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Historically, the use of health claims on food labels and associated advertising has been prohibited in Australia and New Zealand. In 1996, the then Australia New Zealand Food Authority (ANZFA) raised Proposal P153—Health and Related Claims¹ to review the prohibition on health claims. The review process was complex and caused heated debate among stakeholders about perceived public health risks and benefits of health claims. A challenge for ANZFA was that by virtue of the existing prohibition there was a lack of evidence to inform a review of health claims policy and the possible development of a regulatory framework.

In Australia in mid-1995, voluntary folate fortification of staple foods was introduced² in response to policy recommendations prepared by the National Health and Medical Research Council (NHMRC) as a public health intervention to help reduce the risk of neural tube defects (NTDs).³ On 30 March 1998, the Parliamentary Secretary to ANZFA directed the authority to develop and implement a folate—NTD health claim intervention under the urgency powers of the Australia New Zealand Food Authority Act 1991.⁴ This direction was controversial. The invoking of the act’s urgency powers resulted in the omission of the public consultation and inquiry processes that otherwise would have been required in developing the food standard.

In responding to the direction, ANZFA raised a proposal, P170—Health Claims Management Framework (the pilot), permitting the voluntary use of a health claim on certain folate-rich foods, both fortified and non-fortified, that met prescribed nutrition criteria.⁵ The pilot’s objectives were to test a management framework for regulating health claims being considered by ANZFA under Proposal P153 and to promote public health through communication of the link between increased maternal folate consumption and a reduction in the incidence of NTDs. Verification of a food permitted to use the folate—NTD health claim was undertaken by ANZFA in response to an application from the food manufacturer. Approval meant that the permitted food product was added to a list written into a transitional standard for health claims in the Australia New Zealand Food Standards Code (the code).

The pilot incorporated an education and communication strategy and a monitoring and evaluation strategy that were implemented from November 1998 to May 1999.⁶ The pilot concluded in November 1999 to coincide with the anticipated completion of Proposal P153. However, Proposal P153 was not completed and the temporary provision for the folate—NTD health claim has been extended five times and is now in effect until two years from the start of Standard 1.2.7 - Nutrition, Health and Related Claims.⁷

In 1999 and 2000 reports of evaluations of the pilot were published.⁸ Since that time there has been no dedicated national monitoring of the use of the health claim or the availability of folate-fortified foods in the marketplace. Therefore, there is a lack of information about the health claim's

**Abstract**

**Objective:** To evaluate the implementation of the folate—neural tube defect (NTD) health claim and its impact on the availability of folate-fortified food in Australia.

**Methods:** During late 2005, a survey was conducted in 16 supermarkets across all Australian capital cities to identify the use of the folate—NTD health claim on the labels of the 128 food products listed in food standard 1.1A.2: 'Transitional standard—Health claims' and the number of products fortified with folic acid.

**Results:** Seventy-nine per cent of existing listed food products were found and two of these were implementing the folate—NTD health claim. Forty-four per cent of these listed products, previously fortified with folic acid, were no longer fortified. One hundred and seventeen generally available food products were fortified with folic acid, predominantly breakfast cereals (73%). Twenty-seven per cent of these folate-fortified products were listed in the transitional standard.

**Conclusions:** The health claim was not used widely to inform women of child-bearing age of the importance of periconceptional folate intake. The increased availability of folate-fortified products generally has occurred independently of the health claim. Deficiencies in the verification system of the tested regulatory framework are identified. The voluntary regulatory provisions for both folate fortification and the use of the health claim diminished the States’s influence over their implementation of public health tools.

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longer-term implementation to help inform regulatory reviews
for nutrition, health and related claims\textsuperscript{5} and mandatory folate
fortification.\textsuperscript{10} This paper examines the implementation of the
folate–NTD health claim and the availability of folate-fortified
foods in Australian supermarkets during late 2005 and proposes
explanations for what was observed, particularly in relation to
regulatory reviews for health claims and folate fortification.

