA in the monitoring and evaluation strategy used for the pilot, given that changes in the incidence of NTDs would need to be monitored over a number of years. Despite this, a number of public health nutritionists expressed disappointment that an investigation of long-term outcomes was not part of the evaluation process.
Key informants from the food industry expressed concern that no criteria had been established for judging the success of the pilot, and that this could impact on decisions relating to Proposal P153.

Many stakeholders wanted additional information about the terms of reference for the outcome evaluation to be completed by ANZFA by January 2000.

### 7.3 Issues if health claims are permitted more generally

Key informants raised a number of issues related to monitoring and evaluation, which they perceive are important to consider if health claims are permitted more generally.

#### Monitoring the overall health claims system

Key informants, particularly from the public health sector, expect that the regulated approval of health claims would require ANZFA to undertake systematic monitoring of the implementation and overall impact of a health claims program. There is an expectation that regular information would be made publicly available about the performance of a health claims program against clearly defined indicators.

In particular, key informants highlighted the importance of the periodic assessment of all health claims in the light of changing knowledge of food and nutrition.

#### Monitoring individual health claims

Key informants broadly agreed that some level of monitoring, particularly that related to process and short-term outcomes, is required for all individual health claims. However, there were divergent views about the required extent of monitoring and evaluation.

Key informants from public health agencies generally supported a management framework that required a comprehensive outcome evaluation of all allowed health claims, in order to be able to justify the claimed public health benefits. On the other hand, food industry key informants indicated that detailed outcome studies for each health claim would be prohibitively expensive. They supported specific-purpose evaluations, commissioned by interested parties such as public health agencies or industry associations, to assess the impact of particular health claims.

As with the need for public education campaigns, these views reflect different perceptions of the rationale for health claims. As a public health intervention, it is logical to expect a well-resourced evaluation of the impact of each claim. As a regulatory system to allow food companies to make balanced substantiated claims, there is no need for strict linkage to public health impacts.

#### Monitoring and evaluation undertaken by specialist agencies

Key informants, particularly from the public health sector, indicated that ANZFA was probably not the most appropriate agency for monitoring and evaluating intermediate and long-term outcomes, as ANZFA lacks the required resources and specialist expertise. Comparisons were made with the Australian Institute of Health and Welfare, which has a mandate and history of health and food system monitoring.
Coordination of information collection

Given the cost of monitoring activities, key informants pointed to the need for health claims monitoring to be integrated into broader food and health monitoring systems, although it was acknowledged that existing systems had considerable gaps.

The Australian Department of Health and Aged Care is currently coordinating a major project to improve the integration of the collection and analysis of food and nutrition data.

7.4 Implications for the monitoring and evaluation processes

On the basis of key informant feedback on the monitoring and evaluation processes used in the pilot (Section 7.2) and future issues (Section 7.3), the consultants identified a number of matters which need to be considered to ensure cost-effective monitoring and evaluation processes, if health claims were to be permitted more generally.

Program evaluation plan

ANZFA needs to develop a program evaluation plan for the health claims program covering the implementation and overall impact of the regulated approval of health claims. Such a plan would typically include:

- the criteria against which the public health and other impacts of the health claim program would be assessed;
- performance indicators for monitoring the implementation (for example the number of permitted health claims, the number of products carrying a different health claim and the number of breaches of Food Standards) and overall impact of the health claims program (for example changes in consumer perceptions and attitudes to health claims, changes in consumer awareness and knowledge of the link between certain nutrients or foods and health benefits);
- strategies for collecting performance data;
- strategies for the periodic independent evaluation 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; and
- strategies for periodically reviewing all health claims in the light of changing knowledge of food and nutrition.

Reporting on the health claims program

ANZFA should produce and publish annual reports on the implementation and impact of the health claims program including relevant performance information and findings from periodic program evaluations.

Guidelines on monitoring and evaluation

Guidelines on monitoring and evaluation activities required for each individual health claim should be developed, in line with ANZFA’s health claims policy (see Section 4.4).
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.

Such a strategy would typically include:

- the criteria against which the public health and other impacts of the health claim should be assessed;
- the monitoring data which need to be collected in relation to the health claim (for example health survey data, consumer market research, sales data and incidence of disease);
- strategies for accessing relevant industry data; and
- proposed evaluation activities, if any, which should be undertaken for the health claim, along with a proposed budget and funding sources.

ANZFA should explore linkages between the health claims monitoring and evaluation activities and the broader food and health monitoring systems across Australia and New Zealand. In particular, close liaison is required with the Australian Department of Health and Aged Care and the New Zealand Ministry of Health.
8 Overall management framework

This section of the report presents the consultants’ conclusions and addresses each of the four terms of reference for the evaluation.