Method

\textbf{Store selection}

A store survey was used to identify food products permitted to
use the folate–NTD health claim and folate-fortified food products.
Initially, one Coles (C) and one Woolworths (W)/Safeway (S)
supermarket store located in each capital city was selected for
inclusion in the survey to provide representation from all States
and Territories and to accommodate the two largest food retailers
nationally. A local nutritionist and/or university student enrolled
in a nutrition science degree were the surveyors and they selected
stores within each capital city based on convenience sampling.
Preliminary data analysis indicated that no new food products
were identified after the first eight stores had been surveyed,
\ie a saturation point had been achieved. Hence, no additional
stores were added to the original 16-store sample frame. The
store location and retail chain by State and Territory are shown
in Table 1.

\textbf{Data collection schedule}

The survey was conducted from August to October 2005.

\textbf{Product selection}

The products to identify the use of the folate–NTD health claim
were drawn from the list of 128 foods with permission to use the
health claim written into the table to subclause 3(e) in Standard
1.1A.2: Transitional standard – Health claims (the transitional
standard).\textsuperscript{11}

The products to identify folic acid fortification were drawn from
the list of food product categories specified in the table to clause 3
of Standard 1.3.2 – Vitamins and Minerals. This is the general
food standard that regulates the addition of vitamins and minerals
to foods and the claims that can be made about the vitamin and
mineral content of foods. Surveyors searched for relevant food
products in those sections of the supermarket that coincided with
the product categories provided in the standard. Conversely, those
food products permitted to be fortified with folic acid under the
provisions of specific food product standards, \eg Standard 2.9.3
– Formulated Meal Replacements and Formulated Supplementary
Foods, were not included in the product selection sample frame.

\textbf{Data recording}

All selected products were inspected for use of the folate–NTD
health claim and fortification with folic acid. Use of the health
claim was assessed against the health claim definition provided
in the glossary to the Food Standards Australia New Zealand
(FSANZ) (as ANZFA is now known) initial assessment report for
Proposal P293 – Nutrition, Health and Related Claims\textsuperscript{12} (which
superseded Proposal P153 in 2002). The glossary defines a health
claim as: "...a claim, other than a therapeutic claim, that describes
or indicates the relationship between the consumption of a food, a
category of food or one of its constituents and health". The use of
a folate–NTD health claim was recorded when words describing
or indicating a relationship between the consumption of a food
containing folate and reduced risk of 'birth defects', 'neural tube
defects' and/or 'spina bifida' were identified on a food label.

A product listed in the transitional standard was assessed as
continuing to meet the eligibility criteria in 2005 if it contained
at least 40\,\mu g folate per serve.\textsuperscript{2} Food products regulated under
the general standard for vitamin and minerals were recorded as
folate fortified if:

1. The nutrition information panel stated that the product provided
at least 10\% of the recommended dietary intake (RDI) for folate
per serve; and
2. Folate was listed in the ingredient list.

Products available in different packet sizes were recorded as
a single product. Those products with the same name but available
in different forms, \eg breakfast cereal and breakfast bars, were
recorded as distinct products.

\textbf{Results}

The number of food products listed in the transitional standard
with permission to use the folate–NTD health claim and the
numbers that were found and that were implementing the health
claim in 2005 are shown in Table 2. The list written into the
transitional standard consisted of 128 foods, of which 40 were
primary foods and 88 processed foods. The bread (27\%) and
cereals (23\%) groupings contained the greatest number of products
with permission to use the health claim. Ninety of the 128 products
listed in the transitional standard were found. Despite being listed
in the transitional standard, 14 products were identified in 2001 as
no longer being on the market.\textsuperscript{13} Therefore, 79\% of the 114 existing
listed products were located. Among the 90 found products, 65
contained sufficient folate to meet the eligibility criteria prescribed
for listing in the transitional standard and therefore qualified to
use the health claim.

The folate–NTD health claim was observed on two found food
products that were listed in the transitional standard. Each of these

\begin{table}
\centering
\begin{tabular}{|c|c|c|c|c|c|c|c|}
\hline
State/Territory & ACT & NSW & NT & Qld & SA & Tas. & Vic. & WA \\
\hline
Manuka & C & hornby & C & Darwin & C & Mt Gravatt & C & & \\
(Woden) & (w) & & (W) & & & & & & \\
& & & & & & & & & \\
\hline
Hornsby & C & hornby & C & Darwin city & & & & & \\
(W) & (W) & & (W) & & & & & & \\
& & & & & & & & & \\
\hline
Glenelg & C & Sandy Bay & C & Bentleigh & & & & & \\
& & & & & & & & & \\
& & & & & & & & & \\
\hline
Oaklands Park & C & Sandy Bay & C & Chelseaham & & & & & \\
(W) & (W) & & (W) & & & & & & \\
& & & & & & & & & \\
\hline
South Fremantle & C & & & & & & & & \\
(W) & & & & & & & & & \\
\hline
\end{tabular}
\caption{Store location and retail chain by State and Territory.}
\end{table}
products was manufactured by a different company but both were breads fortified with folic acid and available across Australia. The folate–NTD health claim was identified on three other products, all three of which were manufactured by a third food company, and although these products met the nutrient eligibility criteria for listing in the transitional standard they had not been submitted to ANZPA for verification.

The number of folate-fortified food products within specific food categories available in stores in Australia during three critical development stages for folate fortification policy reform is shown in Table 3. Data collected from an earlier store survey during the time period late 1995 to early 1996 provides a baseline for the voluntary folate fortification policy that was introduced in response to the NHMRC recommendations and came into effect with the gazettal of revised food standard A9 in mid-1995. During this period there was no folate-fortified staple food product found in Australian stores. Fortuitously, data were also collected during the time period May to September 1998 in the earlier store survey and this provided baseline for the pilot. At the pilot’s baseline there were 38 folate-fortified food products available in Australian stores. The data collection period for the current store survey coincides closely with the consideration during 2006 of the draft assessment reports (DARs) for proposals for health claims and mandatory folate fortification policy reforms. In 2005, there were 117 folate-fortified food products available and the highest proportion of these products belonged to the breakfast cereal category (73%). The manufacturers of 32 of these 117 folate-fortified food products had applied for listing in the transitional standard. Conversely, 44% of the 57 found products listed as folate fortified in 2000 were no longer fortified with folic acid in 2005.

**Discussion**

This evaluation provides evidence that after seven years of implementation, the folate–NTD health claim has performed poorly as a public health intervention when measured as a communication strategy and as an incentive for food innovation. In 2005, the folate–NTD health claim was being implemented on just 2% of the 114 existing food products for which manufacturers had sought permission to use the claim to communicate the link between increased maternal folate consumption and a reduction in the risk of NTDs. Curiously, in 1999, when the implementation of the health claim was monitored during the pilot’s original evaluation, there were five times as many food products using the health claim.

The data indicate that in the 10 years since the introduction of the NHMRC’s voluntary folate fortification policy, there has been a progressive increase in the availability of folate-fortified food products in Australia. The first staple food product to be fortified with folic acid appeared on the market in early-mid 1996. Approximately two years later, immediately preceding the start of the pilot, an Australia-wide store survey identified that 38 food products regulated within the provisions of the general food standard were fortified with folic acid. With 117 food products fortified with folic acid available in 2005, there has been an

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**Table 2: Number of food products permitted to use the folate-NTD health claim and the numbers that were found and that were implementing the health claim in 2005.**

<table>
<thead>
<tr>
<th>Food</th>
<th>Number of food products permitted to use the folate-NTD health claim</th>
<th>Number of permitted food products found</th>
<th>Number of found permitted food products using the health claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eggs*</td>
<td>All</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Fruit</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Legumes</td>
<td>17</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Peanuts*</td>
<td>All</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Vegetables</td>
<td>18</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Bread</td>
<td>35</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Cereals</td>
<td>29</td>
<td>27</td>
<td>0*</td>
</tr>
<tr>
<td>Fruit/vegetables (processed)</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Juices</td>
<td>19</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Soy products</td>
<td>1</td>
<td>0</td>
<td>–</td>
</tr>
<tr>
<td>Extracts</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>128</td>
<td>90</td>
<td>2</td>
</tr>
</tbody>
</table>

Notes:

(a) Counted as one item.
(b) Three breakfast cereals that used a folate-NTD health claim had not applied for verification and were not listed in the transitional standard.