8.1 Effectiveness of the management framework

The folate–NTD health claims 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 judgments need further data from the outcome evaluation.

Rather, the key finding from the process evaluation is that the management framework used in the pilot provided a sound basis for the appropriate, effective and efficient management of the folate health claim.

The extent to which the management framework provides a basis for managing future health claims is less certain. Key informants across all sectors expressed reservations about generalising from the findings because of specific features of the folate pilot, in particular that:

• substantiation of the folate claim was relatively straightforward and non-controversial compared with other potential health claims;
• limited use has been made to date of the folate health claim on products and in associated advertising;
• surveillance and enforcement activities so far have been limited;
• key partners had inadequate time to prepare and plan for the pilot because of the need to establish the folate pilot as a matter of urgency; and
• pilot activities were focused on Australia, limiting insights about its relevance to New Zealand.

Notwithstanding these factors, there was no substantial evidence from the folate pilot to suggest that the management framework would not provide a suitable basis for managing other health claims.

8.2 Strengths and limitations of the management framework

On the basis of evidence presented in Sections 3 to 7 on each of the five elements of the management framework, the consultants identified a number of overall strengths and limitations of the management framework.

The consultants identified seven key strengths of the framework in relation to the folate health claim, namely:

1. the five elements of the management framework adequately covered the main areas and issues which needed to be considered when managing the folate health claim;
2 it ensured that relevant partners in Australia were engaged in the elements of the framework that related to their needs and issues (for example involvement with industry in product approval processes; involvement of community and health organisations in education processes);

3 expert committees for scientific assessment processes provided a credible, independent basis for both substantiating the 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 a monitoring strategy which involved collecting an appropriate range of process and short-term outcome data, taking advantage of existing nutrition and health surveys and industry data.

The consultants identified seven key limitations of the framework in relation to the folate health claim, namely:

1 inadequate integration of the differences in policy and industry between Australia and New Zealand, which resulted in much lower levels of interest and engagement by New Zealand industry in the pilot;

2 the need for guidelines on the requirements and standards for scientific substantiation for future health claims;

3 the lack of a public consultation process that considered diverse views on the rationale for, and merits of, the folate health claim;

4 the need for improved promotion of the role and functioning 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 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 (for example responsibility for undertaking regular surveillance audits to identify possible breaches of the Code);

6 the inability to sustain the public education campaign; and

7 uncertainties in the comparability and usefulness of monitoring data in establishing the outcomes of the pilot.

8.3 Implications for future use of the management framework

There was sufficient depth and consistency of evidence across all five elements of the management framework to draw out the implications of these findings for the future management of health claims and so provide advice on directions. However, there is a need for ANZFA to review these implications before making decisions under Proposal P153, in
the light of additional insights from the second half of the pilot (June 1999 – February 2000) and the findings from the outcome evaluation.

While detailed findings on each element of the management framework are presented in Sections 3 to 7, the key implications and suggested future directions for management are summarised below.

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 panel convened by ANZFA or outsourced to a research body such as the NHMRC. It is appropriate that such an expert panel cover a broad spectrum of expertise including public health nutrition.

To help applicants prepare a case for scientific substantiation, there is a need to develop guidelines on requirements and standards for scientific substantiation, such as the types of studies needed and presentation formats, as well as procedures for the adjudication process, such as the timetable and expected length of time of adjudication as well as appeal mechanisms.

An expert panel would also establish the criteria for eligible foods in relation to each health claim. Following consultation, ANZFA would need to develop and publish guidelines for the expert panel on establishing the criteria for eligible foods. In line with the guidelines used in the pilot, they should state that approved foods should support the aims of the Australian National Food and Nutrition Policy and the Dietary Guidelines for Australians.

In addition, the guidelines would specify standard disqualifying criteria which should accompany health claims to ensure consistency with the Dietary Guidelines for Australians and include, for example, maximum allowable levels of fat, saturated fat, sodium and sugar in one serving. These disqualifying criteria would be used in all health claims, except where the expert panel assessed that the health claim was justifiable on public health grounds without connection to the dietary guidelines, for example where the claim only related to a single nutrient with a single disease outcome.

Regulatory systems

A co-regulatory system for managing health claims is appropriate, based on legally binding rules specified in the Food Standards Code and supported by an industry code of practice which provided additional information and guidelines on the use of health claims in the pilot. However, additional promotion of the concept of co-regulation is required, particularly in Australia where it is confused with self-regulation.