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**Table 3: Number of folate-fortified food products available in Australia during three critical development stages for folate fortification policy reform.**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bread</td>
<td>0</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Breakfast cereal</td>
<td>0</td>
<td>31*</td>
<td>85*</td>
</tr>
<tr>
<td>Cereal flours</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Pasta</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Extracts</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Fruit juice, vegetable juice, fruit drink and fruit cordial</td>
<td>0</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Analogues derived from legumes</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>38*</td>
<td>117</td>
</tr>
</tbody>
</table>

Notes:

(a) The source of the data in the first two columns is reference 11.
(b) Includes one and two products, respectively, produced by the one food manufacturer and claiming to be good sources of folate based on ingredients containing folate described as “naturally occurring from pure plant extract”.
(c) 1998 survey findings reported elsewhere recorded an additional nine products as the product selection for the survey included foods products standardised as meal replacements and supplementary foods.

2006 VOL. 30 NO. 4 AUSTRALIAN AND NEW ZEALAND JOURNAL OF PUBLIC HEALTH 365
approximately 300% increase in the number of folate-fortified products in Australia in the seven years since the survey that coincided with the pilot’s baseline. The increase in the availability of folate-fortified food products from 1998 to 2005 appears to have occurred independently of the option to use a health claim. Manufacturers have made an application to the food authority seeking permission to implement the folate–NTD health claim for just 29% of the 117 folate-fortified products available in 2005 and none since 2000. Moreover, in 2005 almost half of the found products that had been folate fortified and listed in the transitional standard in 2000 were no longer fortified.

Caution is required in interpreting the findings of this evaluation. Thirty-eight of the 128 products listed in the transitional standard were not found. The survey was conducted in capital cities only and some of the missing products may be available exclusively in other areas of Australia. Also, the list of approved products has not been updated since September 2000. Products may not have been located because they had changed names or been discontinued since that time. For example, in August 2001, the FSANZ Board raised Proposal P244 requesting 14 products to be removed from the table in the transitional standard because they were no longer on the market. However, in December 2001, this proposal was abandoned by the FSANZ Board as the presence of foods in the table that are no longer for sale had no effect on the operation of the Food Standards Code. Hence, 14 unavailable products continued to be listed in the transitional standard in 2005.

The consultants who undertook the process evaluation conducted at the end of the six-month trial period concluded that the education and communication and the monitoring and evaluation strategies for a single health claim were effective, albeit for the relatively brief period of time and limited indicators they employed. An outcome evaluation was also undertaken and it was reported that during the six-month trial period there was a significant increase in knowledge about folate as well as about the folate–NTD relationship among women of childbearing age. However, as the ANZFA chairperson commented at the time, the extent to which these findings could be attributed to the health claim alone was uncertain.

Based on the pilot’s original evaluation findings, ANZFA stated in its inquiry report into P153 that a health claim “could be effective in raising awareness about the claimed relationship … [on this basis] … it has been concluded that there is insufficient justification for a total prohibition of health claims and that, in the interest of providing for informed choice by consumers, there is scope for claims linking a particular food to health/disease outcomes to be provided in relation to food”. Subsequently, the findings from the pilot’s original evaluation were used in the development of the Australia New Zealand Food Regulation Ministerial Council’s (Ministerial Council) policy guideline on health claims and Proposal P293 – Nutrition, health and related claims. Within the DAR for Proposal P293 the folate–NTD health claim has been selected as a pre-approved, high-level health claim on a voluntary basis to be included in the new nutrition, health and related claims standard upon gazettal.

The findings from the present evaluation complement those from the pilot’s original evaluation. The findings have implications for the regulatory reviews of health claims, particularly for the management of high-level health claims and mandatory folate fortification. The findings from the pilot’s original evaluation are cited in the P293 DAR to suggest that a system of pre-approval of individual health claims on a product-by-product basis is ineffective and resource intensive. An alternative claim-by-claim approval system for high-level health claims is proposed in the P293 DAR. The findings from this present evaluation do not contradict the assessment on this matter presented in the P293 DAR.

Nevertheless, caution is indicated when extrapolating the findings from the pilot and ongoing health claim permission to inform the development of regulatory management systems for health claims in general. The reason(s) for the poor implementation of the folate–NTD health claim is unclear. The product-by-product approval system may have inherent limitations that compromised the use of the folate–NTD health claim. However, there are other explanations that might account for the health claim’s poor implementation. Food manufacturers may have been reluctant to commit to an intervention trial that was conducted over a relatively short time period and then observed that when the health claim permission was extended beyond the pilot there was effectively no further government support for nutrition education and monitoring and evaluation activities. Another alternative explanation for the poor use of the health claim might be that the folate–NTD health claim lacked broad appeal to the food industry, e.g. the limited population group for which the claim is applicable. This explanation is borne out by data that indicate that during the pilot period, sales of breakfast cereals using the health claim did not rise.