A critical factor in the success of the co-regulatory system will be an appropriately resourced public consultation process for each health claim proposal. However, given the divergent views about the rationale for, and merits of, health claims, ANZFA will need to develop a health claims policy that articulates the basis on which the relative benefits of individual

---

Subsequently amended to August 2002.
health claims will be assessed. Such a policy would be used to guide decisions following the public consultation process.

In line with the pilot, 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.

**Surveillance and enforcement**

A Code of Practice Management Committee would provide the primary mechanism for surveillance and enforcement of the 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 and Territory regulatory authorities.

There is a need to promote the role and function of the Committee to food companies, government enforcement agencies, public health agencies and consumer groups, including procedures for making complaints and for mediating and attempting to resolve alleged breaches and complaints.

Building on guidelines developed for the pilot, there is a need to clarify who is responsible for undertaking regular surveillance audits to identify possible breaches of the Code and how audits could be resourced, procedures for following up of potential breaches identified from a surveillance audit, procedures for handling anonymous complaints, the criteria for determining the importance of the complaints, and details of what constitutes a ‘timely’ response to a request or recommendation of the Management Committee.

A future health claims program will need to examine the resource implications for New Zealand and Australian State and Territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee for unresolvable breaches.

**Education and communication**

Education and communication strategies are an integral component of a health claims system, although guidelines are needed on the requirements of public health campaigns used in conjunction with 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.

The key policy issue for consideration is the relative importance of the public health and regulatory focus of a health claims system. If health claims are perceived as a public health intervention, then it is logical to expect a well-resourced public education campaign. If the health claims system is primarily a regulatory system to allow food companies to make balanced substantiated claims, then there may be no need for strict linkage to public health campaigns.
Monitoring and evaluation

Monitoring and evaluation strategies are an integral part of a health claims system. 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 collecting 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 could 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 the 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.

8.4 Costs associated with the pilot

It was estimated that over its full period, the folate pilot will cost of the order of $1.1 million to fully implement, with 80% of the costs managed by ANZFA (see Section 2.2).

The report identified a number of different strategies for reducing the costs associated with the management framework processes including:

- placing the onus on the health claim applicant to prepare the case for scientific substantiation using the most efficient means at their disposal;
- using the same panel to adjudicate on multiple health claims where appropriate. For example, it may be possible to convene a single expert panel to review the applicability to Australia of health claims already substantiated by the USFDA;
- using the same panel for adjudication and establishment of the criteria for eligible foods where feasible. Although such a process would require expansion of the membership of the panel to ensure the full range of necessary expertise was available, there could be administrative savings associated with a one-step process; and
- placing the onus on applicants to seek independent regulatory and technical advice before submitting an application for pre-market approval.
However, the appropriateness of these strategies depends on ANZFA’s approach to health claims as articulated in a health claims policy. In the same way, the future costs associated with management framework processes will depend on guidelines developed in response to this policy. Examples covered in the report include:

- guidelines specifying the situations, if any, in which public health campaigns would be required for a particular health claim and the scope of such a campaign;
- guidelines specifying the situations, if any, in which a monitoring and evaluation strategy would be required for a particular health claim and the scope of such a strategy; and
- resource implications for New Zealand and Australian State and Territory government enforcement agencies in undertaking legal action when they receive referrals from the Code of Practice Management Committee for unresolvable breaches.

Once such decisions are made by ANZFA as part of its consideration of P153, the resource implications of a health claim system can be fully investigated. 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 from applicants wanting to use health claims.

### 8.5 Management of the pilot across Australia and New Zealand

The folate–NTD health claims pilot has been professionally and effectively managed by ANZFA with the support of the Pilot Steering Committee, within the constraints of the available budget and timeframe.

Key informants from all sectors acknowledged the professionalism of ANZFA staff and their partners in establishing and implementing the pilot to date, particularly given the sensitivity of issues which had to be negotiated in the early stages. Food companies and industry associations participating in the pilot were generally very positive about the support and practical assistance provided by ANZFA staff during the pilot.

However, since April 1999 a number of informants noted an apparent decline in the responsiveness and support available from ANZFA staff. This coincided with the departure of a number of key project staff from ANZFA.

Concerns about the management of the pilot included the need for:

- greater consultation and involvement in the initial negotiations about the pilot. Some stakeholders, particularly New Zealand stakeholders, were unable to fully participate because they were not adequately informed in the early stages of the pilot;
- improved ongoing communication about the progress of the pilot and information that clearly and concisely explained the legal, regulatory and scientific issues associated with the pilot; and
- greater notice for upcoming pilot events, particularly media events such as the retail strategy launch.
There is considerable potential for ANZFA to improve ongoing communication about the implementation of the pilot during the second half of the pilot. Distribution of the findings of this evaluation could support this process.