Relative to a claim-by-claim approval system, a pre-approval system on a product-by-product basis for high-level health claims may be resource intensive but it offers potential advantages for the regulatory system. For example, a listing of products permitted to use a certain high-level health claim could be generated from the implementation of a pre-approval system and would provide a valuable reference to assist environmental health officers in assessing marketplace compliance with the new nutrition, health and related claims standard. What is apparent from this present evaluation is that if a system of product-specific approvals was to be adopted in the future, the tested verification system would need to be monitored more rigorously to represent accurately what is occurring in the marketplace. A mechanism is needed to determine which of the listed foods are carrying the health claim at any point in time, if they continue to be fortified, and if so at what level to avoid indicating greater marketplace implementation than might be occurring in practice.

The findings also have relevance to Proposal P295 – Consideration of mandatory fortification with folic acid. The findings support the view that when a serious public health issue arises, greater control over an intervention response may need to rest with government. For example, government may need to introduce regulation that mandates the use of a corresponding
health claim when relying on voluntary provisions for which the policy's implementation is at food manufacturers' discretion. In relation to mandating the folate–NTD health claim, an earlier evaluation of the pilot concluded: "written educational material is the preferred preference for conveying information about folate and NTDs, rather than food labelling". Others have argued that if a folate–NTD health claim is to be implemented, it is important that sufficient investment also is directed towards consumer education.20

The ongoing extension of the health claim permission has provided an opportunity for the present evaluation also to examine the pilot and the use of the folate–NTD health claim themselves in the context of their role in the broader health claims policy development process. In terms of the pilot's initiation, there are inconsistencies associated with the Parliamentary Secretary's direction and its invoking of urgency powers. First, if the pilot required urgency powers for its establishment, why was it developed with voluntary provisions so control over its implementation rested with food manufacturers? This inconsistency might have been raised by public health practitioners. However, the direction had the effect of preventing public consultation. At the time, the Public Health Association of Australia wrote to the Federal Minister for Health and Family Services to register its concern about the accelerated food regulation processes for the pilot, especially in the context of the review of health claims and the pressure to remove the prohibition more broadly.21 The urgent nature of the pilot's development appears to be at odds with the observation that there were alternative policy interventions that had not received substantial support. Indeed, the NHMRC's expert panel on folate fortification had not recommended a health claim on this topic and was itself due to evaluate its policy in mid-1998.3

A second inconsistency associated with the direction was that the urgency powers were invoked because of the seriousness of NTDs as a health concern, yet there were limited resources invested in the pilot's nutrition education and monitoring and evaluation activities. Effectively, there was no commitment to these activities beyond the six-month trial period despite the health claim being extended over the subsequent seven years. These inconsistencies raise questions for future research investigation about the initiation, implementation and evaluation of the pilot and the folate–NTD health claim within the broader health claims policy development context.

Conclusion

The pilot and ongoing permission to use the folate–NTD health claim together represent a critical phase in the health claims policy development process in Australia and New Zealand. They established a precedent public health intervention and a trial for a health claims regulatory framework. This study's findings indicate that the pilot and ongoing health claim permission performed poorly in both of these roles. The health claim was not used widely; the observed increase in the availability of folate-fortified food products appears to have occurred independently of the health claim permission. In terms of the tested regulatory framework, deficiencies were identified with the product-by-product approach and its verification system in particular. Given the peculiar nature of the folate–NTD relationship, the findings cannot necessarily be used to anticipate the implementation of future health claims in Australia.

As a public health intervention, the folate–NTD health claim was not necessarily a failure of itself as it was conceived as a component of a broader intervention that received limited support. The findings from the pilot's original evaluation and the present evaluation highlight the importance of timely and adequately resourced nutrition education and monitoring and evaluation activities to complement the new standard for nutrition, health and related claims. When considered within the broader health claims policy development context, this present evaluation's findings raise questions for further research investigation about the pilot and ongoing health claim permission's initiation, implementation and evaluation processes.

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References